VIRGINIA REGISTER OF REGULATIONS

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VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

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

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

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

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

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

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

FAST-TRACK RULEMAKING PROCESS

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

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency, upon consultation with the Attorney General, and at the discretion of the Governor, may adopt emergency regulations that are necessitated by an emergency situation. An agency may also adopt an emergency regulation when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment. The emergency regulation becomes operative upon its adoption and filing with the Registrar of Regulations, unless a later date is specified. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under certain circumstances as provided for in § 2.2-4011 D. Emergency regulations are published as soon as possible in the *Register*.

During the time the emergency status is in effect, the agency may proceed with the adoption of permanent regulations through the usual procedures. To begin promulgating the replacement regulation, the agency must (i) file the Notice of Intended Regulatory Action with the Registrar within 60 days of the effective date of the emergency regulation and (ii) file the proposed regulation with the Registrar within 180 days of the effective date of the emergency regulation. If the agency chooses not to adopt the regulations, the emergency status ends when the prescribed time limit expires.

STATEMENT

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

CITATION TO THE *VIRGINIA REGISTER*

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

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

PUBLICATION SCHEDULE AND DEADLINES

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

May 2016 through July 2017

Volume: Issue	Material Submitted By Noon*	Will Be Published On
32:20	May 11, 2016	May 30, 2016
32:21	May 25, 2016	June 13, 2016
32:22	June 8, 2016	June 27, 2016
32:23	June 22, 2016	July 11, 2016
32:24	July 6, 2016	July 25, 2016
32:25	July 20, 2016	August 8, 2016
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33:18	April 12, 2017	May 1, 2017
33:19	April 26, 2017	May 15, 2017
33:20	May 10, 2017	May 29, 2017
33:21	May 24, 2017	June 12, 2017
33:22	June 7, 2017	June 26, 2017
33:23	June 21, 2017	July 10, 2017

*Filing deadlines are Wednesdays unless otherwise specified.

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Agency Decision

Title of Regulation: **12VAC5-408. Certificate of Quality Assurance of Managed Care Health Insurance Plan Licensees.**

Statutory Authority: § 32.1-137.1 of the Code of Virginia.

Name of Petitioner: The Medical Society of Virginia.

Nature of Petitioner's Request: The Medical Society of Virginia (MSV) respectfully submits a petition for rulemaking, per § 2.2-4007 of the Code of Virginia, on behalf of our nearly 11,000 members. The Medical Society of Virginia represents physician, medical student and physician assistant members and aims to make Virginia the best place to practice and receive medical care.

Specifically, MSV proposes amending 12VAC5-408-170: Provider credentialing and recredentialing. The purpose of these suggested changes is to update and streamline the credentialing and recredentialing process. Many physicians have expressed concern over the current process, as it takes significant time and resources away from delivering care to patients. MSV has engaged with key stakeholders including several health plans on this topic and have mutually agreed upon the proposed changes. As such, we hope the agency will consider these proposed changes eligible for the fast-track regulatory process.

MSV appreciates the department's consideration of this request and looks forward to our continued work together to make Virginia the healthiest state in the nation.

MSV proposed changes to Provider Credentialing and Recredentialing:

12VAC5-408-170. Provider Credentialing and Recredentialing.

A. The MCHIP licensee shall establish and maintain a comprehensive credentialing verification program to ensure its providers meet the minimum standards of professional licensure or certification. Written supporting documentation for providers who have completed their residency or fellowship requirements for their specialty area more than 12 months prior to the credentialing decision shall include:

1. Current valid license and history of licensure or certification;

2. Status of hospital privileges, if applicable;

3. Valid DEA certificate, if applicable;

4. Information from the National Practitioner Data Bank, as available;

5. Education and training, including post graduate training, if applicable;

6. Specialty board certification status, if applicable;

7. Practice or work history covering at least the past five years; and

8. Current, adequate malpractice insurance and malpractice history of at least the past five years.

B. The MCHIP licensee may grant provisional credentialing for providers who have completed their residency or fellowship requirements for their specialty area within 12 months prior to the credentialing decision. Written supporting documentation necessary to provisionally credential a practitioner shall include:

1. Primary source verification of a current, valid license to practice prior to granting the provisional status;

2. Written confirmation of the past five years of malpractice claims or settlements, or both, from the malpractice carrier or the results of the National Practitioner Data Bank query prior to granting provisional status; and

3. A completed application and signed attestation.

C. Providers provisionally credentialed may remain so for 60 calendar days.

D. Policies for credentialing and recredentialing shall include:

1. Criteria used to credential and recredential;

2. Process used to make credentialing and recredentialing decisions;

3. Type of providers, including network providers, covered under the credentialing and recredentialing policies;

4. Process for notifying providers of information obtained that varies substantially from the information provided by the provider;

5. Process for receiving input from participating providers to make recommendations regarding the credentialing and recredentialing process; ~~and~~

6. Process and timeframes for communicating credentialing application receipt, progress and decisions to the primary credentialing contact at the address, either electronic or physical, listed on the credentialing application; and

~~6.~~ 7. A requirement that the MCHIP licensee notify the applicant or his designee if permission is granted by the applicant within 60 calendar days of receipt of an application if information is missing or if there are other deficiencies in the application. The MCHIP licensee shall complete the credentialing process within 90 calendar days of the receipt of a complete and accurate application ~~all such information requested by the MCHIP licensee or, if~~

~~information is not requested from the applicant, within 120 calendar days of receipt of an application~~. The department may impose administrative sanctions upon an MCHIP licensee for failure to complete the credentialing process as provided herein if it finds that such failure occurs with such frequency as to constitute a general business practice. The current policies shall be made available to participating providers and applicants ~~upon written request~~ via publication on the MCHIP licensee's website or within the licensee's provider manual.

E. A provider fully credentialed by an MCHIP licensee, who changes his place of employment or his nonMCHIP licensee employer, shall, if within 60 calendar days of such change and if practicing within the same specialty, continue to be credentialed by that MCHIP licensee upon receipt by the MCHIP licensee of the following:

1. The effective date of the change;

2. The new tax ID number and copy of W-9, as applicable;

3. The name of the new practice, contact person, address, telephone and fax numbers; and

4. Other such information as may materially differ from the most recently completed credentialing application submitted by the provider to the MCHIP licensee. This provision shall not apply if the provider's prior place of employment or employer had been delegated credentialing responsibility by the MCHIP licensee. Nothing in this section shall be construed to require an MCHIP licensee to contract or recontract with a provider.

F. The ~~appropriate credentialing process~~ applicant shall be considered to be participating with the MCHIP licensee on the effective date which, for the purposes of this section, is the date of credentialing committee approval or the date the applicant executes a contract with the MCHIP licensee as an individual or is subject to be governed by an existing contract with the MCHIP licensee, whichever occurs later. If credentialing provides information about the malpractice insurance and if that insurance is not effective until after these dates, the effective date will be the effective date of the malpractice insurance. Beginning on the effective date the provider shall be obligated to the terms and conditions of the contract and shall be entitled to be paid as a participating provider pursuant to the terms of the contract. The MCHIP licensee shall notify the applicant and the primary credentialing contact of the effective date in a reasonable timeframe; in the event of a negative decision, the communication will include instructions for appeal, if any.

~~completed before the provider:~~

~~1. Begins seeing covered persons;~~

~~2. Enters into the employment or contractual relationship with the MCHIP licensee; and~~

~~3. Is included in the listing of health care providers as a participating provider in any marketing and covered person materials.~~

G. The providers shall be recredentialed at least every three years. Recredentialing documentation shall include:

1. Current valid license or certification;

2. Status of hospital privileges, if applicable;

3. Current valid DEA registration, if applicable;

4. Specialty board eligibility or certification status, if applicable;

5. Data from covered person complaints and the results of quality reviews, utilization management reviews and covered persons satisfaction surveys, as applicable; and

6. Current, adequate malpractice insurance and history of malpractice claims and professional liability claims resulting in settlements or judgments.

H. All information obtained in the credentialing process shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being reviewed. Nothing in the previous sentence shall require an MCHIP or MCHIP licensee to disclose to a provider, or any other person or party, information or documents: (i) that the MCHIP or the MCHIP licensee, itself, develops or causes to be developed as part of the MCHIP's credentialing process or (ii) that are privileged under applicable law. The department may require the MCHIP licensee to provide a copy of its credentialing policies.

I. Providers shall be required by the MCHIP licensee to notify the MCHIP of any changes in the status of any credentialing criteria.

J. The MCHIP licensee shall not refuse to initially credential or refuse to reverify the credentials of a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.

K. The MCHIP licensee shall have policies and procedures for altering the conditions of the provider's participation with the MCHIP licensee. The policies shall include actions to be taken to improve performance prior to termination and an appeals process for instances when the MCHIP licensee chooses to alter the condition of provider participation based on issues of quality of care or service, except in circumstances where an covered person's health has been jeopardized. Providers shall have complete and timely access to all data and information used by the licensee to identify or determine the need for altering the conditions of participation.

L. The MCHIP licensee shall retain the right to approve new providers and sites based on quality issues, and to terminate or suspend individual providers. Termination or suspension of individual providers for quality of care considerations shall be

supported by documented records of noncompliance with specific MCHIP expectations and requirements for providers. The provider shall have a prescribed system of appeal of this decision available to them as prescribed in the contract between the MCHIP or its delegated service entity and the provider.

M. Providers shall be informed of the appeals process. Profession specific providers actively participating in the MCHIP plan shall be included in reviewing appeals and making recommendations for action.

N. The MCHIP licensee shall notify appropriate authorities when a provider's application or contract is suspended or terminated because of quality deficiencies by the health care provider whose credentials are being reviewed.

O. There shall be an organized system to manage and protect the confidentiality of personnel files and records. Records and documents relating to a provider's credentialing application shall be retained for at least seven years.

Agency Decision: Request granted.

Statement of Reason for Decision: The Virginia Department of Health will prepare and submit a Notice of Intended Regulatory Action.

Agency Contact: Erik Bodin, Director, Office of Licensure and Certification, Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, telephone (804) 367-2102, or email erik.bodin@vdh.virginia.gov.

VA.R. Doc. No. R16-13; Filed June 3, 2016, 3:12 p.m.

TITLE 6. CRIMINAL JUSTICE AND CORRECTIONS

CRIMINAL JUSTICE SERVICES BOARD

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Criminal Justice Services Board intends to consider amending **6VAC20-60, Rules Relating to Compulsory Minimum Training Standards for Dispatchers**. The purpose of the proposed action is to amend the regulation as a result of a periodic review and small business impact review, and this Notice of Intended Regulatory Action serves as the report of the findings of the regulatory review pursuant to § 2.2-4007.1 of the Code of Virginia.

The proposed substantive amendments being considered include requiring dispatcher academies to have coursework approved by the Department of Criminal Justice Services (DCJS) prior to the first scheduled class and enhancing training by requiring that dispatchers complete in-service training. Other proposed revisions to the regulation will remove dated language and add clarifying language where appropriate.

The regulation identifies broad training categories. Specific performance outcomes, training objectives, criteria for testing, and lesson plan guides are located on the DCJS website. The proposed action will add a reference to the DCJS website to assist dispatchers in locating the Virginia Criminal Justice Services Training Manual and Compulsory Minimum Training Standards - Performance Outcomes for Dispatchers. In addition, DCJS will review and consider the appropriateness of setting a minimum number of training hours for basic dispatcher training as part of this action.

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

Statutory Authority: § 9.1-102 of the Code of Virginia.

Public Comment Deadline: July 27, 2016.

Agency Contact: Barbara Peterson-Wilson, Law Enforcement Program Coordinator, Department of Criminal Justice Services, 1100 Bank Street, Richmond, VA 23219, telephone (804) 225-4503, FAX (804) 786-0410, or email barbara.peterson-wilson@dcjs.virginia.gov.

VA.R. Doc. No. R16-4634; Filed May 26, 2016, 8:17 a.m.

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Health intends to consider amending **12VAC5-450, Rules and Regulations Governing Campgrounds**. The purpose of the proposed action is to address current camping practices, update terminology, and remove or replace outdated requirements. The goals are to increase consistency and understanding in the campground program, reduce the number of requests the Virginia Department of Health receives and ultimately grants to waive the regulatory requirements, and apply current public health practices industrywide to promote public safety while reducing burdensome regulatory oversight.

This Notice of Intended Regulatory Action serves as the report of the findings of the regulatory review pursuant to § 2.2-4007.1 of the Code of Virginia.

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

Statutory Authority: §§ 35.1-11 and 35.1-17 of the Code of Virginia.

Public Comment Deadline: July 27, 2016.

Agency Contact: David Tiller, Environmental Health Coordinator, Department of Health, P.O. Box 298, Shacklefords, VA 23156, telephone (804) 785-2135, FAX (804) 785-2490, or email dave.tiller@vdh.virginia.gov.

VA.R. Doc. No. R16-4752; Filed June 3, 2016, 2:59 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD FOR CONTRACTORS

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board for Contractors intends to consider amending **18VAC50-22, Board for Contractors Regulations**. The purpose of the proposed action is to amend the specialty definitions to include those contractors who provide remediation services to remove contaminants or site work necessary to make certain real property usable for human occupancy according to the guidelines established pursuant to § 32.1-11.7 of the Code of Virginia.

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

Statutory Authority: §§ 54.1-201 and 54.1-1102 of the Code of Virginia.

Public Comment Deadline: July 27, 2016.

Agency Contact: Eric L. Olson, Executive Director, Board for Contractors, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-2785, FAX (866) 430-1033, or email contractors@dpor.virginia.gov.

VA.R. Doc. No. R16-4674; Filed June 2, 2016, 5:58 p.m.

TITLE 1. ADMINISTRATION

DEPARTMENT OF GENERAL SERVICES

Final Regulation

Title of Regulation: **1VAC30-45. Certification for Noncommercial Environmental Laboratories (amending 1VAC30-45-10, 1VAC30-45-30 through 1VAC30-45-130, 1VAC30-45-300 through 1VAC30-45-400, 1VAC30-45-500, 1VAC30-45-510, 1VAC30-45-520, 1VAC30-45-600, 1VAC30-45-610, 1VAC30-45-660, 1VAC30-45-670, 1VAC30-45-720 through 1VAC30-45-771, 1VAC30-45-775, 1VAC30-45-791, 1VAC30-45-796, 1VAC30-45-798, 1VAC30-45-811, 1VAC30-45-850; adding 1VAC30-45-95; repealing 1VAC30-45-530, 1VAC30-45-780 through 1VAC30-45-788, 1VAC30-45-800 through 1VAC30-45-808, 1VAC30-45-820 through 1VAC30-45-829).**

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Effective Date: September 1, 2016.

Agency Contact: Rhonda Bishton, Regulatory Coordinator, Department of General Services, 1100 Bank Street, Suite 420, Richmond, VA 23219, telephone (804) 786-3311, FAX (804) 371-8305, or email rhonda.bishton@dgs.virginia.gov.

Summary:

The amendments (i) streamline the procedures for application and renewal of certification, (ii) reduce the requirement to perform proficiency test studies to one study annually for each field of certification, (iii) expand the time between on-site assessments from two years to three years for laboratories regularly meeting certification standards, (iv) eliminate requirements for specialized testing that noncommercial laboratories currently do not perform, (v) add procedures for suspension of certification to provide a laboratory time to correct problems to avoid decertification, (vi) make explicit the requirements to notify a laboratory that the agency has cause to deny certification or to decertify, (vii) simplify the appeal procedure language, (viii) restructure and modify the fee system and increase the fees paid by laboratories, and (ix) eliminate, or provide increased flexibility for, a number of quality system provisions (Article 4).

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

Part I
General Provisions

1VAC30-45-10. Purpose.

Section 2.2-1105 of the Code of Virginia directs the Division of Consolidated Laboratory Services to establish a program to certify environmental laboratories that perform tests, analyses, measurements or monitoring required pursuant to the Commonwealth's air, waste and water laws and regulations. This chapter sets out the required standards and the process by which owners of noncommercial environmental laboratories may obtain certification for their laboratories. ~~1VAC30-46 covers commercial environmental laboratories and NELAP accredited environmental laboratories seeking reciprocal accreditation in Virginia.~~

1VAC30-45-30. Applicability.

A. This chapter applies to any owner of a noncommercial environmental laboratory.

B. Any environmental laboratory owned by an agency of the federal government may be certified as follows:

1. By ~~DGS DCLS~~ DCLS to the standards set out in this chapter; or

2. By a federal primary ~~accrediting authority~~ accreditation body to the standards established by ~~the National Environmental Laboratory Accreditation Conference~~ TNI.

C. Citizen monitoring groups. Section 62.1-44.19:11 of the Code of Virginia both establishes a citizen water quality monitoring program for Virginia and encourages the growth of the program. The Department of Environmental Quality (DEQ) has a separate program of quality assurance and quality control (QA/QC) standards for citizen monitoring groups and their laboratories to follow. The following laboratories shall meet the [~~DEG~~ DEQ] QA/QC requirements developed for the purposes of citizen monitoring of water quality in lieu of the requirements of 1VAC30-45 or 1VAC30-46:

1. Laboratories owned by citizen monitoring groups.

2. Laboratories at institutions of higher education affiliated with citizen monitoring groups for the purposes of analyzing samples for the groups.

D. ~~Environmental research performed by environmental laboratories owned by institutions of higher education.~~ Institutions of higher education. Environmental laboratories owned by institutions of higher education located in Virginia that perform analyses for the purpose of providing environmental research data to DEQ at DEQ's request shall meet the QA/QC requirements specified by DEQ. An

environmental laboratory owned by an institution of higher education located in Virginia that performs environmental research for DEQ shall not be subject to the requirements of either 1VAC30-45 or 1VAC30-46 unless DEQ requires the laboratory to do so.

1VAC30-45-40. Definitions.

~~Where a term is defined in this section, the term shall have no other meaning, even if it is defined differently in the Code of Virginia or another regulation of the Virginia Administrative Code. Unless specifically defined in this section, the terms used in this chapter shall have the meanings commonly ascribed to them by recognized authorities.~~ The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

"Acceptance criteria" means specified limits placed on characteristics of an item, process, or service defined in requirement documents.

"Accuracy" means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. Accuracy is an indicator of data quality.

"Algae" means simple single-celled, colonial, or multicelled, mostly aquatic plants, containing chlorophyll and lacking roots, stems and leaves that are either suspended in water (phytoplankton) or attached to rocks and other substrates (periphyton).

"Aliquot" means a portion of a sample taken for analysis.

"Analyte" means the substance or physical property to be determined in samples examined.

"Analytical method" means a technical procedure for providing analysis of a sample, defined by a body such as the Environmental Protection Agency or the American Society for Testing and Materials, that may not include the sample preparation method.

"Assessment" means the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and its systems or both to defined criteria.

"Assessor" means the person ~~who performs on-site assessments of laboratories' capability and capacity for meeting the requirements under this chapter by examining the records and other physical evidence for each one of the tests for which certification has been requested~~ assigned by DCLS to perform, alone or as part of an assessment team, an assessment of an environmental laboratory.

"Audit" means a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

"Authority" means, in the context of a governmental body or local government, an authority created under the provisions of the Virginia Water and Waste Authorities Act, Chapter 51 (§ 15.2-5100 et seq.) of Title 15.2 of the Code of Virginia.

"Batch" means environmental samples that are prepared together or analyzed together or both with the same process and personnel, using the same lot or lots of reagents. "Analytical batch" means a batch composed of prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. "Preparation batch" means a batch composed of one to 20 environmental samples of the same matrix that meets the criteria in this definition for "batch" and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

"Benthic macroinvertebrates" means bottom dwelling animals without backbones that live at least part of their life cycles within or upon available substrates within a body of water.

"Blank" means a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include the following types:

1. Field blank. A blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken.

2. Method blank. A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

"Calibration" means to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

"Calibration curve" means the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

"Calibration standard" means a substance or reference material used to calibrate an instrument.

"Certified reference material" means a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

"Client" or "customer" means the Department of Environmental Quality (DEQ) when used in the context of quality assurance and specific quality control provisions.

"Commercial environmental laboratory" means an environmental laboratory where environmental analysis is performed for another person.

"Corrective action" means the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

~~"DGS-DCLS"~~ "DCLS" means the Division of Consolidated Laboratory Services of the Department of General Services.

"Demonstration of capability" means the procedure to establish the ability of the analyst to generate data of acceptable accuracy and precision.

"Detection limit" means the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence.

"Environmental analysis" or "environmental analyses" means any test, analysis, measurement, or monitoring used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the Code of Virginia). For the purposes of these regulations, any test, analysis, measurement, or monitoring required pursuant to the regulations promulgated under these three laws, or by any permit or order issued under the authority of any of these laws or regulations is "used for the purposes" of these laws. The term shall not include the following:

1. Sampling of water, solid and chemical materials, biological tissue, or air and emissions.

2. Field testing and measurement of water, solid and chemical materials, biological tissue, or air and emissions, except when performed in an environmental laboratory rather than at the site where the sample was taken.

3. Taxonomic identification of samples for which there is no national accreditation standard such as algae, benthic macroinvertebrates, macrophytes, vertebrates and zooplankton.

4. Protocols used pursuant to § 10.1-104.2 of the Code of Virginia to determine soil fertility, animal manure nutrient content, or plant tissue nutrient uptake for the purposes of nutrient management.

5. Geochemical and permeability testing for solid waste compliance.

6. Materials specification for air quality compliance when product certifications specify the data required by an air permit such as fuel type, Btu content, sulfur content, or VOC content.

"Environmental laboratory" or "laboratory" means a facility or a defined area within a facility where environmental analysis is performed. A structure built solely to shelter field personnel and equipment from inclement weather shall not be considered an environmental laboratory.

"Establishment date" means the date set for the accreditation program under 1VAC30-46 and the certification program to be established under this chapter.

"Establishment of certification program" or "established program" means that ~~DGS-DCLS~~ DCLS has completed the initial accreditation of environmental laboratories covered by 1VAC30-46 and the initial certification of environmental laboratories covered by 1VAC30-45.

"Facility" means something that is built or installed to serve a particular function.

"Field of certification" or "FoC" means ~~an approach to certifying laboratories by~~ those matrix, technology/method, and ~~analyte/analyte group~~ analyte combinations for which DCLS offers certification.

"Field of proficiency testing" or "FoPT" means analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain certification, collectively defined as matrix, technology/method, and analyte.

"Field testing and measurement" means any of the following:

1. Any test for parameters under 40 CFR Part 136 for which the holding time indicated for the sample requires immediate analysis; or

2. Any test defined as a field test in federal regulation.

The following is a limited list of currently recognized field tests or measures that is not intended to be inclusive: continuous emissions monitoring; ~~on-line~~ online monitoring; flow monitoring; tests for pH, residual chlorine, temperature and dissolved oxygen; and field analysis for soil gas.

"Finding" means an assessment conclusion ~~that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition.~~ referenced to a laboratory certification standard and supported by objective evidence that identifies a deviation from a laboratory certification standard requirement.

"Governmental body" means any department, agency, bureau, authority, or district of the United States government, of the government of the Commonwealth of Virginia, or of any local government within the Commonwealth of Virginia.

"Holding time ~~(or maximum allowable holding time)~~" means the maximum time that ~~a sample may be held prior to analysis and still be considered valid or not compromised~~ can elapse between two specified activities.

~~"Initial certification period" means the period during which DGS-DCLS is accepting and processing applications for the first time under this chapter as specified in 1VAC30-45-60.~~

"International System of Units (SI)" means the coherent system of units adopted and recommended by the General Conference on Weights and Measures.

"Laboratory control sample" or "LCS" means a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. "Laboratory control sample" or "LCS" may also be named laboratory fortified blank, spiked blank, or QC check sample.

"Laboratory manager" means the person who has overall responsibility for the technical operation of the environmental laboratory and who exercises actual day-to-day supervision of laboratory operation for the appropriate fields of testing and reporting of results. The title of this person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager.

"Legal entity" means an entity, other than a natural person, who has sufficient existence in legal contemplation that it can function legally, be sued or sue, and make decisions through agents as in the case of corporations.

"Limit of detection" or "LOD" means an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte and matrix specific and may be laboratory dependent.

"Limit of quantitation" or "LOQ" means the minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

"Local government" means a municipality (city or town), county, sanitation district, or authority.

"Macrophytes" means any aquatic or terrestrial plant species that can be identified and observed with the eye, unaided by magnification.

"Matrix" means the component or substrate that may contain the analyte of interest. A matrix can be a field of certification matrix or a quality system matrix.

1. Field of certification matrix. These matrix definitions shall be used when certifying a laboratory.

a. ~~Non-potable~~ Nonpotable water. Any aqueous sample that has not been designated a potable or potential potable water source. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

b. Solid and chemical materials. Includes soils, sediments, sludges, products and byproducts of an industrial process that results in a matrix not previously defined.

c. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

d. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

2. Quality system matrix. For purposes of batch and quality control requirement determinations, the following matrix types shall be used:

a. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.

b. Aqueous. Any aqueous sample excluded from the definition of drinking water matrix or saline/estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

c. Saline/estuarine. Any aqueous sample from an ocean or estuary, or other salt water source.

d. Nonaqueous liquid. Any organic liquid with less than 15% settleable solids.

e. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

f. Solids. Includes soils, sediments, sludges and other matrices with more than 15% settleable solids.

g. Chemical waste. A product or ~~by-product~~ byproduct of an industrial process that results in a matrix not previously defined.

h. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

"Matrix spike (spiked sample or fortified sample)" means a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

"Matrix spike duplicate (spiked sample or fortified sample duplicate)" means a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

"National Environmental Laboratory Accreditation Conference (NELAC)" means a voluntary organization of state and federal environmental officials and interest groups with the primary purpose to establish mutually acceptable standards for accrediting environmental laboratories. ~~A subset of NELAP.~~

~~"National Environmental Laboratory Accreditation Program (NELAP)" means the overall National Environmental Laboratory Accreditation Program of which NELAC is a part.~~

"National Institute of Standards and Technology" or "NIST" means an agency of the U.S. Department of Commerce's Technology Administration that is working with EPA, states, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested states can be certified by NIST to provide NIST-traceable proficiency testing (PT) samples.

"Negative control" means measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

"Noncommercial environmental laboratory" means either of the following:

1. An environmental laboratory where environmental analysis is performed solely for the owner of the laboratory.

2. An environmental laboratory where the only performance of environmental analysis for another person is one of the following:

a. Environmental analysis performed by an environmental laboratory owned by a local government for an owner of a small wastewater treatment system treating domestic sewage at a flow rate of less than or equal to 1,000 gallons per day.

b. Environmental analysis performed by an environmental laboratory operated by a corporation as part of a general contract issued by a local government to operate and maintain a wastewater treatment system or a waterworks.

c. Environmental analysis performed by an environmental laboratory owned by a corporation as part of the prequalification process or to confirm the identity or characteristics of material supplied by a potential or existing customer or generator as required by a hazardous waste management permit under 9VAC20-60.

d. Environmental analysis performed by an environmental laboratory owned by a Publicly Owned Treatment Works (POTW) for an industrial source of wastewater under a permit issued by the POTW to the industrial source as part of the requirements of a pretreatment program under Part VII (9VAC25-31-730 et seq.) of 9VAC25-31.

e. Environmental analysis performed by an environmental laboratory owned by a county authority for any municipality within the county's geographic jurisdiction when the environmental analysis pertains solely to the purpose for which the authority was created.

f. Environmental analysis performed by an environmental laboratory owned by an authority or a sanitation district for any participating local government of the authority or sanitation district when the environmental analysis pertains solely to the purpose for which the authority or sanitation district was created.

"Owner" means any person who owns, operates, leases or controls an environmental laboratory.

"Person" means an individual, corporation, partnership, association, company, business, trust, joint venture or other legal entity.

"Physical," for the purposes of fee test categories, means the tests to determine the physical properties of a sample. Tests for solids, turbidity and color are examples of physical tests.

"Positive control" means measures taken to ensure that a test or its components are working properly and producing correct or expected results from positive test subjects.

"Precision" means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is an indicator of data quality. Precision is expressed usually as standard deviation, variance or range, in either absolute or relative terms.

"Primary ~~accrediting authority~~ accreditation body" means the ~~agency or department designated at the territory, state or federal level as the recognized authority with the responsibility and accountability for granting NELAC accreditation to a specific laboratory for a specific field of~~ accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

"Proficiency test or testing (PT)" means evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

~~"Proficiency test (PT) field of testing" means the approach to offer proficiency testing by maxtrix, technology/method, and analyte/analyte group.~~

"Proficiency test (PT) sample" means a sample, the composition of which is unknown to ~~both the analyst and~~ the laboratory and is provided to test whether the ~~analyst or laboratory or both~~ laboratory can produce analytical results within specified acceptance criteria.

"Proficiency testing (PT) program" means the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

"Program," in the context of a regulatory program, means the relevant U.S. Environmental Protection Agency program such as the water program under the Clean Water Act (CWA), the air program under the Clean Air Act (CAA), the waste program under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund) or the waste program under the Resource Conservation and Recovery Act (RCRA).

"Publicly Owned Treatment Works (POTW)" means a treatment works as defined by § 212 of the CWA, which is owned by a state or municipality (as defined by § 502(4) of the CWA). This definition includes any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes, and other conveyances only if they convey wastewater to a POTW treatment plant. The term also means the municipality as defined in § 502(4) of the CWA, which has jurisdiction over the indirect discharges to and the discharges from such a treatment works.

"Quality assurance" or "QA" means an integrated system of management activities involving planning, ~~quality control, quality~~ implementation, assessment, reporting and quality improvement to ensure that a ~~product~~ process, item, or service ~~meets defined standards of quality with a stated level of confidence~~ is of the type and quality needed and expected by the client.

"Quality assurance officer" means the person who has responsibility for the quality system and its implementation. Where staffing is limited, the quality assurance officer may also be the laboratory manager.

"Quality control" or "QC" means the overall system of technical activities ~~whose purpose is to measure and control the quality of a product or service so that it meets the needs of users~~ that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; and also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

"Quality manual" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

"Quality system" means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control activities.

"Range" means the difference between the minimum and maximum of a set of values.

"Reference material" means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement test method, or for assigning values to materials.

"Reference standard" means a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

"Responsible official" means one of the following, as appropriate:

1. If the laboratory is owned or operated by a private corporation, "responsible official" means (i) a president, secretary, treasurer, or a vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy-making or decision-making functions for the corporation or (ii) the manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $25 million (in second-quarter 1980 dollars), if authority to sign documents has been assigned or delegated in accordance with corporate procedures.

2. If the laboratory is owned or operated by a partnership, association, or a sole proprietor, "responsible official" means a general partner, officer of the association, or the proprietor, respectively.

3. If the laboratory is owned or operated by a governmental body, "responsible official" means a director or highest official appointed or designated to oversee the operation and performance of the activities of the environmental laboratory.

4. Any person designated as the responsible official by an individual described in subdivision 1, 2 or 3 of this definition, provided the designation is in writing, the designation specifies an individual or position with responsibility for the overall operation of the environmental laboratory, and the designation is submitted to ~~DGS-DCLS~~ DCLS.

"Sampling" means the act of collection for the purpose of analysis.

"Sanitation district" means a sanitation district created under the provisions of Chapters 3 (§ 21-141 et seq.) through 5 (§ 21-291 et seq.) of Title 21 of the Code of Virginia.

"Sewage" means the water-carried human wastes from residences, buildings, industrial establishments or other places together with such industrial wastes and underground, surface, storm, or other water as may be present.

"Simple test procedures" or "STP" means any of the following:

1. Field testing and measurement performed in an environmental laboratory.

2. The test procedures to determine:

a. Biochemical oxygen demand (BOD) or carbonaceous BOD (CBOD);

b. Fecal coliform;

c. Total coliform;

d. Fecal streptococci;

e. E. coli;

f. Enterococci;

g. Settleable solids (SS);

h. Total dissolved solids (TDS);

i. Total solids (TS);

j. Total suspended solids (TSS);

k. Total volatile solids (TVS); and

l. Total volatile suspended solids (TVSS).

"Standard operating procedure ~~(SOP)~~" or "SOP" means a written document that details the method ~~of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted~~ for an operation, analysis, or action with thoroughly prescribed techniques and steps. An SOP is officially approved as the method for performing certain routine or repetitive tasks.

"Standardized reference material ~~(SRM)~~" or "SRM" means a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method.

"System laboratory" means a noncommercial laboratory that analyzes samples from multiple facilities having the same owner.

~~"TCLP" or "toxicity characteristic leachate procedure" means Test Method 1311 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in 40 CFR 260.11. This method is used to determine whether a solid waste exhibits the characteristic of toxicity (see 40 CFR 261.24).~~

"Test" means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Air Pollution Control Law" means any method of analysis required by the Virginia Air Pollution Control Law (§ 10.1-1300 et seq.); by the regulations promulgated under this law (9VAC5) including any method of analysis listed either in the definition of "reference method" in 9VAC5-10-20, or listed or adopted by reference in 9VAC5; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Waste Management Act" means any method of analysis required by the Virginia Waste Management Act (§ 10.1-1400 et seq.); by the regulations promulgated under this law (9VAC20), including any method of analysis listed or adopted by reference in 9VAC20; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Water Control Law" means any method of analysis required by the Virginia Water Control Law (§ 62.1-44.2 et seq.); by the regulations promulgated under this law (9VAC25), including any method of analysis listed or adopted by reference in 9VAC25; or by any permit or order issued under and in accordance with this law and these regulations.

"Test method" means an adoption of a scientific technique for performing a specific measurement as documented in a laboratory standard operating procedure or as published by a recognized authority.

"The NELAC Institute" or "TNI" means the organization whose standards environmental laboratories must meet to become accredited under 1VAC30-46, the regulation governing commercial environmental laboratories in Virginia.

"Toxicity characteristic leachate procedure" or "TCLP" means Test Method 1311 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in 40 CFR 260.11. This method is used to determine whether a solid waste exhibits the characteristic of toxicity (see 40 CFR 261.24).

"Traceability" means the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

"U.S. Environmental Protection Agency" or "EPA" means the federal government agency with responsibility for protecting, safeguarding and improving the natural environment (i.e., air, water and land) upon which human life depends.

"Virginia Air Pollution Control Law" means Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 of the Code of Virginia, which is titled "Air Pollution Control Board."

"Virginia Environmental Laboratory Accreditation Program" or "VELAP" means the program DCLS operates to certify environmental laboratories under this chapter.

"Wastewater" means liquid and water-carried industrial wastes and domestic sewage from residential dwellings, commercial buildings, industrial and manufacturing facilities and institutions.

"Waterworks" means each system of structures and appliances used in connection with the collection, storage, purification, and treatment of water for drinking or domestic use and the distribution thereof to the public, except distribution piping.

"Zooplankton" means microscopic animals that float freely with voluntary movement in a body of water.

1VAC30-45-50. Scope of certification.

A. Noncommercial environmental laboratories shall be certified based on the general laboratory standards set out in Part II (1VAC30-45-200 et seq.) of this chapter and on the specific test methods or analysis, monitoring or measurement required by regulatory permit or other requirement under the Virginia Air Pollution Control Law, Virginia Waste Management Act, or Virginia Water Control Law, the regulations promulgated under these laws, and by permits and orders issued under and in accordance with these laws or regulations.

B. ~~DGS DCLS~~ DCLS shall review alternative test methods and procedures for certification when these are proposed by the applicant laboratory. The provisions of 1VAC30-45-70 E and 1VAC30-45-90 B govern alternative test methods and procedures.

C. Certification shall be granted for one or more fields of certification, including the matrix, the technology and methods ~~used by the noncommercial environmental laboratory~~, and the individual analytes ~~or analyte groups~~ determined by the particular method used by the laboratory.

1VAC30-45-60. General: certification requirements.

A. Components of certification. The components of certification include review of personnel qualifications, on-site assessment, proficiency testing, and quality systems. The criteria for these components, set out in Part II (1VAC30-45-200 et seq.) of this chapter, shall be fulfilled for certification.

B. Individual laboratory sites and mobile laboratories.

1. Individual laboratory sites are subject to the same application process, assessments, and other requirements as environmental laboratories. Any remote laboratory sites are considered separate sites and subject to separate on-site assessments.

2. Laboratories located at the same physical location shall be considered an individual laboratory site if these laboratories are owned by the same person, and have the same laboratory manager and quality system.

~~3. Laboratories located at separate, noncontiguous physical locations may request to be considered as an individual laboratory site if these laboratories are owned by the same person and have the same laboratory manager and quality system.~~

~~4.~~ 3. A mobile laboratory, which is configured with equipment to perform analyses, whether associated with a fixed-based laboratory or not, is considered an environmental laboratory and shall require separate certification. This certification shall remain with the mobile laboratory and be site independent. Moving the configured mobile laboratory to a different site will not require a new or separate certification. Before performing analyses at each new site, the laboratory shall ensure that instruments and equipment have been checked for performance and have been calibrated.

1VAC30-45-70. Process to apply and obtain certification.

A. Duty to apply. All owners of noncommercial environmental laboratories shall apply for certification as specified by the provisions of this section. Applications for certification must be obtained from DCLS program staff by email at Lab_Cert@dgs.virginia.gov.

~~B. Timely initial applications.~~

~~1. Owners of noncommercial environmental laboratories applying for certification under this chapter for the first time shall submit an application to DGS DCLS no later than September 29, 2009.~~

~~2. Owners of noncommercial environmental laboratories that come into existence after January 1, 2009, shall submit an initial application to DGS DCLS no later than 180 calendar days prior to beginning operation.~~

~~C. Timely renewal applications. The owner of a certified noncommercial environmental laboratory shall submit an application for renewal of certification at least 90 calendar days prior to expiration of certification.~~

B. Owners of noncommercial environmental laboratories applying for certification under this chapter for the first time shall submit an application to DCLS as specified under subsection F of this section.

C. Renewal and reassessment.

1. DCLS shall renew certification annually for the certified laboratory provided the laboratory does the following:

a. Maintains compliance with this chapter.

b. Attests to this compliance by signing the certificate of compliance provided under subdivision F 3 of this section.

c. Reports acceptable proficiency test values as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

d. Pays the fee required by 1VAC30-45-130.

2. DCLS shall reassess the certified environmental laboratory during an on-site assessment as required by Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter.

D. Responsibilities of the owner and operator when the laboratory is owned by one person and operated by another person.

1. When an environmental laboratory is owned by one person but is operated by another person, the operator may submit the application for the owner.

2. If the operator fails to submit the application, the owner is not relieved of his responsibility to apply for certification.

3. While ~~DGS DCLS~~ DCLS may notify noncommercial environmental laboratories of the date their applications are due, failure of ~~DGS DCLS~~ DCLS to notify does not

relieve the owner of his obligation to apply under this chapter.

E. Submission of applications for modifications to certification. An owner of a certified noncommercial environmental laboratory shall follow the process set out in 1VAC30-45-90 B ~~to add a new matrix, technology/method, an analyte or analyte group, modify a test method or institute use of a method or technology not in the laboratory's standard operating procedures, including alternative test methods or procedures~~ to modify the laboratory's scope of certification.

F. Contents of application.

1. Applications shall include but not be limited to the following information and documents:

a. Legal name of laboratory;

b. Name of owner of laboratory;

c. Name of operator of laboratory, if different than owner;

d. Street address and description of location of laboratory;

e. Mailing address of laboratory, if different from street address;

f. Address of owner, if different from laboratory address;

g. Name, address, telephone number, facsimile number and ~~e-mail~~ email, as applicable, of responsible official;

h. Name, address, telephone number, facsimile number and ~~e-mail~~ email, as applicable, of laboratory manager;

i. Name, address, telephone number, facsimile number and ~~e-mail~~ email, as applicable, of designated quality assurance officer;

j. Name ~~title,~~ and telephone number of laboratory contact person;

k. Laboratory type (e.g., public water system, public wastewater system or combination of the two, or industrial (with type of industry indicated));

l. Laboratory hours of operation;

m. Fields of certification (matrix, technology/method, and ~~analyte/analyte group)~~ analyte) for which certification is sought;

~~n. Methods employed, including analytes;~~

~~o.~~ n. The results of ~~the three most recent proficiency test studies~~ one successful unique PT study for each field of proficiency testing as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter;

~~p.~~ o. Quality assurance manual; and

~~q. Lab identification number (for renewal only); and~~

~~r.~~ p. For mobile laboratories, a unique vehicle identification number, such as a manufacturer's vehicle identification number (VIN#), serial number, or license number.

2. Fee. The application shall include payment of the fee as specified in 1VAC30-45-130.

3. Certification of compliance.

a. The application shall include a "Certification of Compliance" statement signed and dated by the responsible official, by the quality control officer and by the laboratory manager.

b. The certification of compliance shall state: "The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the Virginia environmental laboratory certification program regulation (1VAC30, Chapter 45) and is subject to the provisions of 1VAC30-45-100 in the event of noncompliance. I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the laboratory or those persons directly responsible for gathering and evaluating the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. Submitting false information or data shall result in denial of certification or decertification. I hereby further certify that I am authorized to sign this application."

G. Completeness determination.

1. ~~DGS-DCLS~~ DCLS shall determine whether an application is complete and notify the laboratory of the result of such determination. ~~During the initial certification period, DGS-DCLS~~ DCLS shall provide this notice within 90 calendar days of its receipt of a laboratory's initial application. ~~Following the initial certification period, DGS-DCLS shall provide this notice within 60 calendar days of DGS-DCLS's receipt of a laboratory's initial application and within 30 calendar days of DGS-DCLS' receipt of a laboratory's renewal application.~~

2. An application shall be determined complete if it contains all the information required pursuant to subsection F of this section and is sufficient to evaluate the laboratory prior to the on-site assessment. Designating an application complete does not preclude ~~DGS-DCLS~~ DCLS from requesting or accepting additional information.

3. If ~~DGS-DCLS~~ DCLS determines that an application is incomplete, ~~DGS-DCLS's~~ the DCLS notification of such determination shall explain why the application is incomplete and specify the additional information needed to make the application complete.

4. ~~Except during the initial certification period, if~~ If DCLS makes no determination ~~is made within 60~~ within 90 calendar days of ~~DGS-DCLS's~~ its receipt of either (i) the application or (ii) additional information, in the case of an application determined to be incomplete, the application

shall be determined to be complete. ~~During the initial certification period, the time period shall be 90 calendar days.~~

5. If the laboratory has not submitted the required additional information within 90 days of receiving a notice from ~~DGS DCLS~~ DCLS requesting additional information, ~~DGS DCLS~~ DCLS may ~~return the incomplete application and~~ inform the laboratory that the application cannot be processed. The laboratory may then submit a new application.

H. Grant of interim certification pending final determination on application.

1. ~~DGS DCLS~~ DCLS shall grant a laboratory interim certification status under the following conditions:

a. The laboratory's application is determined to be complete;

b. The laboratory has satisfied all the requirements for certification, including all requests for additional information, with the exception of on-site assessment; and

c. ~~DGS DCLS~~ DCLS is unable to schedule the on-site assessment within ~~90~~ 120 days of its determination that the application is complete ~~(for initial applications) or before the laboratory's certification expires (for renewal applications)~~.

2. A laboratory with interim certification status shall have the same rights and status as a laboratory that has been granted certification by ~~DGS DCLS~~ DCLS.

3. Interim certification expires when ~~DGS DCLS~~ DCLS issues a final determination on certification.

I. On-site assessment. ~~1.~~ An on-site assessment shall be performed and the follow-up and reporting procedures for such assessments shall be completed in accordance with Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter prior to issuance of a final determination on certification.

~~2. Alternative on-site assessment option. If DGS DCLS is unable to schedule an on-site assessment under the conditions of subsection H 1 c of this section, the owner of the applicant laboratory may use third-party on-site assessors instead of DGS DCLS on-site assessors under the following conditions:~~

~~a. The third-party on-site assessors are on a DGS DCLS-approved list of on-site assessors; and~~

~~b. The owner of the applicant laboratory agrees to pay the third-party on-site assessors.~~

J. Final determination on certification. ~~1.~~ Upon completion of the certification review process and corrective action, if any, ~~DGS DCLS~~ DCLS shall grant certification in accordance with subsection K of this section or deny certification in accordance with subsection L of this section.

~~2. Except during the initial certification period, DGS DCLS shall complete action on a laboratory's application within nine months from the time a completed application is received from the laboratory.~~

K. Grant of certification.

1. When a laboratory meets the requirements specified for receiving certification, ~~DGS DCLS~~ DCLS shall issue a certificate to the laboratory. ~~The~~ DCLS shall send the certificate ~~shall be sent~~ to the laboratory manager~~,~~ and shall notify the responsible official ~~shall be notified~~.

2. The director of ~~DGS DCLS~~ DCLS or his designee shall sign the certificate. The certificate shall include the following information:

a. Name of owner of laboratory;

b. Name of operator of laboratory, if different from owner;

c. Name of responsible official;

d. Address and location of laboratory;

e. Laboratory identification number;

f. Fields of certification (matrix, technology/method, ~~analyte/analyte group)~~ and analyte) for which certification is granted;

g. Any addenda or attachments; and

h. Issuance date and expiration date.

3. The laboratory shall post the most recent certificate of certification and any addenda to the certificate issued by ~~DGS DCLS~~ DCLS in a prominent place in the laboratory facility.

4. Certification shall expire ~~two years~~ one year after the date on which certification is granted.

L. Denial of certification.

1. ~~DGS DCLS~~ DCLS shall deny certification to an environmental laboratory in total if the laboratory is found to be falsifying any data or providing false information to support certification.

2. Denial of certification in total or in part.

a. ~~DGS DCLS~~ DCLS may deny certification to an environmental laboratory in total or in part if the laboratory fails to do any of the following:

(1) Pay the required fees.

(2) Employ laboratory staff to meet the personnel qualifications as required by Part II (1VAC30-45-200 et seq.) of this chapter.

(3) Successfully analyze and report proficiency testing samples as required by Part II of this chapter.

(4) Submit a corrective action ~~report~~ plan in accordance with Part II of this chapter in response to a deficiency report from the on-site assessment team within the required 30 calendar days.

(5) Implement the corrective actions detailed in the corrective action ~~report~~ plan within the [~~time frame~~ timeframe] specified by ~~DGS DCLS~~ DCLS.

(6) Pass required on-site assessment as specified in Part II of this chapter.

(7) Implement a quality system as defined in Part II of this chapter.

b. ~~DGS-DCLS~~ DCLS may deny certification to an environmental laboratory in total or in part if the laboratory's application is not determined to be complete within 90 calendar days following notification of incompleteness because the laboratory is delinquent in submitting information required by ~~DGS-DCLS~~ DCLS in accordance with this chapter.

c. ~~DGS-DCLS~~ DCLS may deny certification to an environmental laboratory in total or in part if the ~~DGS-DCLS~~ DCLS on-site assessment team is unable to carry out the on-site assessment pursuant to Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter because a representative of the environmental laboratory denied the team entry during the laboratory's normal business hours that it specified in its application.

3. ~~DGS-DCLS~~ DCLS shall follow the process specified in 1VAC30-45-110 when denying certification to an environmental laboratory.

M. Reapplication following denial of certification. ~~1. Upon denial of certification, the laboratory shall wait six months before reapplying for certification. 2. DGS-DCLS~~ DCLS shall not waive application fees for a laboratory reapplying for certification.

1VAC30-45-80. Maintaining certification.

A. Certification remains in effect until withdrawn by ~~DGS-DCLS~~ DCLS, withdrawn voluntarily at the written request of the certified laboratory, or until expiration of the certification period. To maintain certification, the certified laboratory shall comply with the elements listed in this section and in 1VAC30-45-90.

B. Quality systems. Laboratories seeking to maintain certification under this chapter shall assure consistency and promote the use of quality assurance and quality control procedures. Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter specifies the quality assurance and quality control requirements that shall be met to maintain certification.

C. Proficiency tests. Laboratories seeking to maintain certification under this chapter shall perform proficiency tests as required under Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

D. Recordkeeping and retention. All laboratory records associated with certification parameters shall be kept as provided by the requirements for records under Part II (1VAC30-45-200 et seq.) of this chapter. These records shall be maintained for a minimum of three years unless the records are required to be maintained for a longer period by another section of this regulation or another regulation. All such records shall be available to ~~DGS-DCLS~~ DCLS upon request.

1VAC30-45-90. Notifications and changes to certification elements and status.

A. Changes to key certification criteria. The certified laboratory shall notify ~~DGS-DCLS~~ DCLS in writing of any changes in key certification criteria within 30 calendar days of the change. Key certification criteria are laboratory ownership, location, key personnel, and major instrumentation.

B. Changes to scope of certification.

1. ~~DGS-DCLS~~ DCLS may approve a laboratory's application to add a new matrix, technology, analyte, or test method to a laboratory's scope of certification or to otherwise modify the laboratory's scope of certification by performing a data review.

2. To apply, the owner of the certified laboratory shall submit the following to ~~DGS-DCLS~~ DCLS:

a. A ~~letter~~ written request signed by the owner that briefly summarizes the addition to be made to the laboratory's scope of certification.

b. Pertinent information demonstrating the laboratory's capability to perform the additional matrix, technology/method, or ~~analyte/analyte group~~ analyte, such as proficiency testing performance and quality control performance.

c. A written standard operating procedure covering the new matrix, technology/method, or ~~analyte/analyte group~~ analyte.

3. ~~DGS-DCLS~~ DCLS may approve a laboratory's application for modification to its scope of certification by performing a review of the application materials submitted, without an on-site assessment. The addition of a technology or test method requiring the use of specific equipment may require an on-site assessment. Other reviews of performance and documentation may be carried out by ~~DGS-DCLS~~ DCLS depending on the modification for which the laboratory applies.

4. Within 90 calendar days of the receipt of the application from the certified environmental laboratory, ~~DGS-DCLS~~ DCLS shall review and determine whether the proposed modification may be approved.

5. If the proposed modification to the laboratory's scope of certification is approved, ~~DGS-DCLS~~ DCLS shall amend the laboratory's certificate of certification.

6. DCLS shall not send the amended certificate of certification to the laboratory until DCLS receives the payment of the fee required under 1VAC30-45-130 F 1.

C. Change of ownership or location of laboratory.

1. The certified laboratory shall submit a written notification to ~~DGS-DCLS~~ DCLS of the change of ownership or location of the laboratory within 30 calendar days of the change. This requirement ~~applies only to fixed-~~

~~based and not~~ pertaining to change of location does not apply to mobile laboratories.

2. Certification may be transferred when the legal status or ownership of a certified laboratory changes as long as the transfer does not affect the laboratory's personnel, equipment, or organization.

3. If the laboratory's personnel, equipment, or organization are affected by the change of legal status or ownership, ~~DGS DCLS~~ DCLS may require recertification or reapplication in any or all of the categories for which the laboratory is certified.

4. ~~DGS DCLS~~ DCLS may require an on-site assessment depending on the nature of the change of legal status or ownership. ~~DGS DCLS~~ DCLS shall determine the elements of any on-site assessment required.

~~5. When there is a change in ownership, the new owner of the certified laboratory shall assure historical traceability of the laboratory identification numbers.~~

~~6.~~ 5. When there is a change in ownership, the new owner of the certified laboratory shall keep all records and analyses performed by the previous owner ~~under his scope of~~ pertaining to certification for a period of three years, or longer if required by other regulations. These records and analyses are subject to inspection by ~~DGS DCLS~~ DCLS during this three-year period. This provision applies regardless of change of ownership, accountability or liability.

D. Voluntary withdrawal. Any environmental laboratory owner who wishes to withdraw the laboratory from its certification status or from being certified, in total or in part, shall submit written notification to ~~DGS DCLS no later than 30 calendar days before the end of the laboratory's certification term~~ DCLS. ~~Within 30 calendar days, DGS DCLS~~ DCLS shall provide the laboratory with a written notice of withdrawal.

1VAC30-45-95. Suspension of certification.

A. DCLS may suspend certification from an environmental laboratory in total or in part to allow the laboratory time to correct the reason for which DCLS may withdraw certification. Suspension is limited to the reasons listed in subsection B of this section.

B. DCLS may suspend certification from an environmental laboratory in part or in total when the laboratory has failed to do any of the following:

1. Participate in the proficiency testing program as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

2. Satisfactorily complete proficiency testing studies as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

3. Maintain a quality system as defined in Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter.

4. Employ staff that meets the personnel qualifications of Article 1 (1VAC30-45-200 et seq.) of Part II of this chapter.

5. Notify DCLS of any changes in key certification criteria as set forth in 1VAC30-45-90.

C. Process to suspend certification.

1. When DCLS becomes aware of a cause to suspend a laboratory, the agency shall send notification to the responsible official and the laboratory manager stating it appears to DCLS that the laboratory has failed to meet the 1VAC30-45 standards for one or more of the reasons listed in subsection B of this section. DCLS shall send the notification by certified mail.

2. The DCLS notification shall do the following:

a. Require the laboratory to provide DCLS with documentation of the corrective action already taken with regard to its failure to meet a standard under subsection B of this section.

b. State the corrective action the laboratory must take and the time allowed for this corrective action to be completed in order to retain certification.

3. The environmental laboratory may proceed to correct the deficiencies for which DCLS may suspend the laboratory's certification.

4. Alternatively the laboratory may state in writing that DCLS is incorrect in its observations regarding potential suspension and give specific reasons why the laboratory believes DCLS should not suspend certification. The laboratory has the right to due process as set forth in 1VAC30-45-110, the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), and Part 2A of the Rules of the Supreme Court of Virginia.

5. With the exception of subdivision B 4 of this section, DCLS may allow the laboratory up to 60 days to correct the problem for which it may have its certification suspended.

6. DCLS shall set a date for suspension that follows the period provided under subdivision 5 of this subsection to restore certification.

7. If the laboratory does not correct its deficiencies within the time period allowed or pursue options under subdivision 4 of this subsection, DCLS may suspend a laboratory in part or in total.

8. DCLS shall notify the laboratory by letter if the laboratory's certification is suspended in part or in total. DCLS shall send the notification by certified mail. DCLS shall also notify the pertinent Virginia state agency of the laboratory's suspension status.

9. The laboratory may provide information demonstrating why suspension is not warranted in accordance with subdivision 4 of this subsection.

D. Responsibilities of the environmental laboratory and DCLS when certification has been suspended.

1. The term of suspension shall be limited to six months or the period of certification whichever is longer.

2. The environmental laboratory shall not continue to analyze samples or report analysis for the fields of certification for which DCLS has suspended certification.

3. The environmental laboratory shall retain certification for the fields of certification, methods, and analytes where it continues to meet the requirements of this chapter.

4. The laboratory's suspended certification status shall change to certified when the laboratory demonstrates to DCLS that the laboratory has corrected the deficiency or deficiencies for which its certification was suspended.

5. An environmental laboratory with suspended certification shall not have to reapply for certification if the cause or causes for suspension are corrected within the term of suspension.

6. If the laboratory fails to correct the causes of suspension within the term of suspension, DCLS shall decertify the laboratory in total or in part.

1VAC30-45-100. Decertification.

A. ~~DGS-DCLS~~ DCLS shall decertify an environmental laboratory in total if the laboratory is found to be falsifying any data or providing false information to support certification.

B. ~~DGS-DCLS~~ DCLS may decertify an environmental laboratory in part or in total when the laboratory has failed to do any of the following:

1. Participate in the proficiency testing program as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

2. ~~Complete~~ Satisfactorily complete proficiency testing studies ~~and maintain a history of at least two successful proficiency testing studies for each affected certified field of testing out of the three most recent proficiency testing studies as defined in~~ as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

3. Maintain a quality system as defined in Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter.

4. Employ staff that ~~meet~~ meets the personnel qualifications in Article 1 (1VAC30-45-200 et seq.) of Part II of this chapter.

5. Submit an acceptable corrective action ~~report~~ plan after two opportunities as specified in 1VAC30-45-390.

6. Implement corrective action specified in the laboratory's corrective action ~~report~~ plan as set out under 1VAC30-45-390.

7. Notify ~~DGS-DCLS~~ DCLS of any changes in key certification criteria as set forth in 1VAC30-45-90.

8. Use accurate references to the laboratory's certification status in the laboratory's documentation.

9. Allow a DCLS assessment team entry during normal business hours to conduct an on-site assessment required by Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter.

10. Pay the required fees specified in 1VAC30-45-130.

C. ~~DGS-DCLS~~ DCLS shall follow the process specified in 1VAC30-45-110 when decertifying an environmental laboratory.

D. Responsibilities of the environmental laboratory and ~~DGS-DCLS~~ DCLS when certification has been withdrawn.

1. Laboratories that lose their certification in full shall return their certificate to ~~DGS-DCLS~~ DCLS.

2. If a laboratory loses certification in part, ~~an addendum to the certificate shall be issued by DGS-DCLS~~ DCLS shall issue a revised certificate to the laboratory.

3. When the environmental laboratory has lost certification in full or in part, the laboratory shall not continue to analyze samples or report analyses for the fields of certification that DCLS has decertified.

E. After correcting the reason or cause for decertification under ~~1VAC30-45-100~~ subsection A or B of this section, the laboratory owner may reapply for certification under 1VAC30-45-70.

1VAC30-45-110. Procedures to deny certification~~, to~~ or decertify a laboratory~~, and~~; appeal procedures.

A. Notification.

1. If ~~DGS-DCLS believes it has grounds~~ DCLS becomes aware of a cause to deny certification or to decertify an environmental laboratory, ~~DGS-DCLS~~ DCLS shall notify the environmental laboratory in writing of ~~its intent to hold an informal fact finding under § 2.2-4019 of the Code of Virginia in order to make a decision on the denial of certification or decertification~~ this information and require a response from the responsible official. ~~DGS-DCLS~~ DCLS shall send this notification by certified mail to the responsible official and provide a copy to the manager of the environmental laboratory. ~~The notice of informal fact finding shall provide a detailed explanation of the basis for the notice.~~

2. For a potential denial of certification, the notice shall state that the laboratory has failed to meet the 1VAC30-45 standards and shall specify one or more of the reasons for denial of certification under 1VAC30-45-70 L, providing a detailed explanation of the basis for the denial of certification.

3. For a potential decertification, the notice shall state that the laboratory has failed to meet the 1VAC30-45 standards and shall specify one or more of the reasons for decertification under 1VAC30-45-100 A or B, providing a detailed explanation of the basis for decertification.

4. In its notice, DCLS shall request the laboratory to notify DCLS in writing if the laboratory believes the agency is incorrect in its determination. Before rendering a decision on decertification or denial of certification, DCLS shall provide the opportunity for the laboratory to meet with DCLS in an informal fact-finding proceeding pursuant to § 2.2-4019 of the Code of Virginia.

5. If the laboratory believes DCLS to be incorrect in its determination, the laboratory shall provide DCLS with a detailed written demonstration of why DCLS should not deny certification to or decertify the laboratory. The laboratory shall include this demonstration in the response required under subdivision 6 of this subsection.

6. The laboratory shall provide DCLS with a written response within 30 calendar days of the date of notification from DCLS. The laboratory shall indicate whether it disputes the DCLS determination provided in the agency notice and whether the laboratory requests an informal fact-finding proceeding. If the laboratory does not respond, DCLS shall render its case decision.

~~B. Following the informal fact-finding held pursuant to § 2.2-4019 of the Code of Virginia, the director shall render a decision regarding certification, and shall send this notification by certified mail to the responsible official and provide a copy to the manager of the environmental laboratory. If the director's decision is adverse to the environmental laboratory, the responsible official may appeal this decision in accordance with § 2.2-4026 of the Code of Virginia and Part 2A of the Rules of the Supreme Court of Virginia.~~

~~C. The provisions of this section do not preclude informal discussions between DGS-DCLS and any environmental laboratory that has been notified of a possible denial of certification or of decertification. These informal discussions to resolve the concerns that prompted the notice shall be held prior to the informal fact-finding proceeding.~~

B. An environmental laboratory may appeal a final decision by DCLS to deny certification to or decertify a laboratory pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

~~D.~~ C. The certification status of an environmental laboratory appealing decertification shall not change pending the final decision of the appeals filed under the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) and Part 2A of the Rules of Supreme Court of Virginia.

1VAC30-45-120. Exemptions.

A. ~~DGS-DCLS~~ DCLS may grant a partial or full exemption from the requirements of this chapter based on compliance and performance.

B. ~~DGS-DCLS~~ DCLS may consider granting an exemption if a laboratory applies for an exemption and has met all certification requirements for a period of four consecutive years.

C. An environmental laboratory may apply for an exemption by submitting a request. The request shall include the following information:

1. The scope of the requested exemption;

2. Whether the exemption should be partial or total;

3. If partial, what form the exemption will take; and

4. Why the exemption is appropriate.

D. Upon receiving an application for an exemption, ~~DGS-DCLS~~ DCLS shall provide notice of the request for an exemption in the Virginia Register of Regulations.

E. The notice shall provide a 30-day comment period on the request and shall specify the nature of the request.

F. ~~DGS-DCLS~~ DCLS shall grant or deny the exemption request and provide a written response to the requesting laboratory within 90 calendar days of receipt of the request.

G. Exemptions granted by ~~DGS-DCLS~~ DCLS shall be for a period of no more than 24 months.

1VAC30-45-130. Fees.

A. General.

1. ~~Fees shall be submitted with all applications, including reapplications, for certification and all renewal applications for certification. Applications shall not be designated as complete until the fee is received by DGS-DCLS.~~ Environmental laboratories shall pay a fee with all applications, including reapplications, for certification. DCLS shall not designate an application as complete until it receives payment of the fee.

2. Each certified environmental laboratory shall pay an annual fee to maintain its certification. DCLS shall send an invoice to the certified environmental laboratory.

3. Fees shall be nonrefundable.

~~B. Fee computation.~~

~~1. Fees shall be computed based on the test methods for which a laboratory seeks certification and on the laboratory type. For the purpose of fee calculation, the designations for the laboratory type are (i) a general environmental laboratory or (ii) an environmental laboratory performing only simple test procedures.~~

~~2. The fee shall be the total of the base fee and the test category fees for the specific laboratory type to be certified.~~

~~3. The test category fees cover categories for the test methods to be certified as specified in the laboratory's application.~~

~~4. If the total of the base fee and the test category fees is more than the maximum fee designated for the specific laboratory type to be certified, the laboratory shall pay the maximum fee.~~

~~C. Laboratories~~ B. Environmental laboratories performing only simple test procedures shall pay an annual fee of $600.

~~1. The base fee shall be $100.~~

~~2. The maximum fee shall be $600.~~

~~D. General environmental laboratories.~~

~~1. The base fee shall be $1,700.~~

~~2. The maximum fee shall be $5,200.~~

~~E. Test category fees.~~

~~1. Fees shall be charged for each category of tests to be certified.~~

~~2. The fee for each category includes one or more analytical methods unless otherwise specified. With the exception of the test categories labeled oxygen demand and physical, test categories related to test methods for water are defined by 40 CFR 136.3.~~

~~3. Fees.~~

~~TEST CATEGORY~~	~~FEE~~
~~Oxygen demand (BOD or COD)~~	~~$375~~
~~Bacteriology~~	~~$375~~
~~Inorganic chemistry, fewer than four methods~~	~~$375~~
~~Inorganic chemistry, four or more methods~~	~~$750~~
~~Chemistry metals, one - two methods~~	~~$450~~
~~Chemistry metals, more than two methods~~	~~$1,000~~
~~Organic chemistry, fewer than four methods~~	~~$600~~
~~Organic chemistry, four or more methods~~	~~$1,200~~
~~Aquatic toxicity, acute methods only~~	~~$400~~
~~Aquatic toxicity, acute and chronic methods~~	~~$700~~
~~Radiochemical~~	~~$1,000~~
~~Physical~~	~~$375~~

C. Fee computation for general environmental laboratories.

1. Fees shall be applied on an annual basis.

2. Environmental laboratories shall pay the total of the base fee and the test category fees set out in subsections D and E of this section.

D. Base fees for general environmental laboratories.

1. DCLS determines the base fee for a laboratory by taking into account both the total number of methods and the total number of field of certification matrices for which the laboratory would be certified.

2. DCLS shall charge the base fees set out in Table 1. The base fee for a laboratory is located by first finding the row for the total number of methods to be certified and then finding the box on that row located in the column headed by the total number of matrices to be certified. For example, DCLS charges a base fee of $1300 to a laboratory performing a total of eight methods for one matrix.

TABLE 1: BASE FEES

Number of Methods	1 Matrix	2 Matrices
1 - 9	$1300	$1430
10 - 29	$1400	$1575
30 - 99	$1550	$1825

E. Test category fees for general environmental laboratories.

1. The test category fees cover the types of testing for which a laboratory may be certified as specified in the laboratory's application or as certified at the time of annual billing.

2. Fees shall be charged for each category of tests to be certified.

3. Fees shall be charged for the total number of field of certification matrices to be certified under the specific test category. For example, if a laboratory is performing inorganic chemistry for both nonpotable water and solid and chemical materials matrices, the fee for this test category would be found in the column for two matrices.

4. The fee for each category includes one or more analytical methods unless otherwise specified.

5. DCLS shall charge the test category fees set out in Table 2. The test category fees for a laboratory are located by first finding the row with the total number of test methods for the test category to be certified. The fee to be charged for the test category will be found on that row in the column headed by the total number of matrices to be certified. A laboratory performing four test methods for inorganic chemistry in nonpotable water and solid and chemical materials (two matrices) would be charged a test category fee of $375.

6. Noncommercial environmental laboratories that perform toxicity, radiochemical, or asbestos testing shall pay the test category fees established for these types of testing in 1VAC30-46-150.

TABLE 2: TEST CATEGORY FEES

Test Category	Fees by Number of Matrices	
	One	Two
Oxygen demand	$225	$335
Bacteriology, 1 - 3 total methods	$175	$265
Bacteriology, 4 or more total methods	$220	$330

Physical, 1 - 5 total methods	$175	$265
Physical, 6 - 10 total methods	$220	$330
Inorganic chemistry, 1 - 10 total methods	$250	$375
Inorganic chemistry, 11 - 20 total methods	$315	$475
Inorganic chemistry, 21 - 49 total methods	$394	$590
Chemistry metals, 1 - 5 total methods	$325	$490
Chemistry metals, 6 - 20 total methods	$410	$615
Organic chemistry, 1 - 5 total methods	$400	$600
Organic chemistry, 6 - 20 total methods	$500	$750

7. Fee examples. Three examples are provided.

a. Example 1:

Base Fee	One matrix and four test methods	$1300
Test Category Fees		
One Matrix		
Nonpotable Water	Bacteriology (2 methods)	$175
Nonpotable Water	Oxygen demand (1 method)	$225
Nonpotable Water	Physical (1)	$175
TOTAL		$1875

b. Example 2:

Base Fee	One matrix and 15 test methods	$1400
Test Category Fees		
One Matrix		
Nonpotable Water	Bacteriology (2 methods)	$175
Nonpotable Water	Inorganic chemistry (9 methods)	$250
Nonpotable Water	Chemistry metals (2 methods)	$325
Nonpotable Water	Oxygen demand (1 method)	$225
Nonpotable Water	Physical (1)	$175
TOTAL		$2550

c. Example 3:

Base Fee	Two matrices and 27 test methods	$1575
Test Category Fees		
One Matrix		
Nonpotable Water	Bacteriology (4 methods)	$220
Nonpotable Water	Oxygen demand (1 method)	$225
Solid and Chemical Materials	Chemistry metals (1 method)	$325
Two Matrices		
Nonpotable Water and Solid and Chemical Materials	Inorganic chemistry (13 methods)	$475
Nonpotable Water and Solid and Chemical Materials	Physical (7 methods)	$330
TOTAL		$3150

F. Additional fees. Additional fees shall be charged to laboratories applying for the following: (i) modification to scope of certification under 1VAC30-45-90 B, (ii) transfer of ownership under 1VAC30-45-90 C, (iii) exemption under 1VAC30-45-120, ~~(iv) request that multiple noncontiguous laboratory sites be considered as one site under 1VAC30-45-60 B 3,~~ or ~~(v)~~ (iv) petition for a variance under 1VAC30-45-140.

1. For any certified environmental laboratory that applies to modify its scope of certification as specified under 1VAC30-45-90 B, DCLS shall assess a fee determined by the method in subsection G of this section.

2. Under 1VAC30-45-90 C, DCLS may charge a transfer fee to a certified laboratory that transfers ownership. A fee shall be charged if DCLS (i) needs to review documentation sent by the laboratory about the transfer of ownership or (ii) determines that an on-site assessment is necessary to evaluate the effect of the transfer of ownership. DCLS shall assess a fee determined by the method in subsection G of this section. If, under 1VAC30-45-90 C, DCLS determines that the change of ownership or location of laboratory requires recertification of or reapplication by the laboratory, the laboratory shall pay the application fees required under this section.

~~1.~~ 3. General environmental laboratories applying for an exemption under 1VAC30-45-120 shall pay an initial application fee of ~~$250 and if the exemption is granted, up to an additional $1,000 depending on the scope of the exemption.~~ $700 plus an additional fee based on the actual time needed for DCLS to assess the exemption request. The total fee shall not exceed the actual time DCLS takes to assess the exemption request. Laboratories performing only simple test procedures applying for an exemption under 1VAC30-45-120 shall pay an initial application fee of ~~$100 and if the exemption is granted, up to an additional $1,000 depending on the scope of the exemption. The fee assessed for the scope of the exemption shall be based on the actual time needed for DGS-DCLS to make the determination~~ $300 plus an additional fee based on the actual time needed for DCLS to assess the exemption request. The total fee shall not exceed the actual time DCLS takes to assess the exemption request. The fee assessed shall be calculated using the method in subsection G of this section.

~~2. For any certified environmental laboratory that applies to modify its scope of certification as specified under 1VAC30-45-90 B, DGS-DCLS shall assess a fee determined by the method in subsection G of this section.~~

~~3. Under 1VAC30-45-90 C, DGS-DCLS may charge a transfer fee to a certified laboratory that transfers ownership. A fee shall be charged if DGS-DCLS (i) needs to review documentation sent by the laboratory about the transfer of ownership or (ii) determines that an on-site assessment is necessary to evaluate the effect of the transfer of ownership. DGS-DCLS shall assess a fee determined by the method in subsection G of this section. If DGS-DCLS determines that a fee should be charged, the fee shall be a minimum of $100 and a maximum of $1,000. If, under 1VAC30-45-90 C, DGS-DCLS determines that the change of ownership or location of laboratory requires recertification of or reapplication by the laboratory, the laboratory shall pay the application fees required under this section.~~

~~4. Under 1VAC30-45-60 B 3, the owner of multiple noncontiguous laboratories may request that DGS-DCLS consider these laboratories to be one site. If, as a result of the request being granted, DGS-DCLS needs to perform multiple on-site assessments, DGS-DCLS shall charge a fee for the additional on-site assessments. The fee shall be the sum of reasonable travel costs and labor charges for the additional on-site assessments. The labor charges will be determined following the method in subsection G of this section.~~

~~5.~~ 4. Under 1VAC30-45-140, any person regulated by this chapter may petition the director to grant a variance from any requirement of this chapter. ~~DGS-DCLS~~ DCLS shall charge ~~a~~ an initial fee ~~for the time needed~~ of $700 plus an additional fee based on the actual time needed for DCLS to review the petition, including any on-site assessment required. The total fee shall not exceed the actual time DCLS takes to review and make a determination on the request for a variance. The fee shall be determined by the method specified in subsection G of this section.

G. Fee determination.

1. The fee shall be the sum of the total hourly charges for all reviewers plus any on-site review costs incurred.

2. An hourly charge per reviewer shall be determined by (i) obtaining a yearly cost by multiplying the reviewer's annual salary by 1.35 (accounts for overhead such as taxes and insurance) and then (ii) dividing the yearly cost by 1,642 (number of annual hours established by Fiscal Services, DGS, for billing purposes).

3. The charge per reviewer shall be determined by multiplying the number of hours expended in the review by the reviewer's hourly charge.

4. If an on-site review is required, travel time and on-site review time shall be charged at the same hourly charge per reviewer, and any travel expenses shall be added.

H. Out-of-state laboratories - travel costs. The owner of an environmental laboratory located in another state who applies for certification under this chapter shall also pay a fee equal to the reasonable travel costs associated with conducting an on-site assessment at the laboratory. Reasonable travel costs include transportation, lodging, per diem, and telephone and duplication charges.

I. ~~DGS-DCLS~~ DCLS shall derive the travel costs charged under subsections G and H of this section from the Commonwealth of Virginia reimbursement allowances and rates for lodging, per diem, and mileage.

Article 2
On-Site Assessment

1VAC30-45-300. Frequency of on-site assessment.

A. [Frequency.

1.] A comprehensive on-site assessment shall be conducted of each laboratory as a condition for granting certification initially ~~and at renewal every two years~~.

[2.] DCLS shall reassess each certified laboratory [~~every two years~~ at least once every three years] starting from the date of the previous assessment plus or minus six months.

[3. DCLS may conduct an on-site assessment of a laboratory every two years plus or minus six months under any of the following circumstances:

a. When a laboratory has received "not acceptable" PT results.

b. When a laboratory's corrective action presented to VELAP for "not acceptable" PT studies does not identify and correct the root cause of the PT study failure.

c. When DCLS has suspended certification for a laboratory in full or in part.

d. When on-site observations include nonconformances previously identified at an on-site assessment, indicating the corrective action was not implemented or not maintained.

e. When on-site observations include failure to qualify nonconforming data to the data user.

f. When on-site observations indicate the laboratory's failure to monitor and maintain regulatory conformance in documentation, traceability, or quality control requirements such that data generated by the laboratory are of questionable quality or defensibility.]

B. Other on-site assessments.

1. If ~~DGS-DCLS~~ DCLS identified a deficiency on a previous on-site assessment, the agency may conduct a follow-up on-site assessment.

2. ~~DGS-DCLS~~ DCLS may conduct an on-site assessment when a laboratory applies to modify its scope of certification~~,~~; when a transfer of owner occurs that affects personnel, equipment, or the laboratory facilities~~,~~; or when a laboratory applies for an exemption or a variance. Any other change occurring in a laboratory's operations that might reasonably be expected to alter or impair analytical capability and quality may trigger an on-site assessment.

1VAC30-45-310. Announced and unannounced on-site assessments.

A. ~~DGS-DCLS~~ DCLS may conduct, at its discretion, either announced or unannounced on-site assessments.

B. Advance notice of an assessment shall not be necessary.

C. To the maximum extent practical, ~~DGS-DCLS~~ DCLS, when necessary, shall work with the owner of an environmental laboratory to obtain government security clearances for assessment personnel as far in advance as possible. The owner of the environmental laboratory shall facilitate expeditious attainment of the necessary clearances.

D. To the maximum extent practical, assessment personnel shall minimize disruption of a laboratory's operations and take into account competing demands on the time of laboratory personnel.

1VAC30-45-320. Request for records.

Prior to the actual site visit, ~~DGS-DCLS~~ DCLS may request in writing from a laboratory those records required to be maintained by this chapter.

1VAC30-45-330. Areas to be assessed.

~~DGS-DCLS~~ DCLS shall assess the laboratory against the personnel and quality control standards in Article 1 (1VAC30-45-200 et seq.) and Article 4 (1VAC30-45-600 et seq.) of this part. The specific areas evaluated in an on-site assessment shall include but not be limited to:

1. Adequacy of the laboratory facility.

2. Organization and management of the laboratory.

3. Qualifications and experience of laboratory personnel.

4. Receipt, tracking and handling of samples.

5. Quantity, condition, and performance of laboratory instrumentation and equipment.

6. Preparation and traceability of calibration standards.

7. Test methods (including the adequacy of the laboratory's standard operating procedures as well as confirmation of the analyst's adherence to SOPs, and the analyst's proficiency with the described task).

8. Data reduction procedures, including an examination of raw data and confirmation that final reported results can be traced to the raw data/original observations.

9. Quality assurance and quality control procedures, including adherence to the laboratory's quality assurance plan and adequacy of the plan.

10. Recordkeeping.

1VAC30-45-340. National security considerations.

A. Assessments at facilities owned or operated by federal agencies or contractors may require security clearances, appropriate badging, or a security briefing before the assessment begins.

B. The laboratory shall notify ~~DGS-DCLS~~ DCLS in writing of any information that is controlled for national security reasons and cannot be released to the public.

1VAC30-45-350. Arrival, admittance, and opening conference.

A. Arrival. Assessment personnel shall arrive at the laboratory during established working hours. The laboratory manager (or, if unavailable, the laboratory manager's designee) shall be located as soon as possible after the assessment personnel arrive on the premises.

B. Admittance of assessment personnel.

1. A laboratory's refusal to admit the assessment personnel for an on-site assessment shall result in an automatic

failure of the laboratory to receive certification or loss of an existing certification by the laboratory, unless there are extenuating circumstances that are accepted and documented by ~~DGS-DCLS~~ DCLS. The team leader for the assessment personnel shall notify ~~DGS-DCLS~~ DCLS as soon as possible after refusal of entry.

2. DCLS shall consider any verbal or physical threat to the health and safety of its assessors or any overt antagonism towards its assessors as a refusal to admit the assessors for the purpose of on-site assessment. The assessors shall vacate the laboratory and shall notify DCLS as soon as possible of the circumstances of this refusal to admit. This refusal to admit shall result in an automatic failure of the laboratory to receive certification or the automatic loss of an existing certification by the laboratory.

C. Health and safety.

1. Under no circumstance, and especially as a precondition to gain access to a laboratory, shall assessment personnel be required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred during an assessment.

2. Assessment personnel shall comply with all facility and laboratory safety procedures.

D. Opening conference. An opening conference shall be conducted and shall address the following topics:

1. The purpose of the assessment;

2. The identification of assessment personnel;

3. The test methods that will be examined;

4. Any pertinent records and procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing assessment personnel with such records;

5. The roles and responsibilities of laboratory staff and managers;

6. Any special safety procedures that the laboratory may think necessary for the protection of assessment personnel;

7. The standards and criteria that will be used in judging the adequacy of the laboratory operation;

8. Confirmation of the tentative time for the exit conference; and

9. Discussion of any questions the laboratory may have about the assessment process.

1VAC30-45-380. Closing conference.

A. Assessment personnel shall meet with representatives of the laboratory following the assessment for a closing conference.

B. During the closing conference, assessment personnel shall inform the laboratory of the preliminary findings and the basis for such findings. The laboratory shall have an opportunity to provide further explanation or clarification relevant to the preliminary findings. If the laboratory objects to the preliminary findings during the closing conference, all objections shall be documented by the assessment personnel and included in the final report to ~~DGS-DCLS~~ DCLS.

C. Additional problem areas may be identified in the final report.

D. Any potentially illegal activity that may be the subject of further action shall not be discussed in the closing conference.

1VAC30-45-390. Follow-up and reporting procedures.

A. ~~DGS-DCLS~~ DCLS shall present an assessment report to the laboratory within 30 calendar days of the assessment.

B. If there are deficiencies identified in the assessment report, the laboratory shall have 30 calendar days from the date of its receipt of the assessment report to provide a response to ~~DGS-DCLS~~ DCLS. This response shall be called a corrective action ~~report~~ plan.

C. An exception to the deadlines specified in subsections A and B of this section may occur in appropriate circumstances. Two circumstances that may be considered appropriate by ~~DGS-DCLS~~ DCLS are where a possible enforcement investigation or other action has been initiated or where the laboratory shows good cause for an extension.

D. The corrective action ~~report~~ plan shall include the following:

1. Any objections that the laboratory has with regard to the assessment report;

2. The action that the laboratory proposes to implement to correct each deficiency identified in the assessment report; and

3. The time period required to accomplish the corrective action.

E. ~~DGS-DCLS~~ DCLS shall determine and shall notify the laboratory within 30 calendar days of receipt whether the corrective action ~~report~~ plan is an acceptable response to the deficiencies identified in the assessment report.

F. If the corrective action ~~report~~ plan (or a portion of the ~~report)~~ plan) is determined to be unacceptable to remedy the deficiency, ~~DGS-DCLS~~ DCLS shall provide written notification to the responsible official and manager of the laboratory including a detailed explanation of the basis for such determination. Following receipt of such notification, the laboratory shall have an additional 30 calendar days to submit a revised corrective action ~~report~~ plan acceptable to ~~DGS-DCLS~~ DCLS.

1VAC30-45-400. Documentation of on-site assessment.

A. Checklists. The checklists used by assessment personnel during the assessment shall become a part of ~~DGS-DCLS's~~ DCLS's file for the laboratory.

B. Assessment report format.

1. The final assessment report shall contain a narrative description of the adequacy of the laboratory as it relates to

the assessment standards specified in this chapter and in 1VAC30-45-330.

2. Assessment reports shall contain:

a. Name of owner of the laboratory (or operator of the laboratory, if different from the owner);

b. Identification of the laboratory assessed;

c. Date of the assessment;

d. Identification and affiliation of all assessment personnel;

e. Identification of participants in the assessment process;

f. Identification of analytes and test methods assessed;

g. Statement of the objective of the assessment;

h. Summary;

i. Assessment observations, findings (including any deficiencies), objections noted by the laboratory, and requirements; and

j. Comments and recommendations.

3. The assessment findings and requirements shall be referenced to the standards in Part II (1VAC30-45-200 et seq.) of this chapter so that both the finding is understood and the specific requirement is outlined. The assessor shall specify the laboratory records, documents, equipment, procedures, or staff evaluated and the observations that contributed to each identified deficiency. The assessment report shall support with sufficient data all assessment findings and the overall evaluation of the laboratory.

4. The comments and recommendations section may be used to convey recommendations aimed at helping the laboratory improve.

C. Release of report.

1. The assessment report shall be released initially by ~~DGS-DCLS~~ DCLS to the responsible official and the laboratory manager. The assessment report shall not be released to the public until findings of the assessment and the corrective actions have been finalized, all information relating to national security has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory.

2. Once the assessment report has been released to the laboratory, any member of the public may request a copy of the report under the requirements of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

3. Checklists used by assessment personnel during the on-site assessment shall be provided to the laboratory with the final on-site assessment report [upon request].

D. The laboratory shall have access to documentation pertaining to any on-site assessment of its facilities. Any laboratory wishing to review its files shall request such assistance of ~~DGS-DCLS~~ DCLS five days prior to visiting ~~DGS-DCLS~~ DCLS. A laboratory may request copies of its documents without visiting ~~DGS-DCLS~~ DCLS. A reasonable fee may be charged for copying, mailing, and staff time.

Article 3
Proficiency Testing

1VAC30-45-500. Laboratory enrollment in proficiency testing program.

A. Required level of participation.

~~1. To be certified initially and to maintain certification, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, per year for each PT field of testing for which it seeks or wants to maintain certification. Laboratories applying to be certified for environmental toxicology (aquatic toxicity, sediment toxicity, or soils toxicity) shall meet the requirements of subdivision 3 of this subsection.~~

~~2. Laboratories shall obtain PT samples from any PT provider approved under the requirements of the NELAC standards for proficiency test providers set out in Chapter 2 of the 2003 standards such as NIST. For PT fields of testing having no approved providers listed by NELAC, the laboratory shall consult DGS-DCLS for an approved provider.~~

~~3. Laboratories applying to be certified for environmental toxicology (aquatic toxicity, sediment toxicity, or soils toxicity). To be certified initially and to maintain certification, a laboratory shall participate in at least one PT study per year (i.e., not more than 12 months apart), when available, for each method code (matrix, organism, exposure system and endpoint) for which it seeks or wants to maintain certification. Laboratories seeking certification for aquatic toxicity testing shall meet the requirements of 1VAC30-45-530.~~

1. To be certified initially and to maintain certification, a laboratory shall participate in PT studies as specified in 1VAC30-45-520 B for the fields of certification (FoC) for which the laboratory seeks or wants to maintain certification.

2. The applicant laboratory shall obtain PT samples from a PT provider approved by TNI. If a PT sample is not available from a TNI-approved provider, the laboratory shall consult DCLS for an approved provider.

B. Requesting certification.

1. When applying for certification, the laboratory owner shall notify ~~DGS-DCLS~~ DCLS of the fields of ~~testing~~ certification for which the laboratory chooses to become certified and shall participate in the appropriate PT studies.

2. For all fields of ~~testing~~ certification for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a quality system that meets all applicable requirements of Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter.

C. Reporting results. ~~1.~~ Each laboratory shall authorize the PT study provider to release ~~all certification and remediation results and "acceptable" or "not acceptable" status~~ the results of the final evaluation report of the laboratory's PT study directly to ~~DGS DCLS~~ DCLS, in addition to the laboratory.

~~2. The results of all of the PT sample tests including "acceptable" or "not acceptable" status shall be part of the public record.~~

1VAC30-45-510. Requirements for laboratory testing of PT study samples.

A. ~~The samples shall be analyzed and the results returned to the PT study provider no later than 45 calendar days from the scheduled study shipment date. Samples for environmental toxicology shall be analyzed within 45 calendar days of sample receipt. The laboratory shall report the result within 45 calendar days of completion of the PT.~~ The laboratory shall report the analytical results from its analysis of the PT study to the PT provider on or before the closing date of the study using the reporting format specified by the PT provider.

B. The laboratory's management and all analysts shall ensure that all PT samples are managed, analyzed, and reported in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, and facilities. When analyzing a PT sample, the laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

C. Restrictions on exchanging information. Laboratories shall comply with all of the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released. Laboratory management or staff shall not:

1. Send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks certification or is certified.

2. Knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks certification or is certified.

3. Communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.

4. Attempt to obtain the assigned value of any PT sample from their PT provider.

D. Maintenance of records. The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for three years or for as long as is required by the applicable regulatory program. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the DCLS assessors ~~of~~ ~~DGS DCLS~~ during on-site ~~audits~~ assessments of the laboratory.

1VAC30-45-520. PT criteria for laboratory certification.

A. Result categories.

1. The criteria described in this section apply individually to each ~~PT field of testing~~ FoPT, as defined by the laboratory seeking to obtain or maintain certification in its certification request. These criteria apply only to the PT portion of the overall certification standard.

2. There are two PT result categories: "acceptable" and "not acceptable."

B. Initial and continuing certification.

1. A laboratory seeking to obtain or maintain certification shall successfully complete ~~two PT studies~~ one PT study for each requested ~~PT field of testing within the most recent three rounds attempted~~ FoC.

2. Once a laboratory has been granted certification status, it shall continue to complete PT studies for each ~~PT field of testing~~ FoPT and maintain a history of at least ~~two~~ one acceptable PT ~~studies for each PT field of testing out of the most recent three~~ study each calendar year. The laboratory shall complete its PT studies by September 30 of each calendar year.

3. ~~For a laboratory seeking to obtain initial certification, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date.~~ When the PT sample used for initial certification was analyzed by the laboratory prior to the date of application, the analysis date of the PT sample shall be no more than 12 months prior to the application date of certification.

4. ~~For a laboratory seeking initial certification, or for~~ For a laboratory performing supplemental testing, the PT studies shall be at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same ~~PT field of testing~~ FoPT.

~~5. For a laboratory to maintain certification, completion dates of successive proficiency rounds for a given PT field of testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study.~~

5. When the PT study result is reported by the PT provider as "acceptable" the environmental laboratory has satisfied the PT requirement.

6. When the PT study result is "not acceptable," the environmental laboratory shall follow the procedure in subsection C of this section.

7. DCLS shall consider a laboratory's analytical result for a FoPT not acceptable when the laboratory makes any reporting error or omission that results in a nonspecific match between the analytical result for the FoPT and any criterion that identifies the laboratory or the field of

certification for which the PT sample was analyzed for the purpose of initial or continued certification.

C. Procedure and requirements for "not acceptable" PT study results.

1. When a laboratory receives a PT study result of "not acceptable," the laboratory shall determine the cause for the failure and perform and document corrective action. The corrective action documentation shall be completed within 30 days of receiving the "not acceptable" PT study result and be submitted to DCLS upon request. [DCLS may extend the time for corrective action and documentation.]

2. Upon completion of the corrective action the laboratory shall perform another PT study for each FoPT that had a "not acceptable" result.

3. If the laboratory successfully completes the makeup PT study by receiving an "acceptable" result before December 31, DCLS shall not suspend the laboratory's certification for the pertinent FoC.

4. If the laboratory receives a "not acceptable" result on the makeup PT study, DCLS shall notify the laboratory that there is cause to suspend the laboratory's certification for the FoC for which the PT study was "not acceptable."

5. DCLS shall not extend the period for annual PT study completion beyond December 31 each year. Failure to satisfactorily complete a PT study [, including any corrective action and makeup PT study,] by December 31 shall result in suspension of certification in total or in part.

6. If the laboratory receives a "not acceptable" result on three successive PT studies, DCLS shall decertify the laboratory for the pertinent FoC until such time that the laboratory:

a. Completes corrective action for all failed studies and submits its corrective action report to DCLS;

b. Obtains an "acceptable" result for the PT studies; and

c. Applies for a change to its scope of certification and pays applicable fees required by 1VAC30-45-90 B and 1VAC30-45-130 F.

7. DCLS shall follow the provisions of 1VAC30-45-110 in decertifying the laboratory.

~~C. Supplemental studies.~~

~~1. A laboratory may elect to participate in PT studies more frequently than required by the semiannual schedule. This may be desirable, for example, when a laboratory first applies for certification or when a laboratory fails a study and wishes to quickly reestablish its history of successful performance.~~

~~2. These additional studies shall be reported and are counted and scored the same way as routinely scheduled studies and shall be at least 15 calendar days apart.~~

~~D. Failed studies and corrective action.~~

~~1. Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to DGS DCLS both the investigation and the action taken.~~

~~2. If a laboratory fails two out of the three most recent studies for a given field of testing, its performance is considered unacceptable for that field. The laboratory shall then meet the requirements of initial certification as described in subsection B of this section.~~

~~E. Second failed study.~~

~~1. The PT provider reports laboratory PT performance results to DGS DCLS at the same time that it reports the results to the laboratory.~~

~~2. If a laboratory fails a second study out of the most recent three, as described in subdivision D 2 of this section, DGS DCLS shall take action within 60 calendar days to determine the certification status for the unacceptable PT field of testing.~~

~~F. Scheduling of PT studies. Laboratories shall determine the schedule for their PT studies.~~

~~G.~~ D. Withdrawal from PT studies. A laboratory may withdraw from a PT study for ~~an analyte or analytes or for the entire study if the laboratory notifies both the PT provider and DGS DCLS before the closing date of the PT study. This does not exempt the laboratory from participating in the semiannual schedule.~~ any FoPT on or before the close date of the study. Withdrawing from a study shall not exempt the laboratory from meeting the annual analysis requirements necessary for continued certification.

1VAC30-45-530. ~~Special requirements for aquatic toxicity.~~ (Repealed.)

~~A. Laboratories seeking certification for aquatic toxicity testing shall be assessed through on-site assessment and evaluation of EPA Discharge Monitoring Report-Quality Assurance (DMR-QA) test results when available. A failed DMR-QA endpoint shall require both of the following:~~

~~1. A formal response to DGS DCLS with an explanation of the probable cause for the endpoint failure and description of corrective actions to be taken (where appropriate).~~

~~2. A decision by DGS DCLS to accept the response or require additional actions on the part of the laboratory or by DGS DCLS.~~

~~B. If a laboratory's response is unacceptable and DGS DCLS does not require additional on-site assessments, the laboratory shall complete another study. Such additional studies shall be conducted at least 15 calendar days from the previous study until the results are acceptable to DGS DCLS. DGS DCLS may conduct additional on-site assessments as necessary based on the results of any additional studies.~~

~~C. When the DMR-QA whole effluent toxicity portion does not include all test procedures required for a permit, the laboratory shall perform a proficiency test for aquatic toxicity testing.~~

~~D. DGS-DCLS shall not base loss of certification for aquatic toxicity testing solely on PT results.~~

Article 4
Quality System

1VAC30-45-600. Quality system.

A. This article sets out the general requirements that an environmental laboratory has to successfully demonstrate to be recognized as competent to carry out specific environmental tests. The environmental laboratory shall establish, implement and maintain a quality system based on the required elements contained in this article.

B. The quality system shall be appropriate to the type, range and volume of testing, analysis, measurement or monitoring performed by the laboratory.

C. The quality system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. All personnel concerned with testing and calibration activities within the laboratory shall familiarize themselves with the quality documentation and implement the policies and procedures in their work.

~~C.~~ D. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which standard or requirement is more stringent, the standard or requirement from the method or regulation is to be followed.

~~D.~~ E. Provisions pertaining to the management of the quality system appear in 1VAC30-45-610 through 1VAC30-45-700. Provisions pertaining to the technical requirements for the quality system appear in 1VAC30-45-710 through 1VAC30-45-770.

1VAC30-45-610. Quality manual.

A. General.

1. The laboratory shall document its quality system in a quality manual. The quality manual shall reflect all quality assurance and quality control practices and programs used by the laboratory. The required elements of the quality system may be described in more than one document.

2. The quality manual shall be maintained current under the responsibility of the quality assurance officer.

3. The quality manual and any related documents shall be communicated to, understood by, available to, and implemented by all laboratory personnel.

4. The quality manual shall include but not be limited to the elements listed in ~~subsection~~ subsections B and C of this section.

B. The elements of a quality manual shall include but not be limited to:

~~1. Title page. The quality manual shall list the following items on the title page:~~

~~a.~~ 1. A document title;

~~b.~~ 2. The laboratory's full name and address;

~~c.~~ 3. The name, address (if different from above), and telephone number of the responsible official, laboratory manager, and quality assurance officer;

~~d.~~ 4. The laboratory facility or facilities covered by the quality manual;

~~e.~~ 5. Signed and dated concurrence, with appropriate titles, of the responsible official, laboratory manager, and quality assurance officer; ~~and~~

~~f.~~ 6. The effective date of the quality manual~~.~~;

~~2.~~ 7. Table of contents~~.~~ and applicable lists of references, glossaries, and appendices; and

~~3.~~ 8. A quality policy statement, including objectives of the quality system and commitment to ~~good~~ ethical laboratory practices and to upholding the requirements of this chapter's standards.

C. The quality manual shall include or reference but not be limited to:

~~4.~~ 1. The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts.

~~5. The relationship between management, technical operations, support services and the quality system.~~

~~6. The capabilities of the laboratory or scope of its operation.~~

~~7.~~ 2. Job descriptions of key staff and reference to the job descriptions of other staff.

~~8.~~ 3. Processes or procedures for establishing that personnel have adequate training and experience in the duties they are expected to carry out and are receiving any needed training.

~~9. Ethics policy statement developed by the laboratory. Processes and procedures for educating and training personnel in their ethical and legal responsibilities including the potential penalties for improper, unethical or illegal actions.~~

~~10.~~ 4. Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work.

~~11.~~ 5. Procedures to ensure that all records required by this chapter are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force.

~~12.~~ 6. Procedures for dealing with complaints.

~~13.~~ 7. Procedures for audits and data review.

~~14. Reference to verification~~ 8. Verification practices that may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes.

~~15.~~ 9. Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur.

~~16.~~ 10. The laboratory management arrangements for permitting departures from documented policies and procedures or from standard specifications when the departures are planned and controlled.

~~17. Reference to the~~ 11. The major equipment and reference measurement standards used as well as the physical facility and environment used by the laboratory in conducting tests.

~~18. Reference to procedures~~ 12. Procedures for calibration, verification and maintenance of equipment.

~~19.~~ 13. A list of all technology/methods under which the laboratory performs its certified testing.

~~20. The laboratory's procedures~~ 14. Procedures for achieving traceability of measurements, including standards.

~~21.~~ 15. Procedures for receiving, handling, storing, and disposing of submitted samples.

~~22. Reference to procedures~~ 16. Procedures for reporting analytical results.

17. Policy addressing the use of unique electronic signatures, where applicable.

~~C.~~ D. Review and approval of quality manual.

1. The quality assurance officer shall review the laboratory's quality assurance program, manual and any related documentation whenever there is any change in test methods employed by the laboratory, change in equipment, or any other change in the laboratory that affects the quality assurance program.

2. The quality assurance manual shall be reviewed and approved by the quality assurance officer, the laboratory manager, and the responsible official at least annually.

1VAC30-45-660. Required records.

A. Sample handling.

1. The laboratory shall maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory. These shall include but are not limited to all records pertaining to sample preservation, identification, receipt, acceptance or rejection, log-in, storage and tracking. The laboratory shall also maintain sampling information on each sample. This includes time and date of collection, type of sample (grab or composite), type of container, sampling point and preservation.

2. The laboratory shall have documented procedures for the receipt and retention of samples, including provisions necessary to protect the integrity of the samples.

B. Laboratory support activities. The laboratory shall retain the following documents and data:

1. All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms, strip charts, and other instrument response readout records).

2. A written description or reference to the specific test method used that includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value.

3. Copies of final reports.

4. Archived standard operating procedures.

5. Correspondence relating to laboratory activities.

6. All corrective action ~~reports~~ plans, audits, and audit responses.

7. Proficiency test results and raw data.

8. Results of data review, verification, and cross-checking procedures.

C. Analytical records. The laboratory shall retain essential information associated with analytical documents, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs. This information includes, but is not limited to, all manual calculations~~,~~ (e.g., manual integrations); sample preparation; standard and reagent origin, receipt, preparation, and use; quality control protocols and assessment; and method performance criteria.

D. Administrative records. The laboratory shall maintain the following administrative records:

1. Personnel qualifications, experience and training records.

2. Records of demonstration of capability for each analyst or work cell.

3. A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

1VAC30-45-670. Audits.

A. Internal audits.

1. The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management.

2. Trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited, shall carry out these audits. Personnel shall not audit their

own activities except when it can be demonstrated that an effective audit will be carried out.

3. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action.

4. A laboratory may have an audit performed under contract by an outside source competent to audit the laboratory's operations.

B. Managerial review.

1. The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations.

2. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, corrective actions and other relevant factors.

3. The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

4. Where the staff of a laboratory is limited to a single analyst, a supervisor may perform a managerial review.

C. Audit review. All audit and review findings and any corrective actions that arise from them shall be documented. The laboratory management shall ensure that these actions are discharged within the agreed [~~time frame~~ timeframe] as indicated in the quality manual or standard operating procedures or both. For clarification, documentation of audit and review findings should be a simple procedure, essentially a memorandum setting out the findings of the audit and managerial review and any action to follow.

D. Corrective actions.

1. In addition to providing acceptance criteria and specific protocols for corrective actions in the method standard operating procedures, the laboratory shall implement general procedures to be followed to determine consistently when departures from documented policies, procedures and quality control have occurred. These procedures may include but are not limited to the following:

a. Identify the individual or individuals responsible for assessing each quality control data type;

b. Identify the individual or individuals responsible for initiating or recommending corrective actions or both;

c. Define how the analyst shall treat a data set if the associated quality control measurements are unacceptable;

d. Specify how out-of-control situations and subsequent corrective actions are to be documented; and

e. Specify procedures for management (including the quality assurance officer) to review corrective action ~~reports~~ plans.

2. To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data are to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifiers.

1VAC30-45-720. Equipment and reference materials.

A. The laboratory shall be furnished with all items of equipment, including reference materials, required for the correct performance of tests for which certification is sought. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this article are met.

B. All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.

C. Any item of the equipment that has been subjected to overloading or mishandling, or that gives suspect results, or has been shown by verification or otherwise to be defective shall be taken out of service immediately, clearly identified as being out of service and, wherever possible, stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

D. Each item of equipment including reference materials shall be labeled, marked or otherwise identified to indicate its calibration status.

E. Records of each major item of equipment significant to the tests performed shall be maintained. These records shall include documentation on all routine and non-routine maintenance activities. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. The records shall include:

1. The name of the item of equipment;

2. The manufacturer's name, type identification, and serial number or other unique identification;

~~3. Date received and date placed in service (if available);~~

~~4.~~ 3. Current location, where appropriate;

~~5. If available, condition when received (e.g., new, used, reconditioned);~~

~~6.~~ 4. Copy of the manufacturer's instructions, where available;

~~7.~~ 5. Dates and results of calibrations or verifications or both and date of the next calibration or verification;

~~8.~~ 6. Details of maintenance carried out to date and planned for the future; and

~~9.~~ 7. History of any damage, malfunction, modification or repair.

1VAC30-45-730. Test methods and standard operating procedures.

A. Methods documentation.

1. The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples, and for calibration or testing, where the absence of such instructions could jeopardize the calibrations or tests.

2. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up to date and be readily available to the staff.

B. Standard operating procedures (SOPs).

1. Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods. These documents, for example, may be equipment manuals provided by the manufacturer or internally written documents. The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the laboratory methods manual.

2. The SOPs shall be organized. Each SOP shall clearly indicate the effective date of the document, the revision number, and the signature or signatures of the responsible laboratory manager or managers.

3. Copies of all SOPs shall be accessible to all personnel.

C. ~~Laboratory methods manuals.~~ SOPs for laboratory methods.

1. The laboratory shall have and maintain an ~~in-house methods manual or manuals~~ SOP for each certified analyte or test method.

2. This ~~manual may consists of copies of published or referenced methods or standard operating procedures that have been~~ SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each test method shall include or reference where applicable:

a. Identification of the test method;

b. Applicable matrix or matrices;

c. ~~Method detection limit~~ Limits of detection or quantitation;

d. Scope and application, including ~~components~~ parameters to be analyzed;

e. Summary of the test method;

f. Definitions;

g. Interferences;

h. Safety;

i. Equipment and supplies;

j. Reagents and standards;

k. Sample collection, preservation, shipment and storage;

l. Quality control;

m. Calibration and standardization;

n. Procedure;

o. ~~Calculations~~ Data analysis and calculations;

p. Method performance;

q. Pollution prevention;

r. Data assessment and acceptance criteria for quality control measures;

s. Corrective actions for out-of-control data;

t. Contingencies for handling out-of-control or unacceptable data;

u. Waste management;

v. References; and

w. Any tables, diagrams, flowcharts and validation data.

D. Test methods.

1. Laboratories shall use (i) promulgated test methods in accordance with the Code of Federal Regulations; (ii) test methods stated in any current permit issued by ~~Virginia~~ the State Air Pollution Control Board, the Virginia Waste Management Board, or the State Water Control Board; or (iii) alternate test procedures approved by the board issuing the permit or the Department of Environmental Quality, including applicable quality assurance requirements, and sample preservation, container, storage, and holding time requirements. [~~Laboratories shall use the latest valid edition of a method unless it is not appropriate to do so.~~]

2. The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample handling, transport and storage, preparation and analysis). The method and procedures shall be consistent with the accuracy required and with any standard specifications relevant to the calibrations or tests concerned.

3. When the use of reference test methods for a sample analysis is mandated, only those methods shall be used.

4. Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see subsection E of this section).

E. Demonstration of capability.

1. Prior to acceptance and institution of any test method, satisfactory initial demonstration of method capability is required. In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean quality system matrix

sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), ~~e.g.~~ for example, drinking water, solids, biological tissue and air. Laboratories shall follow the procedure in subsection F of this section to demonstrate capability.

2. Thereafter, ~~continuing~~ ongoing demonstration of method performance, such as laboratory control samples, is required.

3. In cases where a laboratory analyzes samples using a test method that has been in use by the laboratory ~~before July 1999~~ for at least one year prior to applying for certification, and there have been no significant changes in instrument type, personnel or test method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency shall be acceptable. The laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

4. In all cases, the laboratory shall [~~complete and retain a certification statement and shall make the statement available upon request. The laboratory shall retain all associated supporting data necessary to reproduce the analytical results summarized in the certification statement~~ document each demonstration of capability as required by subsection G of this section].

5. The laboratory shall complete a demonstration of capability each time there is a change in instrument type, personnel or test method, including the addition of an analyte to a certified test method.

~~6. In laboratories with specialized work cells (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit shall meet the criteria of this subsection. This demonstration of capability shall be fully documented.~~

F. Procedure for demonstration of capability. The following steps shall be performed for mandated test methods. However, before any results are reported using this method, actual sample spike results may be used to meet this standard~~,~~ (i.e., at least four consecutive matrix spikes within the last 12 months). For analytes that do not lend themselves to spiking~~,~~ (e.g., TSS)~~,~~ the demonstration of capability may be performed using quality control samples. The laboratory may document that other approaches to demonstration of capability are adequate. This documentation shall be included in the laboratory's quality manual:

1. A quality control (QC) sample may be obtained from an outside source or may be prepared by the laboratory using alternate source stock standards that are prepared independently from those used in instrument calibration.

2. The analyte or analytes shall be diluted in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of 1-4 times the limit of quantitation.

3. At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

4. Using all of the results, calculate the mean recovery in the appropriate reporting units (such as g/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence or absence of the analyte and logarithmic values, the laboratory shall assess performance against established and documented criteria.

5. Compare the information from subdivision 4 of this subsection to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

6. When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to either subdivision 6 a or 6 b ~~below~~ of this subsection.

a. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with subdivision 3 of this subsection.

b. Beginning with subdivision 3 of this subsection, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with subdivision 3 of this subsection.

[~~G. Certification statement. The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee.~~

~~Demonstration of Capability~~
~~Certification Statement~~

~~Date: Page __ of __~~

~~Laboratory Name:~~

~~Laboratory Address:~~

~~Analyst(s) Name(s):~~

~~Matrix:~~

~~(examples: laboratory pure water, soil, air, solid, biological tissue)~~

~~Method number, SOP#, Rev#, and Analyte, or Class of Analytes or Measured Parameters~~

~~(examples: barium by 200.7, trace metals by 6010 B, benzene by 8021 B, etc.)~~

~~We, the undersigned, CERTIFY that:~~

~~1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the Virginia Environmental Laboratory Certification Program, have met the Demonstration of Capability.~~

~~2. The test method(s) was performed by the analyst(s) identified on this certification.~~

~~3. A copy of the test method(s) and the laboratory specific SOPs are available for all personnel on site.~~

~~4. The data associated with the demonstration capability are true, accurate, complete and self explanatory(1).~~

~~5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.~~

~~Laboratory Manager's Name and Title_____~~
~~Signature_____ Date_____~~

~~Quality Assurance Officer's Name_____~~
~~Signature_____ Date_____~~

~~(1)True - consistent with supporting data. Accurate - based on good laboratory practices consistent with sound scientific principles and practices. Complete - includes the results of all supporting performance testing. Self explanatory - data properly labeled and stored so that the results are clear and require no additional explanation.~~

G. Documentation of demonstration of capability. The laboratory shall document each demonstration of capability so that the following information shall be readily available for each employee:

1. Analyst or analysts involved in preparation and analysis.

2. Matrix.

3. Analytes, class of analytes, measured parameters, or organisms.

4. Identification of methods performed.

5. Identification of laboratory-specific SOP used for analysis, including revision number.

6. Date or dates of analysis.

7. All raw data necessary to reconstruct and validate the analyses.

8. Data evaluation required by subsection F of this section.]

H. Sample aliquots. Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.

I. Data verification. Calculations and data transfers shall be subject to appropriate checks. The laboratory shall establish standard operating procedures to ensure that (i) the reported data are free from transcription and calculation errors and (ii) all quality control measures are reviewed and evaluated before data are reported. The laboratory also shall establish standard operating procedures addressing manual calculations including manual integrations.

J. Documentation and labeling of standards and reagents. Documented procedures shall exist for the reception and storage of consumable materials used for the technical operations of the laboratory.

1. The laboratory shall retain records for all standards, reagents, reference materials and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless its reliability is verified by the laboratory.

2. Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date if this date is provided by the manufacturer or vendor.

3. Records shall be maintained on standard and reference material preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

4. Sufficient identification of containers of prepared reagents and standards shall be provided to ensure proper performance of tests.

K. Computers and electronic data related requirements. Where computers, automated equipment or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure the following:

1. Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

2. Procedures are established and implemented for protecting the integrity of data, such as integrity of data entry or capture, data storage, data transmission and data processing.

3. Computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data.

4. Appropriate procedures are established and implemented for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

1VAC30-45-740. Measurement traceability and calibration.

A. General requirements. All equipment used for environmental tests, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the environmental test or sampling shall be calibrated before being put into service and on a continuing basis. The laboratory shall have an established program and procedure for the calibration of its equipment. This includes balances, thermistors, thermometers and control standards. Such a program shall include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform environmental tests.

B. Traceability of calibration.

1. The laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

2. The overall program of calibration or verification or both and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.

3. Where traceability of measurements to the International System of Units (SI) is not possible or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods ~~and/or~~ or consensus standards, are required. The laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.

C. Reference standards and reference materials.

1. Reference standards. The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards of measurement shall be calibrated by a body that can provide traceability as described in subsection B of this section. Such reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards would not be invalidated. Where commercially available, this traceability shall be to a national standard of measurement.

2. Reference materials. Reference materials shall, where commercially available, be traceable to SI units of measurement, or to certified reference materials. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

D. Calibration. Calibration requirements are divided into two parts: (i) requirements for analytical support equipment and (ii) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification.

1. Support equipment. These standards apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor or dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

a. All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

b. All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used. If not, the laboratory shall either (i) remove the equipment from service until repaired or (ii) maintain records of established correction factors to correct all measurements.

c. Raw data records shall be retained to document equipment performance.

d. ~~Prior to use on each working day~~ On each day the equipment is used, balances, ovens, refrigerators, freezers, and water baths shall be checked in the expected use range, with NIST traceable references where available. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

e. Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory.

f. For chemical tests, the temperature, cycle time and pressure of each run of autoclaves shall be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.

g. For biological tests that employ autoclave sterilization, the following requirements apply:

(1) The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers fitted only with a pressure gauge are not recommended for sterilization of media or decontamination of wastes.

(2) Records of autoclave operations including temperature and time shall be maintained. This shall be done for every cycle. Acceptance and rejection criteria shall be established and used to evaluate the autoclave efficiency and effectiveness.

2. Instrument calibration.

a. This standard specifies the essential elements that define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data shall be of known quality and be appropriate for a given regulation or decision. This standard does not specify detailed procedural steps for calibration, but establishes the essential elements for selection of the appropriate technique or techniques. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.

b. Initial instrument calibrations. The following items are essential elements of initial instrument calibration:

(1) The laboratory shall include or reference the details of the initial instrument calibration procedures, including calculations, integrations, acceptance criteria and associated statistics in the standard operating procedure for the test method. When initial instrument calibration procedures are referenced in the test method, then the laboratory shall retain the referenced material and make it available for review.

(2) The laboratory shall retain sufficient raw data records to permit reconstruction of the initial instrument calibration~~,~~ (e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration).

(3) Sample results shall be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program.

(4) All initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or lot. Traceability shall be to a national standard, when available. This element does not apply to laboratories performing only simple test procedures.

(5) Criteria for the acceptance of an initial instrument calibration shall be established~~,~~ (e.g., correlation coefficient and relative percent difference). The criteria used shall be 0.995 or greater for the calibration coefficient unless a different criterion is included in the method being used.

(6) Results of samples not bracketed by initial calibration standards (within calibration range) shall be reported as having less certainty~~,~~ (e.g., defined qualifiers or flags or explained in the case narrative). The lowest calibration standard shall be above the detection limit.

(7) If the initial instrument calibration results are outside established acceptance criteria, corrective actions shall be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.

(8) Calibration standards shall include concentrations at or below the regulatory limit or decision level, if these limits or levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits.

(9) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory shall have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

c. Continuing instrument calibration verification.

(1) When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration check with each analytical batch. This provision does not apply to laboratories performing only simple test procedures.

(2) The following items are essential elements of continuing instrument calibration verification:

(a) The laboratory shall include or reference the details of the continuing instrument calibration procedure, calculations and associated statistics in the standard operating procedure for the test method.

(b) The laboratory shall verify calibration for each compound, element, or other discrete chemical species, except for multicomponent analytes such as Aroclors, Total Petroleum Hydrocarbons, or Toxaphene where a representative chemical related substance or mixture can be used.

(c) The laboratory shall perform a continuing instrument calibration verification as follows:

(i) At the beginning and end of each analytical batch. If an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch;

(ii) Whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria;

(iii) If the time period for calibration or the most previous calibration verification has expired; or

(iv) For analytical systems that contain a calibration verification requirement.

(d) Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification~~,~~ (e.g., or test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing verification data to the initial instrument calibration.

(e) Criteria for the acceptance of a continuing instrument calibration verification shall be established~~,~~ (e.g., percent recovery or relative percent difference).

(f) If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions shall be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate acceptable performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration shall be performed. If the laboratory has not verified calibration, sample analyses shall not occur until the analytical system is calibrated or calibration verified. If samples are analyzed using a system on which the calibration has not yet been verified, the results shall be flagged. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:

(i) When the acceptance criteria for the continuing calibration verification are exceeded high~~,~~ (i.e., high bias~~,~~) and there are associated samples that are nondetects, then those nondetects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

(ii) When the acceptance criteria for the continuing calibration verification are exceeded low~~,~~ (i.e., low bias~~,~~) those sample results may be reported if they exceed a maximum regulatory limit or decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

1VAC30-45-750. Quality assurance.

A. General. The laboratory shall have quality control procedures for monitoring the validity of environmental tests undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

1. Regular use of certified reference materials ~~and/or~~ or internal quality control using secondary reference materials or both.

2. Participation in interlaboratory comparison or proficiency testing program.

3. Replicate tests using the same or different methods.

4. Retesting of retained samples.

5. Correlation of results for different characteristics of a sample ~~(for example~~ (e.g., total phosphate should be greater than or equal to orthophosphate).

B. Essential quality control procedures. The general quality control principles in [~~subsections~~ subsection] C [~~through F~~] of this section shall apply, where applicable, to all environmental laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory. ~~1VAC30-45-760 through 1VAC30-45-829 specify quality control requirements for specific test types.~~ 1VAC30-45-770 through 1VAC30-45-775, 1VAC30-45-790 through 1VAC30-45-798, and 1VAC30-45-810 through 1VAC30-45-818 specify quality control requirements for chemical testing, microbiological testing, and air testing, respectively. Noncommercial environmental laboratories that analyze environmental samples using other types of testing such as toxicity, radiochemical, or asbestos testing shall meet the quality control standards for the specific method and the specific type of testing in the 2009 TNI Standards for Environmental Laboratories. The standards for any given test type shall assure that the applicable principles are addressed.

C. All laboratories shall have detailed written protocols in place to monitor the following quality controls:

1. Positive and negative controls to monitor tests such as blanks, spikes, reference toxicants.

2. Tests to define the variability or repeatability of the laboratory results or both such as replicates.

3. Measures to assure the accuracy of the test method including calibration or continuing calibrations or both, use of certified reference materials, proficiency test samples, or other measures.

4. Measures to evaluate test method capability, such as method detection limits and quantitation limits or range of applicability such as linearity.

5. Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal and external standard calculations, and statistical analyses.

6. Selection and use of reagents and standards of appropriate quality.

7. Measures to assure the selectivity of the test for its intended purpose.

8. Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.

1VAC30-45-760. Quality control requirements.

A. General.

1. The quality control protocols specified by the laboratory's ~~method manual~~ SOPs shall be followed (1VAC30-45-730 C). The laboratory shall ensure that either the (i) applicable essential standards outlined in this section through ~~1VAC30-45-829~~ 1VAC30-45-775, 1VAC30-45-791 through 1VAC30-45-798, and 1VAC30-45-811 or (ii) mandated methods or regulations, whichever are more stringent, are incorporated into their method ~~manuals~~ SOPs. When it is not apparent which is more stringent, the quality ~~control~~ controls in the mandated method or regulations ~~is~~ are to be followed.

2. All quality control measures shall be assessed and evaluated on an ongoing basis and quality control acceptance criteria shall be used to determine the validity of the data. The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists.

B. Initial test method evaluation. For all test methods other than ~~toxicity and~~ microbiology, the requirements of subdivisions 1 and 2 of this subsection apply. For ~~toxicity and~~ microbiology testing, the initial test method evaluation requirements are contained in ~~1VAC30-45-780 through 1VAC30-45-788 and~~ 1VAC30-45-790 through 1VAC30-45-798~~, respectively~~. For the evaluation of precision and bias (subdivision 3 of this subsection), the requirements of subdivision 3 a of this subsection apply to standard methods. The requirements of subdivision 3 b of this subsection apply to the methods referenced in that subdivision.

1. Limit of detection (LOD).

a. The laboratory shall determine the LOD for the method for each target analyte of concern in the quality system matrices. All sample processing steps of the analytical method shall be included in the determination of the LOD.

b. The validity of the LOD shall be confirmed by qualitative identification of the [~~analyte(s)~~ analyte] in a quality control sample in each quality system matrix containing the analyte at no more than two to three times the LOD for single analyte tests and one to four times the LOD for multiple analyte tests. This verification shall be performed on every instrument that is to be used for analysis of samples and reporting of data.

c. An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the LOD (versus the limit of quantitation or working range of instrument calibration), according to 1VAC30-45-771~~, 1VAC30-45-805,~~ and 1VAC30-45-814~~, and 1VAC30-45-826~~. Where an LOD study is not performed, the laboratory may not report a value below the limit of quantitation.

2. Limit of quantitation (LOQ).

a. The laboratory shall determine the LOQ for each analyte of concern according to a defined, documented procedure.

b. The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).

c. The validity of the LOQ shall be confirmed by successful analysis of a QC sample containing the analytes of concern in each quality system matrix one to two times the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.

3. Evaluation of precision and bias.

a. Standard methods. The laboratory shall evaluate the precision and bias of a standard method for each analyte of concern for each quality system matrix according to either of the following:

(1) The single-concentration four-replicate recovery study procedures in 1VAC30-45-730 F; or

(2) An alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and quality control samples are not commercially available.

b. Nonstandard methods.

(1) For laboratory-developed test methods or nonstandard test methods that were not in use by the laboratory before July 2003, the laboratory shall have a documented procedure to evaluate precision and bias. The laboratory shall also compare results of the precision and bias measurements with criteria given in the reference method or criteria established by the laboratory.

(2) Precision and bias measurements shall evaluate the method across the analytical calibration range of the method. The laboratory shall also evaluate precision and bias in the relevant quality system matrices and shall

process the samples through the entire measurement system for each analyte of interest.

(3) The following are examples of a systematic approach to evaluate precision and bias:

(a) Example 1. Analyze QC samples in triplicate containing the analytes of concern at or near the limit of quantitation, at the upper-range of the calibration (upper 20%) and at a mid-range concentration. Process these samples on different days as three sets of samples through the entire measurement system for each analyte of interest. Each day one QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three days. (Note that the three samples at the LOQ concentration can demonstrate sensitivity as well.) For each analyte, calculate the mean recovery for each day, for each level over days, and for all nine samples. Calculate the relative standard deviation for each of the separate means obtained. Compare the standard deviations for the different days and the standard deviations for the different concentrations. If the different standard deviations are all statistically insignificant (e.g., F-test), then compare the overall mean and standard deviation with the established criteria from above.

(b) Example 2. A validation protocol such as the Tier I, Tier II, and Tier III requirements in U.S. EPA Office of Water's Alternate Test Procedure (ATP) approval process.

4. Evaluation of selectivity. The laboratory shall evaluate selectivity by following the checks established within the method. These checks may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

1VAC30-45-770. Chemical testing: positive and negative controls.

A. Negative control – method performance.

1. Purpose. The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. The method blank shall be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure. Procedures shall be in place to determine if a method blank is contaminated. Any affected samples associated with a contaminated method blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

2. Frequency. The method blank shall be analyzed at a minimum of one per preparation batch. In those instances for which no separate preparation method is used ~~(example:~~ (e.g., volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

3. Composition. The method blank shall consist of a quality system matrix that is similar to the associated samples and is known to be free of the analytes of interest.

4. Evaluation criteria and corrective action. While the goal is to have no detectable contaminants, each method blank shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:

a. The concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, and is greater than 1/10 of the amount measured in any sample.

b. The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.

c. When a blank is determined to be contaminated, the cause shall be investigated and measures taken to minimize or eliminate the problem. Samples associated with a contaminated blank shall be evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes). In all cases the corrective action shall be documented.

B. Positive control – method performance. Laboratory control sample (LCS).

1. Purpose. The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS are compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is "out of control." Any affected samples associated with an out of control LCS shall be reprocessed for re-analysis or the results reported with appropriate data qualifying codes.

2. Frequency. The LCS shall be analyzed at a minimum of one per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

3. Composition. The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known

and verified concentrations of analytes. NOTE: the matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). All analyte concentrations shall be within the calibration range of the methods. The following shall be used in choosing components for the spike mixtures:

The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components the laboratory shall spike per the following:

a. For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.

b. For those test methods that have extremely long lists of analytes, a representative number may be chosen. The analytes selected should be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a two-year period. For methods that include 1-10 targets, spike all components; for methods that include 11-20 targets, spike at least ~~10%~~ 10 components or 80%, whichever is greater; and for methods with more than 20 targets, spike at least 16 components.

4. Evaluation criteria and corrective action.

a. The results of the individual batch LCS are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory shall document the calculation.

b. The individual LCS is compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria.

c. A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be "out of control" shall be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.

5. If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. A ME is defined as being beyond the LCS control limit (3 standard deviations), but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean.

a. The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than 11 analytes.

b. The number of allowable marginal exceedances is as follows:

Number of analytes in LCS	Number of analytes allowed in ME of the LCS control limit
Greater than 90	Five
71-90	Four
51-70	Three
31-50	Two
11-30	One
Fewer than 11	None

c. Marginal exceedances shall be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systemic problem. The source of the error shall be located and corrective action taken. Laboratories shall have a written procedure to monitor the application of marginal exceedance allowance to the LCS to ensure random behavior.

C. Sample specific controls - general.

1. The laboratory shall document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of quality system matrix specific Quality Control (QC) samples and are designed as data quality indicators for a specific sample using the designated test method. These controls alone are not used to judge laboratory performance.

2. Examples of matrix specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); sample duplicates; and surrogate spikes. The laboratory shall have procedures in place for tracking, managing, and handling matrix specific QC criteria including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, evaluating and reporting results based on performance of the QC samples.

D. Sample specific controls - matrix spike and matrix spike duplicates.

1. Purpose. Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.

2. Frequency. The frequency of the analysis of matrix specific samples shall be determined as part of a systematic planning process (e.g., Data Quality Objectives) or as specified by the test method.

3. Composition. The components to be spiked shall be as specified by the mandated test method. Any permit specified analytes, as specified by regulation or client requested analytes shall also be included. If there are no specified components, the laboratory shall spike per the following:

a. For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.

b. For those test methods that have extremely long lists of analytes, a representative number may be chosen using the following criteria for choosing the number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a two-year period.

(1) For methods that include 1-10 targets, spike all components;

(2) For methods that include 11-20 targets, spike at least ~~10%~~ 10 components or 80%, whichever is greater;

(3) For methods with more than 20 targets, spike at least 16 components.

4. Evaluation criteria and corrective action.

a. The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R), relative percent difference (RPD), or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory shall document the calculation for %R, RPD or other statistical treatment used.

b. The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix spike results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

E. Sample specific controls - matrix duplicates.

1. Purpose. Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.

2. Frequency. The frequency of the analysis of matrix duplicates may be determined as part of a systematic planning process (e.g., Data Quality Objectives) or as specified by the mandated test method.

3. Composition. Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known.

4. Evaluation criteria and corrective action.

a. The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences). The laboratory shall document the calculation for relative percent difference or other statistical treatments.

b. Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix duplicates results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

F. Sample specific controls - surrogate spikes.

1. Purpose. Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix.

2. Frequency. Except where the matrix precludes its use or when not commercially available, surrogate compounds shall be added to all samples, standards, and blanks for all appropriate test methods.

3. Composition. Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method or [~~MQO~~ measurement quality objectives]. They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.

4. Evaluation criteria and corrective action. The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should determine internal criteria and document the method used to establish the limits.

Surrogates outside the acceptance criteria shall be evaluated for the effect indicated for the individual sample results. Data quality objectives or other site-specific requirements may guide the appropriate corrective action. Results reported from analyses with surrogate recoveries outside the acceptance criteria should include appropriate data qualifiers.

1VAC30-45-771. Chemical testing: limit of detection and limit of quantitation.

A. General. All procedures used shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained.

B. Limit of detection (LOD). The laboratory shall utilize a test method that provides an LOD that is appropriate and relevant for the intended use of the data. An LOD is not required for a test method when test results are not reported outside of the calibration range. LODs shall be determined by the protocol in the mandated test method or applicable regulation. If the protocol for determining LODs is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the test method.

1. The LOD shall be initially determined for the compounds of interest in each test method in a quality system matrix in which there are no target analytes or interferences at a concentration that would impact the results. Alternatively the LOD shall be determined in the quality system matrix of interest (see definition of matrix).

2. LODs shall be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

~~3. The laboratory shall have established procedures to relate LOD with LOQ.~~

~~4.~~ 3. The LOD shall be verified annually for each quality system matrix, method and analyte according to the procedure specified in 1VAC30-45-760 B 1.

C. Limit of quantitation (LOQ).

1. Any established LOQ shall be above the LOD.

2. The LOQ shall be verified annually for each quality system matrix, method and analyte according to the procedure specified in 1VAC30-45-760 B 2. Alternatively, the annual LOQ verification is not required if the LOD is reevaluated or verified according to subdivision B [~~4~~ 3] of this section.

1VAC30-45-775. Chemical testing: constant and consistent test conditions.

A. The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

~~B. Glassware cleaning. Glassware shall be cleaned to meet the sensitivity of the test method.~~

~~C.~~ B. Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.

1VAC30-45-780. ~~Toxicity testing: general.~~ (Repealed.)

~~These standards apply to laboratories measuring the toxicity and/or bioaccumulation of contaminants in effluents (aquatic toxicity), receiving waters, sediments, elutriates, leachates and soils. In addition to the essential quality control standards set out in 1VAC30-45-781 through 1VAC30-45-788, some methods may have additional or other requirements based on factors such as the type of quality system matrix evaluated.~~

1VAC30-45-781. ~~Toxicity testing: positive and negative controls.~~ (Repealed.)

~~A. Positive control. Reference toxicant tests demonstrate a laboratory's ability to obtain consistent results with the test method and evaluate the overall health and sensitivity of test organisms over time.~~

~~1. The laboratory shall demonstrate its ability to obtain consistent results with standard reference toxicants (SRT) and complete an initial Demonstration of Capability (DOC) in order to attain accreditation in toxicity testing methods.~~

~~a. An initial DOC shall consist of five or more acceptable SRT tests for each test method, species and endpoint with different batches of organisms. Appropriate negative controls (water, sediment, or soil) shall be tested at the frequency and duration specified in the test method. Initial DOCs shall be prepared in accordance with the requirements of 1VAC30-45-730 F.~~

~~b. Initial DOC is established by maintenance of SRT test results on control charts. A laboratory shall record the control performance and statistical endpoints (such as NOEC or ECp) for each method species and endpoint on control charts. Initial DOC is established where 95% of the test results required in subdivision A 1 a of this section fall within the control limits established in accordance with subdivision A 1 c of this section and meet test acceptability criteria (TAC). The laboratory shall evaluate precision (i.e., coefficient of variation (CV)) or sensitivity (i.e., statistical minimum significant difference (SMSD) measures; see subdivision A 1 d of this section) for these tests against method-specific or, lacking the former, laboratory derived criteria to determine validity of the initial DOC.~~

~~c. For endpoints that are point estimates (ICp, ECp), control charts are constructed by plotting the cumulative mean and the control limits that consist of the upper and lower 95% confidence limits (+/- 2 standard deviations). In case of highly variable point estimates that exceed method specific criteria, the control chart limits are adjusted accordingly. For endpoints from hypothesis tests (NOEC, NOAEC), the values are plotted directly and the control limits consist of one concentration interval above~~

and below the concentration representing the central tendency (i.e., the mode).

d. For endpoints that are point estimates, the cumulative mean CV is calculated and for endpoints from hypothesis tests, the SMSD is calculated. These values are maintained on a control chart.

2. Ongoing laboratory performance shall be demonstrated by routine SRT testing for each test method and species and endpoint in accordance with the minimum frequency requirements specified in subdivision A 3 of this section.

a. Intralaboratory precision is determined on an ongoing basis through the use of control charts as established in subdivision A 1 b of this section. The control charts shall be plotted as point estimate values, such as EC25 for chronic tests and LC50 for acute tests, or as appropriate hypothesis test values, such as the NOEC or NOAEC, over time within a laboratory.

b. After initial laboratory DOC is determined, the control limits and CV for an individual test method, endpoints and species shall be adjusted as additional test results are obtained. After 20 data points are collected for a test method and species, the control chart is maintained using only the last 20 data points, i.e., each successive mean value and control limit is calculated using only the last 20 values.

c. Control chart limits are expected to be exceeded occasionally regardless of how well a laboratory performs. Acceptance limits for point estimates (ICp, ECp) that are based on 95% confidence limits should theoretically be exceeded for one in 20 tests. Depending on the dilution factor and test sensitivity, control charts based on hypothesis test values (NOEC, NOAEC) may be expected to be exceeded on a similar frequency. Test results that fall outside of control chart limits at a frequency of 5.0% or less, or that fall just outside control chart limits (especially in the case of highly proficient laboratories that may develop relatively narrow acceptance limits over time), are not rejected de facto. Such data are evaluated in comparison with control chart characteristics including the width of the acceptance limits and the degree of departure of the value from acceptance limits.

d. Consistent with the test methods used, laboratories shall develop acceptance/rejection policies for SRT data that consider the source of test organisms, the direction of the deviation, test dilution factor, test sensitivity (for hypothesis test values), testing frequency, out of control test frequency, relative width of acceptance limits, inter-test CV, and degree of difference between test results and acceptance limits.

e. In the case of reference toxicant data that fails to meet control chart acceptance criteria, the test data are examined for defects, corrective action taken, and the test repeated if necessary, using a different batch of organisms or the data is qualified.

3. The frequency of ongoing laboratory reference toxicant testing shall be as follows unless the method specifically requires less frequent SRT tests (e.g., sediment tests):

a. For test methods conducted at a frequency of monthly or greater, SRT tests shall be conducted at an ongoing frequency of monthly.

b. For test methods and species commonly used in the laboratory, but that are tested at a frequency of less than monthly, SRT tests shall be conducted concurrently with the environmental test.

c. If the test organisms are obtained from an outside source the sensitivity of each batch of organisms received from a supplier shall be determined via a concurrent SRT test unless the supplier can provide control chart data for the last five SRT tests using the same SRT and test conditions. Supplied SRT data may not be older than six months.

d. The DOC for an analyst shall be consistent with 1VAC30-45-220 B but the frequency need not exceed the method specified requirements and subdivision A 3 a and A 3 b of this section.

4. These standards do not currently specify a particular reference toxicant and dilution series. If the permitting authority identifies a reference toxicant or dilution series for a particular test, the laboratory shall follow the specified requirements. All reference toxicant tests conducted for a given test method and species shall use the same reference toxicant, test concentrations, dilution water and data analysis methods. A dilution factor of 0.5x or greater shall be used for both acute and chronic tests.

5. The reference toxicant tests shall be conducted following the same procedures as the environmental toxicity tests for which the precision is being evaluated, unless otherwise specified in the test method (for example, 10-day sediment tests employ 96-h water-only reference toxicant tests). The test duration, laboratory dilution water, feeding, organism age, range and density, test volumes, renewal frequency, water quality measurements, and the number of test concentrations, replicates and organisms per replicate shall be the same as specified for the environmental toxicity test.

B. Negative control: control, brine control, control sediment, control soil or dilution water.

1. The standards for the use, type and frequency of testing of negative controls are specified by the test methods and by permit or regulation and shall be followed. A negative control is included with each test to evaluate test performance and the health and sensitivity of the specific batch of organisms.

2. Appropriate additional negative controls shall be included when sample adjustments (for example, addition

of thiosulfate for dechlorination) or solvent carriers are used in the test.

3. Test acceptability criteria (TAC). The test acceptability criteria specified in the test method shall be achieved for both the reference toxicant and the effluent or environmental sample toxicity test. The criteria shall be calculated and shall meet the method specified requirements for performing toxicity tests.

1VAC30-45-782. Toxicity testing: variability and/or reproducibility. (Repealed.)

Intralaboratory precision shall be determined on an ongoing basis through the use of further reference toxicant tests and related control charts as described in 1VAC30-45-840 A.

1VAC30-45-783. Toxicity testing: accuracy. (Repealed.)

This principle is not applicable to toxicity testing.

1VAC30-45-784. Toxicity testing: test sensitivity. (Repealed.)

A. The statistical minimum significant difference (SMSD) shall be calculated according to the formula specified by the test method and reported with the test results.

B. Point estimates: (LCp, ICp, or ECp) Confidence intervals shall be reported as a measure of the precision around the point estimate value, when the calculation is possible.

C. The SMSD shall be calculated and reported for only hypothesis test values, such as the NOEC or NOAEC.

1VAC30-45-785. Toxicity testing: selection of appropriate statistical analysis methods. (Repealed.)

A. If required, methods of data analysis and endpoints are specified by language in the regulation, permit or the test method.

B. Dose response curves. The data shall be plotted in the form of a curve relating the dose of the chemical or concentration of sample to cumulative percentage of test organisms demonstrating a response such as death. Evaluation criteria shall be established for interpretation of concentration or dose response curves.

1VAC30-45-786. Toxicity testing: selection and use of reagents and standards. (Repealed.)

A. The grade of all reagents used in toxicity tests is specified in the test method except the reference standard. All reference standards shall be prepared from chemicals that are analytical reagent grade or better. The preparation of all standards and reference toxicants shall be documented.

B. All standards and reagents associated with chemical measurements, such as dissolved oxygen, pH or specific conductance, shall comply with the standards outlined in 1VAC30-45-740 D 1 d.

C. Only reagent-grade water collected from distillation or deionization units is used to prepare reagents.

1VAC30-45-787. Toxicity testing: selectivity. (Repealed.)

The permit or regulation specifies the selectivity of the test.

1VAC30-45-788. Toxicity testing: constant and consistent test conditions. (Repealed.)

A. If closed refrigerator sized incubators are used, culturing and testing of organisms shall be separated to avoid cross-contamination.

B. Laboratory space shall be adequate for the types and numbers of tests performed. The building shall provide adequate cooling, heating and illumination for conducting testing and culturing; hot and cold running water shall be available for cleaning equipment.

C. Air used for aeration of test solutions, dilution waters and cultures shall be free of oil and fumes.

D. The laboratory or a contracted outside expert shall positively identify test organisms to species on an annual basis. The taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) shall be kept on file at the laboratory. When organisms are obtained from an outside source, the supplier shall provide this same information.

E. Instruments used for routine support measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, ammonia, and weight shall be calibrated, and/or standardized per manufacturer's instructions. As these are support measurements, only the calibration and verification requirements specified at 1VAC30-45-740 D 1 apply. All measurements and calibrations shall be documented.

F. Test temperature shall be maintained as specified for the test method. Temperature control equipment shall be adequate to maintain the required test temperature(s). The average daily temperature of the test solutions shall be maintained within the method specified range. The minimum frequency of measurement shall be once per 24-hour period. The test temperature for continuous flow toxicity tests shall be recorded and monitored continuously. Where electronic data loggers are used, temperature shall be monitored at a frequency sufficient to capture temporal variations of the environmental control system.

G. Reagent grade water, prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration, shall meet the method specified requirements.

H. The quality of the standard dilution water used for testing or culturing shall be sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance. Water used for culturing and testing shall be analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock, can be identified. It is recognized that the analyte lists of some methods manuals may not include all potential toxicants, are based on estimates of chemical toxicity available at the time of publication and

may specify detection limits that are not achievable in all matrices. However, for those analytes not listed, or for which the measured concentration or limit of detection is greater than the method specified limit, the laboratory shall demonstrate that the analyte at the measured concentration or reported limit of detection does not exceed one tenth of the expected chronic value for the most sensitive species tested and/or cultured. The expected chronic value is based on professional judgment and the best available scientific data. The "USEPA Ambient Water Quality Criteria Documents" and the EPA AQUIRE database provide guidance and data on acceptability and toxicity of individual metals and organic compounds.

I. The quality of the food used for testing or culturing shall be sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance. The laboratory shall have written procedures for the evaluation of food acceptance.

J. A subset of organisms used in bioaccumulation tests shall be analyzed at the start of the test (baseline) for the target compounds to be measured in the bioaccumulation tests.

K. Test chamber size and test solution volume shall be as specified in the test method. All test chambers used in a test shall be identical.

L. Test organisms shall be fed the quantity and type food or nutrients specified in the test method. They shall also be fed at the intervals specified in the test methods.

M. All organisms in a test shall be from the same source. Where available certified seeds are used for soil tests.

N. All organisms used in tests, or used as broodstock to produce neonate test organisms (for example cladocerans and larval fish), shall appear healthy, show no signs of stress or disease and exhibit acceptable survival (90% or greater) during the 24 hour period immediately preceding use in tests.

O. All materials used for test chambers, culture tanks, tubing, etc., and coming in contact with test samples, solutions, control water, sediment or soil or food shall be nontoxic and cleaned as described in the test methods. Materials shall not reduce or add to sample toxicity. Appropriate materials for use in toxicity testing and culturing are described in the referenced manuals.

P. Light intensity shall be maintained as specified in the methods manuals. Measurements shall be made and recorded on a yearly basis. Photoperiod shall be maintained as specified in the test methods and shall be documented at least quarterly. For algal and plant tests, the light intensity shall be measured and recorded at the start of each test.

Q. The testing laboratory shall document the health and culturing conditions of all organisms used for testing. Such documentation shall include culture conditions (e.g., salinity, hardness, temperature, pH) and observations of any stress, disease or mortality. When organisms are obtained from an outside source, the laboratory shall obtain written documentation of these water quality parameters and biological observations for each lot of organism received. These observations shall adequately address the 24 hour time period referenced in subsection N of this section. The laboratory shall also record each of these observations and water quality parameters upon the arrival of the organisms at the testing laboratory.

R. Age and the age range of the test organisms shall be as specified in the test method. Supporting information, such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) shall be documented.

S. The maximum holding time of effluents (elapsed time from sample collection to first use in a test) shall not exceed 36 hours; samples may be used for renewal up to 72 hours after first use except as prescribed by the method and approved by the regulatory agency having authority for program oversight.

T. All samples shall be chilled to 0 to 6°C during or immediately after collection except as prescribed by the method.

U. Organisms used in a given test shall be from the same batch.

V. All tests shall have the minimum number of replicates per treatment as prescribed by the method.

W. The control population of Ceriodaphnia in chronic effluent or receiving water tests shall contain no more than 20% males.

X. The culturing of C. dubia shall be adequate such that blocking by parentage can be established.

Y. Dissolved oxygen and pH in aquatic tests shall be within acceptable range at test initiation and aeration (minimal) is provided to tests if, and only if, acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the test method.

Z. Test soils or sediments shall be within the geochemical tolerance range of the test organism.

AA. An individual test may be conditionally acceptable if temperature, dissolved oxygen, pH and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests (see test conditions and test acceptability criteria specified for each test method).

1VAC30-45-791. Microbiology testing: sterility checks and blanks, positive and negative controls.

A. Sterility checks and blanks. The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure.

1. A sterility blank shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.

2. For filtration technique, the laboratory shall conduct one beginning and one ending sterility check for each ~~laboratory sterilized filtration unit used in a~~ filtration series. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series. For presterilized single use funnels a sterility check shall be performed on one funnel per lot. The filtration series is considered ended when more than 30 minutes elapses between successive filtrations. During a filtration series, filter funnels shall be rinsed with three 20-30 ml portions of sterile rinse water after each sample filtration. In addition, laboratories shall insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration.

3. For pour plate technique, sterility blanks of the medium shall be made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory.

4. Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers with nonselective growth media. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with nonselective growth media.

5. A sterility blank shall be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with nonselective growth media.

6. At least one filter from each new lot of membrane filters shall be checked for sterility with nonselective growth media.

B. Positive controls.

1. Positive culture controls demonstrate that the medium can support the growth of the target [~~organism(s)~~ organism], and that the medium produces the specified or expected reaction to the target [~~organism(s)~~ organism].

2. Each preprepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested and demonstrate a known positive response. This shall be done prior to first use of the medium.

C. Negative controls. The provisions of this subsection shall not apply to wastewater treatment plants.

1. Negative culture controls demonstrate that the medium does not support the growth of [~~non-target~~ nontarget] organisms or does not demonstrate the typical positive reaction of the target ~~organism(s)~~ organism or organisms.

2. Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory shall be analyzed with one or more known negative culture controls~~,~~ (i.e., nontarget organisms~~,~~) as appropriate to the method. This shall be done prior to first use of the medium.

1VAC30-45-796. Microbiology testing: quality of standards, reagents, and media.

A. The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.

B. Culture media may be prepared from commercial dehydrated powders or may be purchased ready to use. The laboratory may prepare media from basic ingredients when commercial media are not available or when it can be demonstrated that commercial media do not provide adequate results. Media prepared by the laboratory from basic ingredients shall be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, growth inhibition) prior to first use. Detailed testing criteria information shall be defined in either the laboratory's test methods, SOPs, quality manual, or similar documentation.

C. Reagents, commercial dehydrated powders and media shall be used within the shelf-life of the product and shall be documented according to 1VAC30-45-730 J.

D. Distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances shall be used in the preparation of media, solutions and buffers. The quality of the water shall be monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month.

E. Analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) shall be performed annually. Results of these analyses shall meet the specifications of the required method and records of analyses shall be maintained for three years. (An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.)

F. Media, solutions and reagents shall be prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method. Documentation for media prepared in the laboratory shall include date of preparation, preparer's initials, type and amount of media prepared, manufacturer and lot number, final pH of the media, and expiration date. Documentation for media purchased pre-prepared, ready to use shall include manufacturer, lot number, type ~~and amount~~ of media received, date of receipt, expiration date of the media, and pH of the media.

1VAC30-45-798. Microbiology testing: constant and consistent test conditions.

A. Laboratory facilities. Floors and work surfaces shall be nonabsorbent and easy to clean and disinfect. Work surfaces shall be adequately sealed. Laboratories shall provide sufficient storage space, and shall be clean and free from dust accumulation. Plants, food, and drink shall be prohibited from the laboratory work area.

B. Laboratory equipment.

1. Temperature measuring devices. Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment shall be the appropriate quality to meet ~~specification(s)~~ specifications in the test method. The graduation of the temperature measuring devices shall be appropriate for the required accuracy of measurement and they shall be calibrated to national or international standards for temperature (see 1VAC30-45-740 C). Calibration shall be done at least annually.

2. Autoclaves.

a. The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media.

b. Demonstration of sterilization temperature shall be provided by use of continuous temperature recording device or by use of a maximum registering thermometer with every cycle. Appropriate biological indicators shall be used once per month to determine effective sterilization. Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.

c. Records of autoclave operations shall be maintained for every cycle. Records shall include date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.

d. Autoclave maintenance shall be performed annually, either internally or by service contract, ~~shall be performed annually~~ and shall include a pressure check and calibration of temperature device. Records of the maintenance shall be maintained in equipment logs. If the laboratory demonstrates regular monitoring of pressure (e.g., for each autoclaved batch) and annual calibration of the maximum registering thermometer, the annual autoclave pressure and temperature device checks shall not be required.

e. The autoclave mechanical timing device shall be checked quarterly against a stopwatch and the actual time elapsed documented.

3. Volumetric equipment. Volumetric equipment shall be calibrated as follows:

a. Equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be verified for accuracy quarterly.

b. Equipment such as filter funnels, bottles, nonclass A glassware, and other marked containers shall be calibrated once per lot prior to first use.

c. The volume of the disposable volumetric equipment such as sample bottles and disposable pipettes shall be checked once per lot.

4. UV instruments. UV instruments used for sanitization shall be tested quarterly for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.

5. Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments shall be calibrated according to the method specified requirements (see 1VAC30-45-740 D 1 d).

6. Incubators, water baths, and ovens.

a. The ~~stability and~~ uniformity of temperature distribution ~~and time required after test sample addition to reestablish equilibrium conditions~~ in incubators and water baths shall be established. Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use.

b. Ovens used for sterilization shall be checked for sterilization effectiveness monthly with appropriate biological indicators. Records shall be maintained for each cycle that include date, cycle time, temperature, contents and analyst's initials.

7. Labware (glassware and plasticware).

a. The laboratory shall have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use shall be used.

b. Glassware shall be made of borosilicate or other noncorrosive material, free of chips and cracks, and shall have readable measurement marks.

c. Labware that is washed and reused shall be tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent or washing procedures.

d. Washed labware shall be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH

indicator such as bromothymol blue. Records of tests shall be maintained.

1VAC30-45-800. ~~Radiochemical testing: general.~~ (Repealed.)

~~These standards apply to laboratories undertaking the examination of environmental samples by radiochemical analysis. These procedures for radiochemical analysis may involve some form of chemical separation followed by detection of the radioactive decay of analyte (or indicative daughters) and tracer isotopes where used. For the purpose of these standards, procedures for the determination of radioactive isotopes by mass spectrometry (e.g., ICP-MS or TIMS) or optical (e.g., KPA) techniques are not addressed herein.~~

1VAC30-45-801. ~~Radiochemical testing: negative and positive controls.~~ (Repealed.)

~~A. Negative controls.~~

~~1. Method blank shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the quality control measures to be used to assess the batch. The method blank result shall be assessed against the specific acceptance criteria specified in the laboratory method manual. When the specified method blank acceptance criteria is not met, the specified corrective action and contingencies shall be followed and results reported with appropriate data qualifying codes. The occurrence of a failed method blank acceptance criteria and the actions taken shall be noted in the laboratory report.~~

~~2. In the case of gamma spectrometry, generally a nondestructive analysis, a method blank shall be prepared using a calibrated counting geometry similar to that used for the samples. The container of the appropriate geometry can be empty or filled to similar volume to partially simulate gamma attenuation due to a sample matrix.~~

~~3. There shall be no subtraction of the required method blank result from the sample results in the associated preparation or analytical batch unless permitted by method or program. This does not preclude the application of any correction factor (e.g., instrument background, analyte presence in tracer, reagent impurities, peak overlap, etc.) to all analyzed samples, both program/project submitted and internal quality control samples. However, these correction factors shall not depend on the required method blank result in the associated analytical batch.~~

~~4. The method blank sample shall be prepared with similar aliquot size to that of the routine samples for analysis and the method blank result and acceptance criteria shall be calculated in a manner that compensates for sample results based upon differing aliquot size.~~

~~B. Positive controls.~~

~~1. Laboratory control samples shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the quality control measures to be used to assess the batch. The laboratory control sample result shall be assessed against the specific acceptance criteria specified in the laboratory method manual. When the specified laboratory control sample acceptance criteria is not met the specified corrective action and contingencies shall be followed. The occurrence of a failed laboratory control sample acceptance criteria and the actions taken shall be noted in the laboratory report.~~

~~2. Matrix spike shall be performed at a frequency of one per preparation batch for those methods that include a chemical separation process without the use of an internal standard or carrier, and where there is sufficient sample to do so. Although gross alpha, gross beta and tritium measurements do not involve a chemical separation process, matrix spikes shall be performed for these analyses on aqueous samples. The results of this analysis shall be one of the quality control measures to be used to assess the batch. The matrix spike result shall be assessed against the specific acceptance criteria specified in the laboratory method manual. When the specified matrix spike acceptance criteria is not met, the specified corrective action and contingencies shall be followed. The occurrence of a failed matrix spike acceptance criteria and the actions taken shall be noted in the laboratory report. The lack of sufficient sample aliquot size to perform a matrix spike shall be noted in the laboratory report.~~

~~3. The activity of the laboratory control sample shall (i) be at least five times the limit of detection and (ii) at a level comparable to that of routine samples when such information is available if the sample activities are expected to exceed five times the limit of detection.~~

~~4. The activity of the matrix spike analytes(s) shall be greater than five times the limit of detection.~~

~~5. The laboratory standards used to prepare the laboratory control sample and matrix spike shall be from a source independent of the laboratory standards used for instrument calibration and shall meet the requirements for reference standards provided in 1VAC30-45-807 A.~~

~~6. The matrix spike shall be prepared by adding a known activity of target analyte after subsampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.). Where a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g., plutonium, Pu-238 and Pu-239, using alpha spectrometry), only one of the analyte isotopes need be included in the laboratory control or matrix spike sample at the indicated activity level. However, where more than one analyte isotope is present above the specified limit of detection, each shall be assessed against the specified acceptance criteria.~~

~~7. Where gamma spectrometry is used to identify and quantitate more than one analyte isotope, the laboratory control sample shall contain isotopes that represent the low (e.g., americium-241), medium (e.g., cesium-137) and high~~

(e.g., cobalt-60) energy range of the analyzed gamma spectra. As indicated by these examples the isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.

8. The laboratory control sample shall be prepared with similar aliquot size to that of the routine samples for analyses.

C. Other controls.

1. Tracer. For those methods that utilize a tracer (i.e., internal standard) each sample result shall have an associated tracer recovery calculated and reported. The tracer shall be added to the sample after subsampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method. The tracer recovery for each sample result shall be one of the quality control measures to be used to assess the associated sample result acceptance. The tracer recovery shall be assessed against the specific acceptance criteria specified in the laboratory method manual. When the specified tracer recovery acceptance criteria is not met the specified corrective action and contingencies shall be followed. The occurrence of a failed tracer recovery acceptance criteria and the actions taken shall be noted in the laboratory report.

2. Carrier. For those methods that utilize a carrier for recovery determination, each sample shall have an associated carrier recovery calculated and reported. The carrier shall be added to the sample after subsampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method. The carrier recovery for each sample shall be one of the quality control measures to be used to assess the associated sample result acceptance. The carrier recovery shall be assessed against the specific acceptance criteria specified in the laboratory method manual. When the specified carrier recovery acceptance criteria is not met the specified corrective action and contingencies shall be followed. The occurrence of a failed carrier recovery acceptance criteria and the actions taken shall be noted in the laboratory report.

1VAC30-45-802. Radiochemical testing: analytical variability/reproducibility. (Repealed.)

A. Replicate shall be performed at a frequency of one per preparation batch where there is sufficient sample to do so. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The replicate result shall be assessed against the specific acceptance criteria specified in the laboratory method manual. When the specified replicate acceptance criteria is not met the specified corrective action and contingencies shall be followed. The occurrence of a failed replicate acceptance criteria and the actions taken shall be noted in the laboratory report.

B. For low level samples (less than approximately three times the limit of detection) the laboratory may analyze duplicate laboratory control samples or a replicate matrix spike (matrix spike and a matrix spike duplicate) to determine reproducibility within a preparation batch.

1VAC30-45-803. Radiochemical testing: method evaluation. (Repealed.)

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

1. Initial demonstration of capability shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type (e.g., different detection technique), personnel or method.

2. Proficiency test samples. The laboratory shall use the results of such analysis to evaluate its ability to produce accurate data.

1VAC30-45-804. Radiochemical testing: radiation measurement instrumentation. (Repealed.)

A. General. Because of the stability and response nature of modern radiation measurement instrumentation, it is not typically necessary to verify calibrate these systems each day of use. However, verification of calibration is required as outlined in subsection B of this section. This section addresses those practices that are necessary for proper calibration and those requirements of 1VAC30-45-740 D (instrument calibrations) that are not applicable to some types of radiation measurement instrumentation.

B. Instrument calibration.

1. Given that activity detection efficiency is independent of sample activity at all but extreme activity levels, the requirements of 1VAC30-45-740 D 2 b (7) are not applicable to radiochemical method calibrations except mass attenuation in gas proportional counting and sample quench in liquid scintillation counting. Radiation measurement instruments are subject to calibration prior to initial use, when the instrument is placed back in service after malfunctioning and the instrument's response has changed as determined by a performance check or when the instrument's response exceeds predetermined acceptance criteria for the instrument quality control.

2. Instrument calibration shall be performed with reference standards as defined in 1VAC30-45-807 A. The standards shall have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples.

3. The frequency of calibration shall be addressed in the laboratory method manual if not specified in the method. A specific frequency (e.g., monthly) or observations from the associated control or tolerance chart, as the basis for calibration shall be specified.

C. Continuing instrument calibration verification (performance checks). Performance checks shall be performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the detector response has not significantly changed and, therefore, the

~~instrument calibration has not changed. The same check source used in the preparation of the tolerance chart or control chart at the time of calibration shall be used in the calibration verification of the instrument. The check sources shall provide adequate counting statistics for a relatively short count time and the source should be sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel.~~

~~1. For gamma spectroscopy systems, the performance checks for efficiency and energy calibration shall be performed on a day of use basis along with performance checks on peak resolution.~~

~~2. For alpha spectroscopy systems, the performance check for energy calibration shall be performed on a weekly basis and the performance check for counting efficiency shall be performed on at least a monthly basis.~~

~~3. For gas proportional and liquid scintillation counters, the performance check for counting efficiency shall be performed on a day of use basis. For batches of samples that uninterruptedly count for more than a day a performance check can be performed at the beginning and end of the batch as long as this time interval is no greater than one week. Verification of instrument calibration does not directly verify secondary calibrations, e.g., the mass efficiency curve or the quench curve.~~

~~4. For scintillation counters the calibration verification for counting efficiency shall be performed on a day of use basis.~~

~~D. Background measurement. Background measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives. These values may be subtracted from the total measured activity in the determination of the sample activity.~~

~~1. For gamma spectroscopy systems, background measurements shall be performed on at least a monthly basis.~~

~~2. For alpha spectroscopy systems, background measurements shall be performed on at least a monthly basis.~~

~~3. For gas proportional counters, background measurements shall be performed on at least on a weekly basis.~~

~~4. For scintillation counters, background measurements shall be performed each day of use.~~

~~E. Instrument contamination monitoring. The laboratory shall have a written procedure for monitoring radiation measurement instrumentation for radioactive contamination. The procedure shall indicate the frequency of the monitoring and shall indicate criteria, which initiates corrective action.~~

1VAC30-45-805. ~~Radiochemical testing: Minimum detectable activity (MDA)/Minimum detectable concentration (MDC)/Lower level of detection (LLD).~~ (Repealed.)

~~A. MDA/MDC/LLD shall be determined prior to sample analysis and shall be redetermined each time there is a significant change in the test method or instrument type.~~

~~B. The procedures employed shall be documented and consistent with mandated method or regulation.~~

1VAC30-45-806. ~~Radiochemical testing: data reduction.~~ (Repealed.)

~~A. The requirements of 1VAC30-45-730 K apply.~~

~~B. Measurement uncertainties. Each result shall be reported with the associated measurement uncertainty. The procedures for determining the measurement uncertainty shall be documented and be consistent with mandated method and regulation.~~

1VAC30-45-807. ~~Radiochemical testing: quality of standards and reagents.~~ (Repealed.)

~~A. The quality control program shall establish and maintain provisions for radionuclide standards.~~

~~1. Reference standards that are used in a radiochemical laboratory shall be obtained from the National Institute of Standards and Technology (NIST), or suppliers who participate in supplying NIST standards or NIST traceable radionuclides. Any reference standards purchased outside the United States shall be traceable back to each country's national standards laboratory. Commercial suppliers of reference standards shall conform to ANSI N42.22 to assure the quality of their products.~~

~~2. Reference standards shall be accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates.~~

~~3. Laboratories should consult with the supplier if the laboratory's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value. The laboratory shall not use a value other than the decay corrected certified value. The laboratory shall have a written procedure for handling, storing and establishment of expiration dates for reference standards.~~

~~B. All reagents used shall be analytical reagent grade or better.~~

1VAC30-45-808. ~~Radiochemical testing: constant and consistent test conditions.~~ (Repealed.)

~~The laboratory shall maintain a radiological control program that addresses analytical radiological control. The program shall address the procedures for segregating samples with potentially widely varying levels of radioactivity. The radiological control program shall explicitly define how low level and high level samples will be identified, segregated and processed in order to prevent sample cross-contamination. The radiological control program shall include the measures taken to monitor and evaluate background activity or contamination on an ongoing basis.~~

1VAC30-45-811. Air testing: negative and positive controls.

A. Negative controls.

1. Method blanks shall be performed at a frequency of at least one per batch of 20 environmental samples or less per sample preparation method. The results of the method blank analysis shall be used to evaluate the contribution of the laboratory provided sampling media and analytical sample preparation procedures to the amount of analyte found in each sample. If the method blank result is greater than the limit of quantitation and contributes greater than 10% of the total amount of analyte found in the sample, the source of the contamination shall be investigated and measures taken to eliminate the source of contamination. If contamination is found, the data shall be qualified in the report.

2. Collection efficiency. Sampling trains consisting of multiple sections (e.g., filters, sorbent tubes, impingers) that are received intact by the laboratory shall be separated into "front" and "back" sections if required by the client. Each section shall be processed and analyzed separately and the analytical results reported separately.

B. Positive controls. Laboratory control sample (LCS) shall be analyzed at a rate of at least one per batch of 20 or fewer samples per sample preparation method for each analyte. If a spiking solution is not available, a calibration solution whose concentration approximates that of the samples shall be included in each batch and with each lot of media. ~~If a calibration solution must be used for the LCS, the client will be notified prior to the start of analysis.~~ The concentration of the LCS shall be relevant to the intended use of the data and either at a regulatory limit or below it.

C. Surrogates shall be used as required by the test method.

D. Matrix spike shall be used as required by the test method.

1VAC30-45-820. ~~Asbestos testing: general.~~ (Repealed.)

~~These standards apply to laboratories undertaking the examination of asbestos samples. These standards are organized by analytical technique, including transmission electron microscopy (TEM) for the analysis of water, wastewater, air, and bulk samples; phase contrast microscopy (PCM) for analysis of workplace air; and polarized light microscopy (PLM) for analysis of bulk samples. These procedures for asbestos analysis involve sample preparation followed by detection of asbestos. If NIST SRMs specified below are unavailable, the laboratory may substitute an equivalent reference material with a certificate of analysis.~~

1VAC30-45-821. ~~Asbestos testing: negative controls.~~ (Repealed.)

~~A. Transmission electron microscopy.~~

~~1. Water and wastewater.~~

~~a. Blank determinations shall be made prior to sample collection. When using polyethylene bottles, one bottle from each batch, or a minimum of one from each 24 shall be tested for background level. When using glass bottles, four bottles from each 24 shall be tested. An acceptable bottle blank level is defined as ≤0.01 MFL > 10 µm. (EPA/600/R-94/134, Method 100.2, Section 8.2)~~

~~b. A process blank sample consisting of fiber-free water shall be run before the first field sample. The quantity of water shall be ≥10 mL for a 25-mm diameter filter and ≥ 50 mL for a 47-mm diameter filter. (EPA/600/R-94/134, Method 100.2, Section 11.8)~~

~~2. Air.~~

~~a. A blank filter shall be prepared with each set of samples. A blank filter shall be left uncovered during preparation of the sample set and a wedge from that blank filter shall be prepared alongside wedges from the sample filters. At minimum, the blank filter shall be analyzed for each 20 samples analyzed. (40 CFR Part 763, Appendix A to Subpart E (AHERA), Table 1)~~

~~b. Maximum contamination on a single blank filter shall be no more than 53 structures/mm^2. Maximum average contamination for all blank filters shall be no more than 18 structures/mm^2. (AHERA, III.F.2)~~

~~3. Bulk samples.~~

~~a. Contamination checks using asbestos-free material, such as the glass fiber blank in SRM 1866 (Page C-3, NIST Handbook 150-3, August 1994) shall be performed at a frequency of one for every 20 samples analyzed. The detection of asbestos at a concentration exceeding 0.1% will require an investigation to detect and remove the source of the asbestos contamination.~~

~~b. The laboratory shall maintain a list of nonasbestos fibers that can be confused with asbestos (Section 7.5, Page C-8, NIST Handbook 150-3, August 1994). The list shall include crystallographic and/or chemical properties that disqualify each fiber being identified as asbestos (Section 2.5.5.2.1 Identification, Page 54, EPA/600/R-93/116).~~

~~c. The laboratory should have a set of reference asbestos materials from which a set of reference diffraction and X-ray spectra have been developed.~~

~~B. Phase contrast microscopy. At least two field blanks (or 10% of the total samples, whichever is greater) shall be submitted for analysis with each set of samples. Field blanks shall be handled in a manner representative of actual handling of associated samples in the set with a single exception that air shall not be drawn through the blank sample. A blank cassette shall be opened for approximately 30 seconds at the same time other cassettes are opened just prior to analysis. Results from field blank samples shall be used in the calculation to determine final airborne fiber concentration. The identity of blank filters should be unknown to the counter until all counts have been completed. If a field blank yields~~

greater than seven fibers per 100 graticule fields, report possible contamination of the samples.

C. Polarized light microscopy.

1. Friable materials. At least one blank slide shall be prepared daily or with every 50 samples analyzed, whichever is less. This is prepared by mounting a subsample of an isotropic verified non-ACM (e.g., fiberglass in SRM 1866) in a drop of immersion oil (n_D should reflect usage of various n_D's) on a clean slide, rubbing preparation tools (forceps, dissecting needles, etc.) in the mount and placing a clean coverslip on the drop. The entire area under the coverslip shall be scanned to detect any asbestos contamination. A similar check shall be made after every 20 uses of each piece of homogenization equipment. An isotropic verified non-ACM shall be homogenized in the clean equipment, a slide prepared with the material and the slide scanned for asbestos contamination. (This can be substituted for the blank slide mentioned in this section.)

2. Nonfriable materials. At least one non-ACM nonfriable material shall be prepared and analyzed with every 20 samples analyzed. This non-ACM shall go through the full preparation and analysis regimen for the type of analysis being performed.

1VAC30-45-822. Asbestos testing: test variability/reproducibility. (Repealed.)

A. Transmission electron microscopy. Quality assurance analyses shall be performed regularly covering all time periods, instruments, tasks, and personnel. The selection of samples shall be random and samples of special interest may be included in the selection of samples for quality assurance analyses. When possible, the checks on personnel performance shall be executed without their prior knowledge. A disproportionate number of analyses shall not be performed prior to internal or external audits. It is recommended that a laboratory initially be at 100% quality control (all samples reanalyzed). The proportion of quality control samples can later be lowered gradually, as control indicates, to a minimum of 10%.

1. Water and wastewater. All analyses shall be performed on relocator grids so that other laboratories can easily repeat analyses on the same grid openings. Quality assurance analyses shall not be postponed during periods of heavy workloads. The total number of QA samples and blanks shall be greater than or equal to 10% of the total sample workload. Precision of analyses is related to concentration, as gleaned from interlaboratory proficiency testing. Relative standard deviations (RSD) for amphibole asbestos decreased from 50% at 0.8 MFL to 25% at 7 MFL in interlaboratory proficiency testing, while RSD for chrysotile was higher, 50% at 6 MFL.

a. Replicate. A second, independent analysis shall be performed on the same grids but on different grid openings than used in the original analysis of a sample. Results shall be within 1.5X of Poisson standard deviation. This shall be performed at a frequency of 1 per 100 samples. (EPA/600/R-94/134, Method 100.2, Table 2)

b. Duplicate. A second aliquot of sample shall be filtered through a second filter, prepared and analyzed in the same manner as the original preparation of that sample. Results shall be within 2.0X of Poisson standard deviation. This shall be performed at a frequency of one per 100 samples. (EPA/600/R-94/134, Method 100.2, Table 2)

c. Verified analyses. A second, independent analysis shall be performed on the same grids and grid openings used in the original analysis of a sample. The two sets of results shall be compared according to Turner and Steel (NISTIR 5351). This shall be performed at a frequency of one per 20 samples. Qualified analysts shall maintain an average of $\geq$ 80% true positives, $\leq$ 20% false negatives, and $\leq$ 10% false positives.

2. Air.

a. All analyses shall be performed on relocator grids so that other laboratories can easily repeat analyses on the same grid openings.

b. The laboratory and TEM analysts shall obtain mean analytical results on NIST SRM 1876b so that trimmed mean values fall within 80% of the lower limit and 110% of the upper limit of the 95% confidence limits as published on the certificate. These limits are derived from the allowable false positives and false negatives given in subdivision A 2 e (3) of this subsection. SRM 1876b shall be analyzed a minimum of once per year by each TEM analyst.

c. The laboratory shall have documentation demonstrating that TEM analysts correctly classify at least 90% of both bundles and single fibrils of asbestos structures greater than or equal to 1 mm in length in known standard materials traceable to NIST, such as NIST bulk asbestos SRM 1866.

d. Interlaboratory analyses shall be performed to detect laboratory bias. The frequency of interlaboratory verified analysis shall correspond to a minimum of 1 per 200 grid square analyses.

e. If more than one TEM is used for asbestos analysis, intermicroscope analyses shall be performed to detect instrument bias.

(1) Replicate. A second, independent analysis shall be performed in accordance with Section D.6.2.1.1.a. (AHERA, Table III)

(2) Duplicate. A second wedge from a sample filter shall be prepared and analyzed in the same manner as the original preparation of that sample. Results shall be within 2.0X of Poisson standard deviation. This shall be

performed at a frequency of 1 per 100 samples. (AHERA, Table III)

(3) Verified analyses. A second, independent analysis shall be performed on the same grids and grid openings in accordance with subdivision A 1 c of this section.

3. Bulk samples. Determination of precision and accuracy should follow guidelines in NISTIR 5951, Guide for Quality Control on the Qualitative and Quantitative Analysis of Bulk Asbestos Samples: Version 1. Because bulk samples with low (< 10%) asbestos content are the most problematic, a laboratory's quality control program should focus on such samples. At least 30% of a laboratory's QC analyses shall be performed on samples containing from 1.0% to 10% asbestos.

a. Intra-analyst precision. At least one out of 50 samples shall be reanalyzed by the same analyst. For single analyst laboratories, at least one out of every 10 samples shall be reanalyzed by the same analyst.

b. Inter analyst precision. At least one out of 15 samples shall be reanalyzed by another analyst. Inter analyst results will require additional reanalysis, possibly including another analyst, to resolve discrepancies when classification (ACM vs. non ACM) errors occur, when asbestos identification errors occur, or when inter-analyst precision is found to be unacceptable.

c. Inter laboratory precision. The laboratory shall participate in round robin testing with at least one other laboratory. Samples shall be sent to this other lab at least four times per year. These samples shall be samples previously analyzed as QC samples. Results of these analyses shall be assessed in accordance with QC requirements. As a minimum, the QC requirements shall address misclassifications (false positives, false negatives) and misidentification of asbestos types.

B. Phase contrast microscopy.

1. Inter-laboratory precision. Each laboratory analyzing air samples for compliance determination shall implement an inter laboratory quality assurance program that as a minimum includes participation of at least two other independent laboratories. Each laboratory shall participate in round robin testing at least once every six months with at least all the other laboratories in its inter-laboratory quality assurance group. Each laboratory shall submit slides typical of its own workload for use in this program. The round robin shall be designed and results analyzed using appropriate statistical methodology. Results of this QA program shall be posted in each laboratory to keep the microscopists informed.

2. Intra- and inter-analyst precision. Each analyst shall select and count a prepared slide from a "reference slide library" on each day on which air counts are performed. Reference slides shall be prepared using well behaved samples taken from the laboratory workload. Fiber densities shall cover the entire range routinely analyzed by the laboratory. These slides shall be counted by all analysts to establish an original standard deviation and corresponding limits of acceptability. Results from the daily reference sample analysis shall be compared to the statistically derived acceptance limits using a control chart or a database. It is recommended that the labels on the reference slides be periodically changed so that the analysts do not become familiar with the samples. Intra- and inter analyst precision may be estimated from blind recounts on reference samples. Inter analyst precision shall be posted in each laboratory to keep the microscopists informed.

C. Polarized light microscopy. Refer to subdivision A 3 of this section.

1VAC30-45-823. ~~Asbestos testing: other quality control measures.~~ (Repealed.)

A. Transmission electron microscopy.

1. Water and wastewater.

a. Filter preparations shall be made from all six asbestos types from NIST SRMs 1866 and 1867. These preparations shall have concentrations between one and 20 structures (> 10 μm) per 0.01 mm^2. One of these preparations shall be analyzed independently at a frequency of one per 100 samples analyzed. Results shall be evaluated as verified asbestos analysis in accordance with Turner and Steel (NISTIR 5351).

b. NIST SRM 1876b shall be analyzed annually by each analyst. Results shall be evaluated in accordance with limits published for that SRM. This SRM is not strictly appropriate for waterborne asbestos but analysts can demonstrate general TEM asbestos competence by producing results within the published limits of this (the only recognized TEM counting standard) SRM.

2. Air.

a. Filter preparations shall be made from all six asbestos types in accordance with subdivision A 1 a of this section.

b. NIST SRM 1876b shall be analyzed annually in accordance with subdivision A 1 b of this section.

3. Bulk samples. All analysts shall be able to correctly identify the six regulated asbestos types (chrysotile, amosite, crocidolite, anthophyllite, actinolite, and tremolite). Standards for the six asbestos types listed are available from NIST (SRMs 1866 and 1867). These materials can also be used as identification standards for AEM (Section 3.2.1 Qualitative Analysis, Page 57, EPA/600/R-93/116).

B. Phase contrast microscopy.

1. Test for nonrandom fiber distribution. Blind recounts by the same analyst shall be performed on 10% of the filters counted. A person other than the counter should re-label

slides before the second count. A test for type II error (NIOSH 7400, Issue 2, 15 August 1994, Section 13) shall be performed to determine whether a pair of counts by the same analyst on the same slide should be rejected due to nonrandom fiber distribution. If a pair of counts is rejected by this test, the remaining samples in the set shall be recounted and the new counts shall be tested against first counts. All rejected paired counts shall be discarded. It shall not be necessary to use this statistic on blank recounts.

2. All individuals performing airborne fiber analysis shall have taken the NIOSH Fiber Counting Course for sampling and evaluating airborne asbestos dust or an equivalent course.

3. All laboratories shall participate in a national sample testing scheme such as the Proficiency Analytical Testing (PAT) program or the Asbestos Analysts Registry (AAR) program, both sponsored by the American Industrial Hygiene Association (AIHA), or equivalent.

C. Polarized light microscopy.

1. Friable materials. Because accuracy cannot be determined by reanalysis of routine field samples, at least one out of 100 samples shall be a standard or reference sample that has been routinely resubmitted to determine analyst's precision and accuracy. A set of these samples should be accumulated from proficiency testing samples with predetermined weight compositions or from standards generated with weighed quantities of asbestos and other bulk materials (Perkins and Harvey, 1993; Parekh et al., 1992; Webber et al., 1982). At least half of the reference samples submitted for this QC shall contain between 1.0% and 10% asbestos.

2. Nonfriable materials. At least one out of 100 samples shall be a verified quantitative standard that has routinely been resubmitted to determine analyst precision and accuracy.

1VAC30-45-824. Asbestos testing: method evaluation. (Repealed.)

In order to ensure the accuracy of reported results, the following procedures shall be in place:

1. Demonstration of capability shall be performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel, or method.

2. Performance audits. The results of such analyses shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

1VAC30-45-825. Asbestos testing: asbestos calibration. (Repealed.)

Refer to methods referenced in the following sections for specific equipment requirements.

1. Transmission electron microscopy: general. Analytical electron microscopy equipment will not be discussed in this document.

2. Transmission electron microscopy: water and wastewater. All calibrations listed below (unless otherwise noted) shall be performed under the same analytical conditions used for routine asbestos analysis and shall be recorded in a notebook and include date and analyst's signature. Frequencies stated below may be reduced to "before next use" if no samples are analyzed after the last calibration period has expired. Likewise, frequencies may have to be increased following non routine maintenance or unacceptable calibration performance.

a. Magnification calibration. Magnification calibration shall be done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting, generally 10,000 and 20,000x. A logbook shall be maintained with the dates of the calibration recorded. Calibrations shall be performed monthly to establish the stability of magnification. Calibration data shall be displayed on control charts that show trends over time. (EPA/600/R-94/134, Method 100.2, Section 10.1)

b. Camera constant. The camera length of the TEM in the Selected Area Electron Diffraction (SAED) mode shall be calibrated before SAED patterns of unknown samples are observed. The diffraction specimen shall be at the eucentric position for this calibration. This calibration shall allow accurate (< 10% variation) measurement of layer-line spacings on the medium used for routine measurement, i.e., the phosphor screen or camera film. This shall also allow accurate (< 5.0% variation) measurement of zone axis SAED patterns on permanent media, e.g., film. Calibrations shall be performed monthly to establish the stability of the camera constant (EPA/600/R-94/134, Method 100.2, Section 10.2). Where nonasbestiform minerals may be expected (e.g., winchite, richterite, industrial talc, vermiculite, etc.), an internal camera constant standard such as gold, shall be deposited and measured on each sample to facilitate accurate indexing of zone axis SAED patterns. In such cases, layer line analysis alone shall not be used. Calibration data shall be displayed on control charts that show trends over time.

c. Spot size. The diameter of the smallest beam spot at crossover shall be less than 250 nm as calibrated quarterly. Calibration data shall be displayed on control charts that show trends over time. (EPA/600/R-94/134, Method 100.2, Section 10.3)

d. Beam dose. The beam dose shall be calibrated so that beam damage to chrysotile is minimized, specifically so that an electron diffraction pattern from a single fibril ≥1 µm in length from a NIST SRM chrysotile sample is stable in the electron beam dose for at least 15 seconds.

e. EDXA system.

(1) The x-ray energy vs. channel number for the EDXA system shall be calibrated to within 20 eV for at least two peaks between 0.7 keV and 10 keV. One peak shall be from the low end (0.7 keV to 2 keV) and the other peak from the high end (7 keV to 10 keV) of this range. The calibration of the x-ray energy shall be checked prior to each analysis of samples and recalibrated if out of the specified range.

(2) The ability of the system to resolve the Na Ka line from the Cu L line shall be confirmed quarterly by obtaining a spectrum from the NIST SRM 1866 crocidolite sample on a copper grid.

(3) The k-factors for elements found in asbestos (Na, Mg, Al, Si, Ca, and Fe) relative to Si shall be calibrated semiannually, or anytime the detector geometry may be altered. NIST SRM 2063a shall be used for Mg, Si, Ca, Fe, while k-factors for Na and Al may be obtained from suitable materials such as albite, kaersutite, or NIST SRM 99a. The k-factors shall be determined to a precision (2s) within 10% relative to the mean value obtained for Mg, Al, Si, Ca, and Fe, and within 20% relative to the mean value obtained for Na. The k-factor relative to Si for Na shall be between 1.0 and 4.0, for Mg and Fe shall be between 1.0 and 2.0, and for Al and Ca shall be between 1.0 and 1.75. The k-factor for Mg relative to Fe shall be 1.5 or less. Calibration data shall be displayed on control charts that show trends over time.

(4) The detector resolution shall be checked quarterly to ensure a full-width half-maximum resolution of <175 eV at Mn Ka (5.90 keV). Calibration data shall be displayed on control charts that show trends over time.

(5) The portions of a grid in a specimen holder for which abnormal x-ray spectra are generated under routine asbestos analysis conditions shall be determined and these areas shall be avoided in asbestos analysis.

(6) The sensitivity of the detector for collecting x-rays from small volumes shall be documented quarterly by collecting resolvable Mg and Si peaks from a unit fibril of NIST SRM 1866 chrysotile.

f. Low temperature asher. The low temperature asher shall be calibrated quarterly by determining a calibration curve for the weight vs. ashing time of collapsed mixed-cellulose ester (MCE) filters. Calibration data shall be displayed on control charts that show trends over time.

g. Grid openings. The magnification of the grid opening measurement system shall be calibrated using an appropriate standard at a frequency of 20 openings/20 grids/lot of 1000 or one opening/sample. The variation in the calibration measurements (2s) is <5.0% of the mean calibration value.

3. Air. All calibrations shall be performed in accordance with subdivision 2 of this section, with the exception of magnification. Magnification calibration shall be done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting, generally 15,000 to 20,000x (AHERA, III.G.1.c). A logbook shall be maintained with the dates of the calibration recorded. Calibrations shall be performed monthly to establish the stability of magnification.

4. Bulk samples. All calibrations shall be performed in accordance with subdivision 3 of this section.

5. Phase contrast microscopy.

a. At least once daily, the analyst shall use the telescope ocular (or Bertrand lens, for some microscopes) supplied by the manufacturer to ensure that the phase rings (annular diaphragm and phase shifting elements) are concentric.

b. The phase shift limit of detection of the microscope shall be checked monthly or after modification or relocation using an HSE/NPL phase contrast test slide for each analyst/microscope combination (refer to NIOSH 7400, Issue 2, 15 August 1994, Section 10b). This procedure assures that the minimum detectable fiber diameter (< ca. 0.25mm) for this microscope is achieved.

c. Prior to ordering the Walton Beckett graticule, calibration, in accordance with NIOSH 7400, Issue 2, 15 August 1994, Appendix A, shall be performed to obtain a counting area 100 mm in diameter at the image plane. The diameter, d_c (mm), of the circular counting area and the disc diameter shall be specified when ordering the graticule. The field diameter (D) shall be verified (or checked), to a tolerance of 100 µm ± 2 µm, with a stage micrometer upon receipt of the graticule from the manufacturer. When changes (zoom adjustment, disassembly, replacement, etc.) occur in the eyepiece-objective-reticle combination, field diameter shall be remeasured (or recalibrated) to determine field area (mm^2). Recalibration of field diameter shall also be required when there is a change in interpupillary distance (i.e., change in analyst). Acceptable range for field area shall be 0.00754 mm^2 to 0.00817 mm^2. The actual field area shall be documented and used.

6. Polarized light microscopy.

a. Microscope alignment. To accurately measure the required optical properties, a properly aligned polarized light microscope (PLM) shall be utilized. The PLM shall be aligned before each use. (Section 2.2.5.2.3, EPA/600/R-93/116, July 1993)

b. Refractive index liquids. Series of n_D = 1.49 through 1.72 in intervals less than or equal to 0.005. Refractive index liquids for dispersion staining, high dispersion series 1.550, 1.605, 1.680. The accurate measurement of the refractive index (RI) of a substance requires the use of calibrated refractive index liquids. These liquids shall be calibrated at first use and semiannually, or next use,

whichever is less frequent, to an accuracy of 0.004, with a temperature accuracy of 2°C using a refractometer or RI glass beads.

1VAC30-45-826. ~~Asbestos testing: analytical sensitivity.~~ (Repealed.)

~~A. Transmission electron microscopy.~~

~~1. Water and wastewater. An analytical sensitivity of 200,000 fibers per liter (0.2 MFL) is required for each sample analyzed (EPA/600/R-94/134, Method 100.2, Section 1.6). Analytical sensitivity is defined as the waterborne concentration represented by the finding of one asbestos structure in the total area of filter examined. This value will depend on the fraction of the filter sampled and the dilution factor (if applicable).~~

~~2. Air. An analytical sensitivity of 0.005 structures/cm^2 is required for each sample analyzed. Analytical sensitivity is defined as the airborne concentration represented by the finding of one asbestos structure in the total area of filter examined. This value will depend on the effective surface area of the filter, the filter area analyzed, and the volume of air sampled (AHERA, Table I).~~

~~3. Bulk samples.~~

~~a. The range is dependent on the type of bulk material being analyzed. The sensitivity may be as low as 0.0001% depending on the extent to which interfering materials can be removed during the preparation of AEM specimens. (Section 2.5.2 Range, Page 51, EPA/600/R-93/116)~~

~~b. There should be an error rate of less than 1.0% on the qualitative analysis for samples that contain chrysotile, amosite, and crocidolite. A slightly higher error rate may occur for samples that contain anthophyllite, actinolite, and tremolite, as it can be difficult to distinguish among the three types. (Section 3, Page 10, NIST Handbook 150-3, August 1994)~~

~~B. Phase contrast microscopy. The normal quantitative working range of the test method is 0.04 to 0.5 fiber/cm^2 for a 1000 L air sample. An ideal counting range on the filter shall be 100 to 1300 fibers/mm^2. The limit of detection (LOD) is estimated to be 5.5 fibers per 100 fields or 7 fibers/mm^2. The LOD in fiber/cc will depend on sample volume and quantity of interfering dust but shall be <0.01 fiber/cm^2 for atmospheres free of interferences. (NIOSH 7400, Issue 2, 15 August 1994)~~

~~C. Polarized light microscopy. The laboratory shall utilize a test method that provides a limit of detection that is appropriate and relevant for the intended use of the data. Limit of detection shall be determined by the protocol in the test method or applicable regulation.~~

1VAC30-45-827. ~~Asbestos testing: data reduction.~~ (Repealed.)

~~A. Transmission electron microscopy.~~

~~1. Water and wastewater.~~

~~a. The concentration of asbestos in a given sample shall be calculated in accordance with EPA/600/R-94/134, Method 100.2, Section 12.1. Refer to 1VAC30-45-730 K for additional data reduction requirements.~~

~~b. Measurement uncertainties. The laboratory shall calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample (EPA/600/R-94/134, Method 100.2, Section 12.2.2).~~

~~2. Air.~~

~~a. The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized, e.g., AHERA. Refer to 1VAC30-45-730 K for additional data reduction requirements.~~

~~b. Measurement uncertainties. The laboratory shall calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample.~~

~~3. Bulk samples.~~

~~a. The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized (e.g., EPA/600/R-93/116, July 1993). Refer to 1VAC30-45-730 K for additional data reduction requirements.~~

~~b. Measurement uncertainties. Proficiency testing for floor tiles analyzed by TEM following careful gravimetric reduction (New York ELAP Certification Manual Item 198.4) has revealed an interlaboratory standard deviation of approximately 20% for residues containing 70% or more asbestos. Standard deviations range from 20% to 60% for residues with lower asbestos content.~~

~~B. Phase contrast microscopy.~~

~~1. Airborne fiber concentration in a given sample shall be calculated in accordance with NIOSH 7400, Issue 2, 15 August 1994, Sections 20 and 21. Refer to 1VAC30-45-730 K for additional data reduction requirements.~~

~~2. Measurement uncertainties. The laboratory shall calculate and report the intra-laboratory and inter-laboratory relative standard deviation with each set of results. (NIOSH 7400, Issue 2, 15 August 1994)~~

~~3. Fiber counts above 1300 fibers/mm^2 and fiber counts from samples with >50% of the filter area covered with particulate should be reported as "uncountable" or "probably biased." Other fiber counts outside the 100-1300 fibers/mm^2 range should be reported as having "greater than optimal variability" and as being "probably biased."~~

~~C. Polarized light microscopy.~~

~~1. The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized (e.g., EPA/600/R-93/116, July 1993). Refer to 1VAC30-45-730 K for additional data reduction requirements.~~

2. Method uncertainties. The individual laboratory shall determine precision and accuracy for the percent range involved. If point counting and/or visual estimates are used, a table of reasonable expanded errors (refer to EPA/600/R-93/116, July 1993, Table 2-1) should be generated for different concentrations of asbestos.

1VAC30-45-828. Asbestos testing: quality of standards and reagents. (Repealed.)

A. Transmission electron microscopy.

1. The quality control program shall establish and maintain provisions for asbestos standards.

a. Reference standards that are used in an asbestos laboratory shall be obtained from the National Institute of Standards and Technology (NIST), EPA, or suppliers who participate in supplying NIST standards or NIST traceable asbestos. Any reference standards purchased outside the United States shall be traceable back to each country's national standards laboratory. Commercial suppliers of reference standards shall conform to ANSI N42.22 to assure the quality of their products.

b. Reference standards shall be accompanied with a certificate of calibration whose content is as described in ANSI N42.22-1995, Section 8, Certificates.

2. All reagents used shall be analytical reagent grade or better.

3. The laboratory shall have mineral fibers or data from mineral fibers that will allow differentiating asbestos from at least the following "look-alikes": fibrous talc, sepiolite, wollastonite, attapulgite (palygorskite), halloysite, vermiculite scrolls, antigorite, lizardite, pyroxenes, hornblende, richterite, winchite, or any other asbestiform minerals that are suspected as being present in the sample.

B. Phase contrast microscopy. Standards of known concentration have not been developed for this testing method. Routine workload samples that have been statistically validated and national proficiency testing samples such as PAT and AAR samples available from the AIHA may be utilized as reference samples (refer to 1VAC30-45-822-B-2) to standardize the optical system and analyst. All other testing reagents and devices (HSE/NPL test slide and Walton-Beckett Graticule) shall conform to the specifications of the method (refer to NIOSH 7400, Issue 2, 15 August 1994).

C. Polarized light microscopy. Refer to 1VAC30-45-828-A.

1VAC30-45-829. Asbestos testing: constant and consistent test conditions. (Repealed.)

The laboratory shall establish and adhere to written procedures to minimize the possibility of cross-contamination between samples.

1VAC30-45-850. Sample handling, sample acceptance policy, and sample receipt.

While the laboratory may not have control of field sampling activities, the following are essential to ensure the validity of the laboratory's data.

1. Sample tracking. The laboratory shall have a documented system for uniquely identifying the items to be tested to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification for all samples, subsamples and subsequent extracts or digestates or both. The use of container shape, size or other physical characteristic, such as amber glass or purple top, is not an acceptable means of identifying the sample. System laboratories shall use a permanent chronological record such as a logbook or electronic database to document receipt of all containers. This sample receipt log shall record the following at a minimum: name of facility where sample was taken, date and time of laboratory receipt, unique laboratory ID code, and signature or initials of the person making the entries.

2. Sample acceptance policy. The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected. The policy shall ensure that only properly obtained samples with appropriate sampling records (see 1VAC30-45-640 B) are analyzed and that the samples are handled properly. This sample acceptance policy shall be made available to sample collection personnel. The policy shall include elements such as appropriate documentation of the sample's identification, use of appropriate sample containers, adherence to specified holding times, adequate sample volume to perform necessary tests, and procedures to be used when samples show signs of damage, contamination or inadequate preservation.

3. Sample receipt protocols.

a. Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified by the sample acceptance policy shall be checked.

b. All samples that require thermal preservation shall be considered acceptable if the arrival temperature is either within 2 ~~degrees Celsius~~ °C of the required temperature or the method specified range. For samples with a specified temperature of 4 ~~degrees Celsius~~ °C, samples with a temperature of ranging from just above freezing temperature of water to 6 ~~degrees Celsius~~ °C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection or on the same day that are collected may not meet ~~this~~ these criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice. Thermal preservation is not required in the field if the laboratory receives the sample and either

begins the analysis or refrigerates the sample within 15 minutes of collection.

c. The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine prior to or during sample preparation or analysis.

d. The results of all checks required by the sample acceptance policy and relevant test method shall be recorded.

4. Storage conditions.

a. The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination or damage to the sample during storage, handling, preparation, and testing. Any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded.

b. Samples shall be stored according to the conditions specified by preservation protocols:

(1) Samples that require thermal preservation shall be stored under refrigeration that is within 2 ~~degrees Celsius~~ °C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4 ~~degrees Celsius~~ °C, storage at a temperature above the freezing point of water to 6 ~~degrees Celsius~~ °C shall be acceptable.

(2) Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

c. Sample fractions, extracts, leachates and other sample preparation products shall be stored according to subdivision 4 a of this section or according to specifications in the test method.

d. Where a sample or portion of the sample is to be held secure ~~(for example~~ (e.g., for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

5. Sample disposal. The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (1VAC30-45)

Application for Certification of Environmental Laboratories DGS-21-156 (eff. 1/09) (Application for Certification under 1VAC30-45 must be obtained from DCLS program staff at Lab_Cert@dgs.virginia.gov)

DOCUMENTS INCORPORATED BY REFERENCE (1VAC30-45)

The Standards for Environmental Laboratories and Accreditation Bodies, 2009, The NELAC Institute (TNI), P.O. Box 2439, Weatherford, TX 76086; www.nelac-institute.org:

Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1-2009)

Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (EL-V2-2009)

VA.R. Doc. No. R12-3334; Filed June 8, 2016, 11:31 a.m.

TITLE 2. AGRICULTURE

BOARD OF AGRICULTURE AND CONSUMER SERVICES

Final Regulation

REGISTRAR'S NOTICE: The Board of Agriculture and Consumer Services is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 13 of the Code of Virginia, which excludes the Board of Agriculture and Consumer Services when promulgating regulations pursuant to § 3.2-5121 of the Code of Virginia, which conform, insofar as practicable, with the federal Food and Drug Administration's Food Code. Pursuant to § 3.2-5121 C, the regulatory action is exempt from portions of the Administrative Process Act provided the State Board of Health adopts the same version and both agencies' regulations have the same effective date.

Title of Regulation: **2VAC5-585. Retail Food Establishment Regulations (amending 2VAC5-585-40 through 2VAC5-585-100, 2VAC5-585-130 through 2VAC5-585-200, 2VAC5-585-220, 2VAC5-585-230, 2VAC5-585-250 through 2VAC5-585-410, 2VAC5-585-430 through 2VAC5-585-600, 2VAC5-585-620, 2VAC5-585-630, 2VAC5-585-650 through 2VAC5-585-680, 2VAC5-585-700 through 2VAC5-585-765, 2VAC5-585-780 through 2VAC5-585-870, 2VAC5-585-900, 2VAC5-585-930 through 2VAC5-585-960, 2VAC5-585-980, 2VAC5-585-990, 2VAC5-585-1000, 2VAC5-585-1070, 2VAC5-585-1090, 2VAC5-585-1100, 2VAC5-585-1110, 2VAC5-585-1120, 2VAC5-585-1180, 2VAC5-585-1190, 2VAC5-585-1230, 2VAC5-585-1240, 2VAC5-585-1300 through 2VAC5-585-1330, 2VAC5-585-1350, 2VAC5-585-**

1360, 2VAC5-585-1370, 2VAC5-585-1450, 2VAC5-585-1460, 2VAC5-585-1500 through 2VAC5-585-1570, 2VAC5-585-1630 through 2VAC5-585-1680, 2VAC5-585-1700, 2VAC5-585-1720, 2VAC5-585-1730, 2VAC5-585-1740, 2VAC5-585-1770, 2VAC5-585-1780, 2VAC5-585-1790, 2VAC5-585-1810, 2VAC5-585-1890, 2VAC5-585-1900, 2VAC5-585-1920, 2VAC5-585-1960, 2VAC5-585-2000, 2VAC5-585-2010, 2VAC5-585-2040 through 2VAC5-585-2110, 2VAC5-585-2120 through 2VAC5-585-2210, 2VAC5-585-2230 through 2VAC5-585-2280, 2VAC5-585-2310 through 2VAC5-585-2360, 2VAC5-585-2420, 2VAC5-585-2430, 2VAC5-585-2460, 2VAC5-585-2490, 2VAC5-585-2520, 2VAC5-585-2540, 2VAC5-585-2550, 2VAC5-585-2570, 2VAC5-585-2840, 2VAC5-585-2930, 2VAC5-585-2990 through 2VAC5-585-3040, 2VAC5-585-3070, 2VAC5-585-3130, 2VAC5-585-3150, 2VAC5-585-3210, 2VAC5-585-3240, 2VAC5-585-3250, 2VAC5-585-3270, 2VAC5-585-3310 through 2VAC5-585-3480, 2VAC5-585-3500, 2VAC5-585-3510, 2VAC5-585-3541, 2VAC5-585-3542, 2VAC5-585-3600, 2VAC5-585-3620, 2VAC5-585-3630, 2VAC5-585-3800 through 2VAC5-585-3840, 2VAC5-585-3860, 2VAC5-585-3910, 2VAC5-585-3930, 2VAC5-585-3940, 2VAC5-585-3950, 2VAC5-585-4040, 2VAC5-585-4050, 2VAC5-585-4060; adding 2VAC5-585-65, 2VAC5-585-67, 2VAC5-585-255, 2VAC5-585-725, 2VAC5-585-755, 2VAC5-585-1435, 2VAC5-585-1535, 2VAC5-585-1885, 2VAC5-585-2045, 2VAC5-585-2505, 2VAC5-585-2595, 2VAC5-585-3047, 2VAC5-585-3655, 2VAC5-585-3660; repealing 2VAC5-585-15, 2VAC5-585-1870).

Statutory Authority: § 3.2-5121 of the Code of Virginia.

Effective Date: July 12, 2016.

Agency Contact: Ryan Davis, Program Manager, Office of Dairy and Foods, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-8910, FAX (804) 371-7792, TTY (800) 828-1120, or email ryan.davis@vdacs.virginia.gov.

Summary:

The Retail Food Establishment Regulations (2VAC5-585) establish minimum sanitary standards for retail food establishments such as supermarkets, grocery stores, and convenience stores. Those standards include the safe and sanitary maintenance, storage, operation, and use of equipment; the safe preparation, handling, protection, and preservation of food including necessary refrigeration or heating methods and procedures for vector and pest control; requirements for toilet and handwashing facilities for employees; requirements for appropriate lighting and ventilation; requirements for an approved water supply and sewage disposal system; personal hygiene standards for employees; and the appropriate use of precautions to prevent the transmission of communicable diseases.

The current regulation is based on the U.S. Food and Drug Administration (FDA) 2005 Food Code and the 2007 Food Code Supplement. The existing regulation is amended to be consistent with the current 2013 FDA Food Code. Many of the changes refine and provide further clarity to existing regulations.

Amendments include requirements that (i) retail food establishments must refrigerate cut leafy greens in order to ensure that the product is safe to consume; (ii) food establishments must have employees who are fully informed regarding food allergens and their dangers; (iii) retail food establishment employees must be aware of their responsibility to inform management of any health or illness issue that might affect the safety of food products; (iv) the food establishment must have procedures in place for addressing vomitus or fecal matter discharge on surfaces in the food establishment; (v) wild mushrooms cannot be sold unless the establishment has been approved to do so by the regulatory authority; (vi) bare hand contact with ready-to-eat food ingredients is allowed in certain instances; (vii) game animals that are sold must be raised, slaughtered, and processed under a voluntary inspection program that is conducted by the U.S. Department of Agriculture or the state agency that has animal health jurisdiction; (viii) the food establishment must discontinue operations and notify the Virginia Department of Agriculture and Consumer Services if an imminent health hazard exists at the establishment; (ix) the food establishment must immediately contact the agency to report a food employee illness due to nontyphoidal Salmonella if it is determined that the illness is of a nature that can be transmitted through food; (x) the food establishment must correct all priority item violations within 72 hours and all priority foundation item violations within 10 days; and (xi) the food establishment must have at least one supervisor who is a certified food protection manager.

Changes made to the final regulation include (i) adding definitions for "approved water system," "potable water," "private well," "pure water," and "waterworks"; (ii) making the person in charge responsible for ensuring that employees are properly maintaining the temperatures of time/temperature control for safety foods during hot and cold holding; (iii) removing definitions for "drinking water" and "public water system"; (iii) requiring food allergy awareness as a component of employee training; (iv) updating the Guide for Control of Molluscan Shellfish to the 2013 edition; (v) exempting eggs sold pursuant to § 3.2-5305 of the Code of Virginia from the U.S. Consumer Grade B tolerances; (vi) requiring a food establishment to provide cleaning agents and sanitizers during hours of operation; (vii) requiring a food establishment to sample its water system before placing the system into service; (viii) requiring a food establishment to test its water for nitrate and total coliform; (ix) requiring food establishments to maintain reports of water samples for five years; (x) requiring that the water source in a food

establishment meet both the maximum daily and peak hourly water demands; (xi) adding provisions to allow dogs to accompany patrons in certain food establishments that provide food service in an outdoor setting; (xii) requiring the inclusion of additional information in a Hazard Analysis and Critical Control Points plan; and (xiii) requiring the Virginia Department of Agriculture and Consumer Services to provide training and continuing education to its inspectors.

The amendments are adopted concurrently with the Virginia Department of Health action adopting certain changes based on the 2013 FDA Food Code and Supplement, also published in this issue of the Virginia Register of Regulations.

2VAC5-585-15. ~~Categories of requirements.~~ (Repealed.)

~~Requirements contained in this regulation are presented as being in one of three categories of importance: critical item (as defined in 2VAC5-585-40); "swing" (i.e., those that may or may not be critical depending on the circumstances); and noncritical. An asterisk (*) after a catchline (the language immediately following a section number that introduces the subject of the section) indicates that all of the provisions within that section are critical unless otherwise indicated, as follows:~~

~~1. Any provisions that are "swing" items are followed by the superscripted letter S and any provisions that are noncritical are followed by the superscripted letter N.~~

~~2. Any unmarked provisions within a section that has an asterisked catchline are critical. All provisions following a catchline that is not marked with an asterisk are noncritical.~~

Article 2
Definitions

2VAC5-585-40. Definitions.

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

"Accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals. "Accredited program" refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, recertification, discipline, and grievance procedures; and test development and administration. "Accredited program" does not refer to training functions or educational programs.

"Additive" means either a (i) "food additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, 21 USC § 321(s) and 21 CFR ~~Part 170~~ 170.3(e)(1) or (ii) "color additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, 21 USC § 321(t) and 21 CFR ~~Part 70~~ 70.3(f).

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, 21 USC § 342.

"Approved" means acceptable to the department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

["Approved water system" means a permitted waterworks constructed, maintained, and operated pursuant to 12VAC5-590 or a private well constructed, maintained, and operated pursuant to 12VAC5-630.]

"Asymptomatic" means without obvious symptoms; not showing or producing ~~indication~~ indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice. Asymptomatic includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

~~"a_w"~~ "A_w" means water activity that is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol ~~a_w~~ A_w.

"Balut" means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

"Beverage" means a liquid for drinking, including water.

"Board" means the Board of Agriculture and Consumer Services.

"Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

"Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

"Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

"CFR" means Code of Federal Regulations. Citations in this chapter to the CFR refer sequentially to the title, part, and section numbers [~~for~~. For] example, 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

"CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. "CIP" does not include the cleaning of equipment such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

~~"CFR" means Code of Federal Regulations. Citations in this regulation to the CFR refer sequentially to the title, part, and section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.~~

~~"Code of Federal Regulations" means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government that:~~

~~1. Is published annually by the U.S. Government Printing Office; and~~

~~2. Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40 CFR, and Wildlife and Fisheries rules in 50 CFR.~~

"Commingle" means:

1. To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or

2. To combine shucked shellfish from containers with different container codes or different shucking dates.

"Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing. "Comminuted" includes (i) fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage~~;~~ and (ii) a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

"Commissioner" means the Commissioner of Agriculture and Consumer Services, his duly designated officer, or his agent.

"Conditional employee" means a potential food employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative ~~organism or chemical~~ agent and epidemiological analysis implicates the food as the source of the illness.

"Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

"Core item" means a provision in this chapter that is not designated as a priority item or a priority foundation item. "Core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures, facilities or structures, equipment design, or general maintenance.

"Corrosion-resistant materials" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

"Counter-mounted equipment" means equipment that is not ~~easily movable~~ portable and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

~~"Critical item" means a provision of this regulation that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard. "Critical item" is an item that is denoted in this regulation with an asterisk (*).~~

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

"Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula, and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

"Dealer" means a person who is authorized by a shellfish control authority for the activities of a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan shellfish according to the provisions of the National Shellfish Sanitation Program.

"Department" means the Virginia Department of Agriculture and Consumer Services.

"Disclosure" means a written statement that clearly identifies the animal-derived foods that are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens ~~in their entirety~~, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

[~~"Drinking water" means water that meets the "water quality standards" requirements for bacteria and nitrates of the Virginia Waterworks Regulations (12VAC5-590). Drinking water is traditionally known as "potable water." Drinking water includes the term water except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and~~] ~~"nondrinking" water~~ [~~"nondrinking water."~~]

"Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not ~~potentially hazardous~~ time/temperature control for safety food and dry goods such as single-service items.

"Easily cleanable" means a characteristic of a surface that:

1. Allows effective removal of soil by normal cleaning methods;

2. Is dependent on the material, design, construction, and installation of the surface; and

3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

"Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified above in this definition to different situations in which varying degrees of cleanability are required such as:

1. The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

2. The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

"Easily movable" means:

1. Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

2. Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

"Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites, or turkey. Egg does not include a balut, egg of the reptile species such as alligator, or an egg product.

"Egg product" means all, or a portion of, the contents found inside eggs separated from the shell and pasteurized in a food processing plant, with or without added ingredients, intended for human consumption, such as dried, frozen, or liquid eggs. Egg product does not include food that contains eggs only in a relatively small proportion such as cake mixes.

"Employee" means the operator, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment.

~~"Enterohemorrhagic *Escherichia coli* (EHEC)" means *E. coli*, which cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with *E. coli* that have the capacity to produce Shiga toxins and to cause attaching and effacing lesion in the intestine. EHEC is a subset of Shiga toxin-producing Escherichia coli (STEC), whose members produce additional virulence factors. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic-euremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: *E. coli* O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; or *E. coli* O111:NM. Also see Shiga toxin-producing *E. coli*.~~

"EPA" means the U.S. Environmental Protection Agency.

"Equipment" means an article that is used in the operation of a food establishment~~. "Equipment" includes, but is not limited to, items,~~ such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine.

"Equipment" does not include ~~items~~ apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

"Exclude" means to prevent a person from working as ~~a food~~ an employee in a food establishment or entering a food establishment as an employee.

~~"°F" means degrees Fahrenheit.~~

"FDA" means the U.S. Food and Drug Administration.

"Fish" means fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals; all mollusks, if such animal life is intended for human consumption; and includes any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner.

"Food" means (i) a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption or (ii) chewing gum.

"Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

"Food-contact surface" means a surface of equipment or a utensil with which food normally comes into contact, or a surface of equipment or a utensil from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.

"Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

"Food establishment~~,~~" ~~as used in this regulation,~~ means an operation that stores, prepares, packages, serves, vends food directly to the consumer, or otherwise ~~offers for retail sale~~ provides food for human consumption (i) such as a market~~;~~, restaurant~~;~~, satellite or catered feeding location~~;~~, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people~~;~~,

vending location~~;~~, conveyance used to transport people~~;~~, institution~~;~~, or food bank and (ii) that relinquishes possession of a food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant ~~take-out~~ takeout orders, or delivery service that is provided by common carriers.

"Food establishment~~,~~" ~~as used in this regulation,~~ includes (i) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location and (ii) an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location~~,~~ where consumption is on or off the premises.

"Food establishment~~,~~" ~~as used in this regulation,~~ does not include:

1. An establishment that offers only prepackaged foods that are not ~~potentially hazardous~~ time/temperature control for safety foods;

2. A produce stand that only offers whole, uncut fresh fruits and vegetables;

3. A food processing plant, including those that are located on the premises of a food establishment;

4. A food warehouse;

5. A kitchen in a private home; or

6. A private home that receives catered or home delivered food.

"Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and provides food for sale or distribution to other business entities such as food processing plants or food establishments. "Food processing plant" does not include a "food ~~establishment" as previously defined in this section.~~ establishment."

"Game animal" means an animal, the products of which are food, that is not classified as ~~cattle,~~ (i) livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR ~~Part 301, Definitions, as Poultry in 9 CFR Part 381, Poultry Products Inspection Regulations, or as fish as previously defined in this section.~~ 301.2; (ii) poultry; or (iii) fish. "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes. "Game animal" does not include ratites ~~such as ostrich, emu, and rhea~~.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175.

"Grade A standards" means the requirements of the ~~United States Public Health Service/FDA "~~Grade "A" Pasteurized Milk Ordinance ~~(2003)",~~ 2013 Revision, (U.S. Food and Drug Administration) ~~and "Grade A Condensed and Dry Milk Ordinance (1995)"~~ with which certain fluid and dry milk and milk products comply.

"HACCP ~~Plan"~~ plan" means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

"Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a plumbing fixture especially placed for use in personal hygiene and designed for the washing of hands. Handwashing sink includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a nurse practitioner, physician assistant, or similar medical ~~profession~~ professional.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are (i) immunocompromised; preschool age children, or older adults; and (ii) obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury.

"Injected" means ~~tenderizing a meat with deep penetration or injecting the meat such as with juices that may be referred to as "injecting," "pinning," or "stitch pumping." During injection infectious or toxigenic microorganisms may be introduced from its surface to its interior.~~ manipulating meat to which a solution has been introduced into its interior by processes such as "injecting," "pump marinating," or "stitch pumping."

"Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or purée. Juice does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

"Kitchenware" means food preparation and storage utensils.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments, including cloth gloves.

"Major food allergen" means milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans~~;~~ or a food ingredient that contains protein derived from one of these foods. Major food allergen does not include (i) any highly refined oil derived from a major food allergen in this definition and any ingredient derived from such highly refined oil~~;~~ or (ii) any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 ~~(P. L. 108-282, Title II, Sec. 201)~~ (Pub. L. No. 108-282).

"Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified under 2VAC5-585-330 A 2 and 3 ~~and 4~~.

"Mechanically tenderized" means manipulating meat with deep penetration by processes that may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles or any mechanical device. "Mechanically tenderized" does not include processes by which solutions are injected into meat.

"mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

"Noncontinuous cooking" means the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service. "Noncontinuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

"Operator" means the entity that is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person.

"Packaged" means bottled, canned, cartoned, ~~securely~~ bagged, or ~~securely packaged~~ wrapped, whether packaged in a food establishment or a food processing plant. "Packaged" does not include ~~a wrapper, carry-out box, or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.~~ wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

"Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance. Personal care items include items such as medicines~~;~~, first aid supplies~~;~~, and other items such as cosmetics~~,~~ and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7.0 indicate acidity and values between 7.0 and 14 indicate alkalinity. The value for pure distilled water is 7.0, which is considered neutral.

"Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

"Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

1. Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

2. Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;

3. Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants~~,~~ ~~paints,~~ and personal care items that may be deleterious to health; and

4. Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

["Potable water" means water fit for human consumption that is obtained from an approved water supply and that is (i) sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii)

adequate in quantity and quality for the minimum health requirements of the person served. Potable water is traditionally known as drinking water and excludes such nonpotable forms as boiler water, mop water, rainwater, wastewater, and nondrinking water.]

"Potentially hazardous food (time/temperature control for safety food)" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation:

1. Potentially hazardous food (time/temperature control for safety food) includes an animal food that is raw or heat-treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut tomatoes, or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic in oil mixtures that are not modified in a way that results in mixtures that do not support pathogenic microorganism growth or toxin formation; and except as specified in subdivision 2 of this definition, a food that because of the interaction of its A_w and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of pH and Aw for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.

Aw values	pH values		
	4.6 or less	>4.6-5.6	>5.6
<0.92	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food
> 0.92-0.95	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
>0.95	non-PHF/non-TCS food	PA	PA

*PHF means Potentially Hazardous Food

**TCS means Time/Temperature Control for Safety Food

***PA means Product Assessment required

Table B. Interaction of pH and Aw for control of vegetative cells and spores in food not heat treated or heat treated but not packaged.

Aw values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
<0.88	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
0.88-0.90	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
>0.90-0.92	non-PHF/non-TCS food	non-PHF/non-TCS food	PA	PA
>0.92	non-PHF/non-TCS food	PA	PA	PA

*PHF means Potentially Hazardous Food

**TCS means Time/Temperature Control for Safety Food

***PA means Product Assessment required

2. Potentially hazardous food (time/temperature control for safety food) does not include:

a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard boiled, but has been pasteurized to destroy all viable *Salmonellae*;

b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

c. A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;

d. A food that is designated as Product Assessment required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

(2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use; or

(3) A combination of intrinsic and extrinsic factors; or

e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, or guineas), guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR Part 381, Poultry Products Inspection Regulations, 381.1 and any migratory waterfowl,

game bird, ~~or squab such as~~ pheasant, partridge, quail, grouse, ~~or guineas,~~ or pigeon ~~or squab~~, whether live or dead, as defined in 9 CFR ~~Part 362~~ 362.1~~, Voluntary Poultry Inspection Regulations~~. ~~"Poultry" does not include ratites.~~

"Premises" means the physical facility, its contents, and the contiguous land or property under the control of the operator ~~or person in charge~~ or the physical facility, its contents, and the land or property not described above if its facilities and contents are under the control of the operator and may impact food establishment personnel, facilities, or operations, and a food establishment is only one component of a larger operation.

"Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.

"Priority item" means a provision in this chapter whose application contributes directly to the elimination, prevention, or reduction to an acceptable level of hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard. "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, and handwashing and is denoted in this chapter with a superscript P^{p}.

"Priority foundation item" means a provision in this chapter whose application supports, facilitates, or enables one or more priority items. "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment, or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or recordkeeping, and labeling and is denoted in this chapter with a superscript Pf^{Pf}.

[~~"Public water system" has the meaning stated in 40 CFR Part 141, National Primary Drinking Water Regulations.~~

"Private well" means any water well constructed for a person on land that is owned or leased by that person and is usually intended for household, groundwater source heat pump, agricultural use, industrial use, or other nonpublic water well.

"Pure water" means potable water fit for human consumption that is (i) sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii) adequate in quantity and quality for the minimum health requirements of the persons served. Potable water is traditionally known as drinking water and excludes such nonpotable forms as boiler water, mop water, rainwater, wastewater, and nondrinking water.]

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

"Ready-to-eat food" means food that:

1. (i) Is in a form that is edible without additional preparation to achieve food safety, as specified under ~~subsections A through C of~~ 2VAC5-585-700 ~~or~~ A, B, and C; 2VAC5-585-710; or 2VAC5-585-730; (ii) is a raw or partially cooked animal food and the consumer is advised as specified under ~~subdivisions D 1 and D 2 of~~ 2VAC5-585-700 D 1 and D 3; or (iii) is prepared in accordance with a variance that is granted as specified under ~~subdivisions D 1 and D 3 of~~ 2VAC5-585-700 D 4; and

2. May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

"Ready-to-eat food" includes:

1. Raw animal food that is cooked as specified under 2VAC5-585-700 or 2VAC5-585-710, or frozen as specified under 2VAC5-585-730;

2. Raw fruits and vegetables that are washed as specified under 2VAC5-585-510;

3. Fruits and vegetables that are cooked for hot holding~~,~~ as specified under 2VAC5-585-720;

4. All ~~potentially hazardous food~~ time/temperature control for safety food that is cooked to the temperature and time required for the specific food under Article 4 (2VAC5-585-700 et seq.) of Part III of this ~~regulation~~ chapter and cooled as specified in 2VAC5-585-800;

5. Plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present, are removed;

6. Substances derived from plants such as spices, seasonings, and sugar;

7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

8. The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

9. Food manufactured according to 21 CFR Part 113~~, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers~~.

"Reduced oxygen packaging" means (i) the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and (ii) a process as specified in clause (i) of this definition that involves a food for which the hazards Clostridium botulinum or Listeria monocytogenes require control in the final packaged form.

"Reduced oxygen packaging" includes:

1. Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package~~, such as sous vide~~;

2. Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

3. Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material;

4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens; or

5. Sous vide packaging, in which raw or partially cooked food is ~~placed in a hermetically sealed,~~ vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens.

"Refuse" means solid waste not carried by water through the sewage system.

"Regulatory authority" means local, state, or federal enforcement body or their authorized representative having jurisdiction over the food establishment.

"Reminder" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Reservice" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

"Restrict" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, ~~and~~ or unwrapped single-service or single-use articles.

"Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR Part 590.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 ~~(pesticides classified for restricted use)~~ and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

"Safe material" means an article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food; an additive that is used as specified in § 409 ~~or 706~~ of the Federal Food, Drug, and Cosmetic Act ~~(21 USC §§ 348 and 376)~~ (21 USC § 348); or other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned ~~food-contact~~ food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a 5-log reduction ~~of five logs~~, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that ~~permit~~ allow the entry or passage of moisture.

"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

"Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

"Shellstock" means raw, in-shell molluscan shellfish.

"Shiga toxin-producing Escherichia coli" ~~(STEC)~~ or "STEC" means any E. coli capable of producing Shiga toxins (also called ~~verocytotoxins or "Shiga-like" toxins)~~ verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild nonbloody diarrhea to hemorrhagic colitis (i.e., bloody diarrhea) to hemolytic uremic syndrome (HUS), which is a type of kidney failure. Examples of serotypes of STEC include ~~both O157 and non-O157 *E.coli*. Also see Enterohemorrhagic *Escherichia coli*.~~: E. coli O157:H7, E. coli O157:NM, E. coli O26:H11, E. coli O145:NM, E. coli O103:H2, and E. coli O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic E. coli) or as EHEC (enterohemorrhagic E. coli). EHEC are a subset of STEC that can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means molluscan shellfish that have one or both shells removed.

"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

"Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded. Single-use articles includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans that do not meet the materials, durability, strength, and cleanability specifications under 2VAC5-585-960, 2VAC5-585-1080, and 2VAC5-585-1100 for multiuse utensils.

"Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -10°F (-23°C) to 25°F (-4°C) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as ~~spinach~~ shrimp.

"Smooth" means a food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number three stainless steel; a nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and a floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

"Temporary food establishment" means a food establishment that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

"Time/temperature control for safety food" or "TCS" (formerly "potentially hazardous food") means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation:

1. Time/temperature control for safety food includes an animal food that is raw or heat treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and except as specified in subdivision 2 d of this definition, a food that because of the interaction of its A_w and pH values is designated as product assessment required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_w for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.

A_w values	pH values		
	4.6 or less	>4.6-5.6	>5.6
≤0.92	non-TCS food*	non-TCS food	non-TCS food
>0.92-0.95	non-TCS food	non-TCS food	PA**
>0.95	non-TCS food	PA	PA

*TCS means time/temperature control for safety food

**PA means product assessment required

Table B. Interaction of pH and A_w for control of vegetative cells and spores in food not heat treated or heat treated but not packaged.

A_w values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
<0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88-0.90	non-TCS food	non-TCS food	non-TCS food	PA**
>0.90-0.92	non-TCS food	non-TCS food	PA	PA
>0.92	non-TCS food	PA	PA	PA

*TCS means time/temperature control for safety food

**PA means product assessment required

2. Time/temperature control for safety food does not include:

a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard boiled, but has been pasteurized to destroy all viable salmonellae;

b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

c. A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-TCS food in Table A or B of this definition;

d. A food that is designated as PA in Table A or B of this definition and has undergone a product assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

(2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf-life and use, or temperature range of storage and use; or

(3) A combination of intrinsic and extrinsic factors; or

e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single service, or single use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices; and probe-type price or identification tags used in contact with food.

"Variance" means a written document issued by the department that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the department, a health hazard or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage ~~and servicing areas on the premises that are used in conjunction with the vending machines~~ areas and areas on the premises that are used to service and maintain the vending machines.

"Warewashing" means the cleaning and sanitizing of utensils and food-contact surfaces of equipment ~~and utensils~~.

["Waterworks" means a system that serves piped water for human consumption to at least 15 service connections or 25 or more individuals for at least 60 days out of the year. Waterworks includes all structures, equipment, and appurtenances used in the storage, collection, purification, treatment, and distribution of potable water except the piping and fixtures inside the building where such water is delivered.]

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Part II
Management and Personnel

Article 1
Supervision

2VAC5-585-50. Assignment ~~of responsibility~~.*

~~The~~ A. Except as specified in subsection B of this section, the operator shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the food establishment during all hours of operation.[Pf]

B. In a food establishment with two or more separately inspected departments that are the legal responsibility of the same operator and that are located on the same premises, the operator may, during specific time periods when food is not being prepared, packaged, or served, designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately inspected food establishment on the premises.[Pf]

[~~2VAC5-585-55. Certified food protection manager.~~

~~A. At least one employee who has supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.~~

~~B. This section does not apply to certain types of food establishments deemed by the~~ regulatory authority ~~to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of food preparation.~~

~~C. For purposes of enforcing this section, this requirement will take effect insert date 18 months after the effective date of this chapter.~~

~~2VAC5-585-57. Food protection manager certification.~~

~~A. A person in charge who demonstrates knowledge by being a food protection manager and is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection recognized accrediting agency as conforming to the Standards for~~

~~Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with subdivision 2 of 2VAC5-585-60.~~

~~B. A food establishment that has an employee who is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection recognized accrediting agency as conforming to the Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with 2VAC5-585-55.~~]

2VAC5-585-60. Demonstration.~~*~~

Based on the risks ~~of foodborne illness~~ inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the department knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of this ~~regulation~~ chapter. The person in charge shall demonstrate this knowledge by:

1. Complying with this ~~regulation~~ chapter by having no violations of priority items during the current inspection;[Pf]

2. Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program;[Pf] or

3. Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:

a. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;[Pf]

b. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;[Pf]

c. Describing the symptoms associated with the diseases that are transmissible through food;[Pf]

d. Explaining the significance of the relationship between maintaining the time and temperature of ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food and the prevention of foodborne illness;[Pf]

e. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;[Pf]

f. Stating the required food temperatures and times for safe cooking of ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food including meat, poultry, eggs, and fish;[Pf]

g. Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food;[Pf]

h. Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(1) Cross contamination;[Pf]

(2) Hand contact with ready-to-eat foods;[Pf]

(3) Handwashing;[Pf] and

(4) Maintaining the food establishment in a clean condition and in good repair;[Pf]

i. Describing ~~the~~ foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction;[Pf]

j. Explaining the relationship between food safety and providing equipment that is:

(1) Sufficient in number and capacity;[Pf] and

(2) Properly designed, constructed, located, installed, operated, maintained, and cleaned;[Pf]

k. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;[Pf]

l. Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;[Pf]

m. Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;[Pf]

n. Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this ~~regulation~~ chapter;[Pf]

o. Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law, this ~~regulation~~ chapter, or an agreement between the department and the food establishment;[Pf]

p. Explaining the responsibilities, rights, and authorities assigned by this ~~regulation~~ chapter to the:

(1) Food employee;[Pf]

(2) Conditional employee;[Pf]

(3) Person in charge;[Pf] and

~~(3)~~ (4) Department;[Pf] and

q. Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and the exclusion or restriction of food employees.[Pf]

[2VAC5-585-65. Certified food protection manager.

A. At least one employee who has supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

B. This section does not apply to certain types of food establishments deemed by the regulatory authority to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of food preparation.

C. For purposes of enforcing this section, this requirement will take effect July 1, 2018.

2VAC5-585-67. Food protection manager certification.

A. A person in charge who demonstrates knowledge by being a food protection manager and is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with subdivision 2 of 2VAC5-585-60.

B. A food establishment that has an employee who is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with 2VAC5-585-65.]

2VAC5-585-70. Duties of person in charge.

The person in charge shall ensure that:

1. Food establishment operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under 2VAC5-585-2990;[Pf]

2. Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination;[Pf]

3. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with this ~~regulation~~ chapter;[Pf]

4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;[Pf]

5. Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;[Pf]

6. Employees are verifying that foods delivered to the food establishment during nonoperating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented;[Pf]

7. Employees are properly cooking ~~potentially hazardous food~~ time/temperature control for safety food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under 2VAC5-585-1180 and 2VAC5-585-1730 B;[Pf]

~~7.~~ 8. Employees are using proper methods to rapidly cool ~~potentially hazardous foods~~ time/temperature control for safety foods that are not held hot or are not for consumption within four hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling;[Pf]

~~8.~~ 9. [Employees are properly maintaining the temperatures of time/temperature control for safety food during hot and cold holding through daily oversight of the employees' routine monitoring of food temperatures;[Pf]

10.] Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under 2VAC5-585-930 that the food is not cooked sufficiently to ensure its safety;[Pf]

~~9.~~ [~~10.~~ 11.] Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing;[Pf]

~~10.~~ [~~11.~~ 12.] Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets as specified under 2VAC5-585-590;[Pf]

~~11.~~ [~~12.~~ 13.] Except when ~~otherwise approved~~ approval is obtained from the department as specified in 2VAC5-585-450 ~~B~~ E, employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment;[Pf]

~~12.~~ [~~13.~~ 14.] Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; ~~and~~[Pf]

~~13.~~ [~~14.~~ 15.] Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge,

information about their health and activities as they relate to diseases that are transmissible through food, as specified under 2VAC5-585-80~~.~~ A;[Pf] and

[~~15.~~ 16.] Written procedures and plans where specified by this chapter and as developed by the food establishment are maintained and implemented as required.[Pf]

Article 2
Employee Health

2VAC5-585-80. Responsibility of ~~the~~ operator, person in charge, and conditional employees.~~*~~

A. The ~~person in charge~~ operator shall require food employees and conditional employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food. A food employee or conditional employee shall report the information in a manner that allows the person in charge to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the food employee or conditional employee:

1. Has any of the following symptoms:

a. Vomiting;[P]

b. Diarrhea;[P]

c. Jaundice;[P]

d. Sore throat with fever;[P] or

e. A lesion containing pus such as a boil or infected wound that is open or draining and is:

(1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;[P]

(2) On exposed portions of the arms, unless the lesion is protected by an impermeable cover;[P] or

(3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;[P]

2. Has an illness diagnosed by a health practitioner due to:

a. Norovirus;[P]

b. Hepatitis A virus;[P]

c. Shigella spp.;[P]

d. ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli; ~~or~~[P]

e. [~~Salmonella Typhi~~ Typhoid fever (caused by Salmonella typhi)];[P] or

f. [~~Nontyphoidal Salmonella~~ Salmonella (nontyphoidal)];[P]

3. Had [~~a previous illness~~ typhoid fever], diagnosed by a health practitioner, within the past three months due to Salmonella [~~Typhi~~ typhi], without having received antibiotic therapy, as determined by a health practitioner;[P]

4. Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the food employee or conditional employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:

a. Norovirus within the past 48 hours of the last exposure;[P]

b. ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days of the last exposure;[P]

c. [~~Salmonella Typhi~~ Typhoid fever] within the past 14 days of the last exposure;[P] or

d. Hepatitis A virus within the past 30 days of the last exposure;[P] or

5. Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about an individual who works or attends a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

a. Norovirus within the past 48 hours of the last exposure;[P]

b. ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli~~,~~ or Shigella spp. within the past three days of the last exposure;[P]

c. [~~Salmonella Typhi~~ Typhoid fever (caused by Salmonella typhi)] within the past 14 days of the last exposure;[P] or

d. Hepatitis A virus within the past 30 days of the last exposure.[P]

B. The person in charge shall notify the ~~regulatory authority~~ department when a food employee is:

1. Jaundiced;[Pf] or

2. Diagnosed with an illness due to a pathogen as specified under subdivisions A 2 a through ~~e~~ f of this section.[Pf]

C. The person in charge shall ensure that a conditional employee:

1. Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under subdivisions ~~A 2 a through e~~ A 1 through 3 of this section, is prohibited from becoming a food employee until the conditional employee meets the criteria for the specific symptoms or diagnosed illness as specified under 2VAC5-585-100;[P] and

2. Who will work as a food employee in a food establishment that serves a highly susceptible population and reports a history of exposure as specified under subdivisions A 4 and 5 of this section, is prohibited from becoming a food employee until the conditional employee meets the criteria specified under subdivision ~~9~~ 10 of 2VAC5-585-100.[P]

D. The person in charge shall ensure that a food employee who exhibits or reports a symptom, or who reports a

diagnosed illness or a history of exposure as specified under ~~subdivision~~ subsection A ~~1 through 5~~ of this section is:

1. Excluded as specified under subdivisions 1 through 3 and 4 a, 5 a, 6 a, ~~or~~ 7, or 8 a of 2VAC5-585-90 and in compliance with the provisions specified under subdivisions 1 through ~~7~~ 8 of 2VAC5-585-100;[P] or

2. Restricted as specified under ~~subdivisions~~ subdivision 4 b, 5 b, 6 b, ~~7 b,~~ 8 b, ~~or~~ 9, or 10 of 2VAC5-585-90 and in compliance with the provisions specified under subdivisions 4 through ~~9~~ 10 of 2VAC5-585-100.[P]

E. A food employee or conditional employee shall report to the person in charge the information as specified under subsection A of this section.[Pf]

F. A food employee shall:

1. Comply with an exclusion as specified under subdivisions 1 through 3 and 4 a, 5 a, 6 a, ~~or~~ 7, or 8 a of 2VAC5-585-90, and with the provisions specified under subdivisions 1 through ~~7~~ 8 of 2VAC5-585-100;[P] or

2. Comply with a restriction ~~as~~ specified under ~~subdivisons~~ subdivision 4 b, 5 b, 6 b, 7 ~~b~~, or 8~~, or 9~~ b of 2VAC5-585-90 or under subdivision 8, 9, or 10 of 2VAC5-585-90 and comply with the provisions specified under ~~subdivisons~~ subdivisions 4 through ~~9~~ 10 of 2VAC5-585-100.[P]

2VAC5-585-90. Exclusions and restrictions.~~*~~

The person in charge shall exclude or restrict a food employee from a food establishment in accordance with the following:

1. Except when the symptom is from a noninfectious condition, exclude a food employee if the food employee is:

a. Symptomatic with vomiting or diarrhea;[P] or

b. Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, Shigella spp., ~~or Enterohemorrhagic~~ [~~nontyphoidal~~] Salmonella [(nontyphoidal)], or ~~Shiga toxin-producing Escherichia~~ Shiga toxin-producing E. coli.[P]

2. Exclude a food employee who is:

a. Jaundiced and the onset of jaundice occurred within the last seven calendar days, unless the food employee provides to the person in charge written medical documentation from a health practitioner specifying that the jaundice is not caused by Hepatitis A virus or other fecal-orally transmitted infection;[P]

b. Diagnosed with an infection from Hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within seven calendar days of the onset of jaundice;[P] or

c. Diagnosed with an infection from Hepatitis A virus without developing symptoms.[P]

3. Exclude a food employee who is diagnosed with [~~an infection from Salmonella Typhi~~ typhoid fever], or reports [~~a previous infection with Salmonella Typhi~~ having had typhoid fever] within the past three months as specified in 2VAC5-585-80 A 3.[P]

4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

5. If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

6. If a food employee is diagnosed with an infection from ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing E. coli, and is asymptomatic:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

7. If a food employee is diagnosed with an infection from [~~nontyphoidal~~] Salmonella [(nontyphoidal)] and is asymptomatic, restrict the food employee who works in a food establishment serving a highly susceptible population or in a food establishment not serving a highly susceptible population.[P]

~~7.~~ 8. If a food employee is ill with symptoms of acute onset of sore throat with fever:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

~~8.~~ 9. If a food employee is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under 2VAC5-585-80 A 1 e, restrict the food employee.[P]

~~9.~~ 10. If a food employee is exposed to a foodborne pathogen as specified under 2VAC5-585-80 A 4 or 5, restrict the food employee who works in a food establishment serving a highly susceptible population.[P]

2VAC5-585-100. Removal of exclusions and restrictions.

The person in charge shall adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee:

1. Except when a food employee is diagnosed with [typhoid fever or] an infection from Hepatitis A virus [~~or Salmonella Typhi~~]:

a. Reinstate a food employee who was excluded as specified under subdivision 1 a of 2VAC5-585-90 if the food employee:

(1) Is asymptomatic for at least 24 hours;[P] or

(2) Provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition.[P]

b. If a food employee was diagnosed with an infection from Norovirus and excluded as specified under subdivision 1 b of 2VAC5-585-90 ~~1 b~~:

(1) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population until the conditions for reinstatement as specified in subdivision 4 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 4 a or b of this section are met.[P]

c. If a food employee was diagnosed with an infection from Shigella spp. and excluded as specified under subdivision 1 b of 2VAC5-585-90:

(1) Restrict the food employee, who is asymptomatic, for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in subdivision 5 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in (i) subdivision 5 a or 5 b of this section, or ~~5 a and c (1)~~ (ii) subdivisions 1 c (1) and 5 a of this section are met.[P]

d. If a food employee was diagnosed with an infection from ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli and excluded as specified under subdivision 1 b of 2VAC5-585-90:

(1) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in subdivision 6 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 6 a or b are met.[P]

e. If a food employee was diagnosed with an infection from [~~nontyphoidal~~] Salmonella [(nontyphoidal)] and excluded as specified in subdivision 1 b of 2VAC5-585-90:

(1) Restrict the food employee, who is asymptomatic, for at least 30 days until conditions for reinstatement as specified in subdivision 7 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is symptomatic, until conditions for reinstatement as specified in subdivision 7 a or b of this section are met.[P]

2. Reinstate a food employee who was excluded as specified under subdivision 2 of 2VAC5-585-90 if the person in charge obtains approval from the ~~regulatory authority~~ department and one of the following conditions is met:

a. The food employee has been jaundiced for more than seven calendar days;[P]

b. The anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days;[P] or

c. The food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Hepatitis A virus infection.[P]

3. Reinstate a food employee who was excluded as specified under subdivision 3 of 2VAC5-585-90 if:

a. The person in charge obtains approval from the ~~regulatory authority~~ department;[P] and

b. The food employee provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from ~~S.~~ [~~Salmonella Typhi infection~~ typhoid fever].[P]

4. Reinstate a food employee who was excluded as specified under subdivision 1 b or 4 a of 2VAC5-585-90, who was restricted under subdivision 4 b of 2VAC5-585-90 if the person in charge obtains approval from the ~~regulatory authority~~ department and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection;[P]

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the food employee became ~~symptomatic~~ asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed.[P]

5. Reinstate a food employee who was excluded as specified under subdivision 1 b or 5 a of 2VAC5-585-90 or who was restricted under subdivision 5 b of 2VAC5-585-90 if the person in charge obtains approval from the ~~regulatory authority~~ department and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Shigella spp. infection based on test results showing two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics;[P] and

(2) At least 24 hours apart;[P]

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than seven calendar days have passed since the food employee became asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than seven calendar days have passed since the food employee was diagnosed.[P]

6. Reinstate a food employee who was excluded or restricted as specified under subdivision 1 b or 6 a of 2VAC5-585-90 or who was restricted under subdivision 6 b of 2VAC5-585-90 if the person in charge obtains approval from the ~~regulatory authority~~ department and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from ~~Enterohemorrhagic or Shiga-toxin producing~~ Shiga toxin-producing Escherichia coli based on test results that show two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after the discontinuance of antibiotics;[P] and

(2) At least 24 hours apart;[P]

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than seven calendar days have passed since the food employee became asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than seven days have passed since the food employee was diagnosed.[P]

7. Reinstate a food employee who was excluded as specified under subdivision 1 b of 2VAC5-585-90 or who was restricted under subdivision 7 of 2VAC5-585-90 if the person in charge obtains approval from the department[P] and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a [~~nontyphoidal~~] Salmonella [(nontyphoidal)] infection based on test results showing two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics,[P] and

(2) At least 24 hours apart;[P]

b. The food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the food employee became asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than 30 days have passed since the food employee was diagnosed.[P]

~~7.~~ 8. Reinstate a food employee who was excluded or restricted as specified under subdivision ~~7~~ 8 a or b of 2VAC5-585-90 if the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

a. Has received antibiotic therapy for Streptococcus pyogenes infection for more than 24 hours;[P]

b. Has at least one negative throat specimen culture for Streptococcus pyogenes infection;[P] or

c. Is otherwise determined by a health practitioner to be free of Streptococcus pyogenes infection.[P]

~~8.~~ 9. Reinstate a food employee who was restricted as specified under subdivision ~~8~~ 9 of 2VAC5-585-90 if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

a. An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;[P]

b. An impermeable cover on the arm if the infected wound or pustular boil is on the arm;[P] or

c. A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.[P]

~~9.~~ 10. Reinstate a food employee who was restricted as specified under subdivision ~~9~~ 10 of 2VAC5-585-90 and was exposed to one of the following pathogens as specified under 2VAC5-585-80 A 4 or 5:

a. Norovirus and one of the following conditions is met:

(1) More than 48 hours have passed since the last day the food employee was potentially exposed;[P] or

(2) More than 48 hours have passed since the food employee's household contact became asymptomatic.[P]

b. Shigella spp. or ~~Enterohemorrhagic or Shiga toxin producing~~ Shiga toxin-producing Escherichia coli and one of the following conditions is met:

(1) More than three calendar days have passed since the last day the food employee was potentially exposed;[P] or

(2) More than three calendar days have passed since the food employee's household contact became asymptomatic.[P]

c. ~~S.~~ [~~Salmonella Typhi~~ typhoid fever (caused by Salmonella typhi)] and one of the following conditions is met:

(1) More than 14 calendar days have passed since the last day the food employee was potentially exposed;[P] or

(2) More than 14 calendar days have passed since the food employee's household contact became asymptomatic.[P]

d. Hepatitis A virus and one of the following conditions is met:

(1) The food employee is immune to Hepatitis A virus infection because of prior illness from Hepatitis A;[P]

(2) The food employee is immune to Hepatitis A virus infection because of vaccination against Hepatitis A;[P]

(3) The food employee is immune to Hepatitis A virus infection because of IgG administration;[P]

(4) More than 30 calendar days have passed since the last day the food employee was potentially exposed;[P]

(5) More than 30 calendar days have passed since the food employee's household contact became jaundiced;[P] or

(6) The food employee does not use an alternative procedure that allows bare hand contact with ready-to-eat food until at least 30 days after the potential exposure, as specified in subdivision ~~9~~ 10 d (4) and (5) of this section, and the food employee receives additional training about:

(a) Hepatitis A symptoms and preventing the transmission of infection;[P]

(b) Proper handwashing procedures;[P] and

(c) Protecting ready-to-eat food from contamination introduced by bare hand contact.[P]

[~~2VAC5-585-125. Clean-up of vomiting and diarrheal events.~~

~~A food establishment shall have procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment.~~

~~The procedures shall address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.~~[Pf]]

Article 3
Personal Cleanliness

2VAC5-585-130. Clean condition of hands and arms.~~*~~

Food employees shall keep their hands and exposed portions of their arms clean.[P]

2VAC5-585-140. Cleaning procedure of hands and arms.~~*~~

A. Except as specified in subsection D of this section, food employees shall clean their hands and exposed portions of their arms ~~(or~~, including surrogate prosthetic devices for hands or ~~arms)~~ arms for at least 20 seconds, using a cleaning compound in a ~~lavatory~~ handwashing sink that is equipped as specified under 2VAC5-585-2190 and 2VAC5-585-3020 through 2VAC5-585-3045.[P]

B. Food employees shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

1. Rinse under clean, running warm water;[P]

2. Apply an amount of cleaning compound recommended by the cleaning compound manufacturer;[P]

3. Rub together vigorously for at least 10 to 15 seconds while:

a. Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure;[P] and

b. Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;[P]

4. Thoroughly rinsing under clean, running warm water;[P] and

5. Immediately follow the cleaning procedure with thorough drying using a method as specified under 2VAC5-585-3030.[P]

C. To avoid recontaminating their hands or surrogate prosthetic devices, food employees may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a handwashing sink or the handle of a restroom door.

D. If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands or surrogate prosthetic devices.

2VAC5-585-160. When to wash.~~*~~

Food employees shall clean their hands and exposed portions of their arms as specified under 2VAC5-585-140 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles[P] and:

1. After touching bare human body parts ~~or hair~~ other than clean hands and clean, exposed portions of arms;[P]

2. After using the toilet room;[P]

3. After caring for or handling ~~support~~ service animals or aquatic animals as allowed under 2VAC5-585-250 B;[P]

4. Except as specified in 2VAC5-585-220 B, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;[P]

5. After handling soiled equipment or utensils;[P]

6. During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;[P]

7. When switching between working with raw ~~foods~~ food and working with ready-to-eat ~~foods~~ food;[P]

8. Before donning gloves ~~for~~ to initiate a task that involves working with food;[P] and

9. ~~Prior to donning single-use gloves if gloves are used; and~~

~~10.~~ After engaging in other activities that contaminate the hands.[P]

2VAC5-585-170. Where to wash.

Food employees shall clean their hands in a ~~hand washing lavatory~~ handwashing sink or approved automatic ~~hand washing~~ handwashing facility and may not clean their hands in a sink used for food preparation or warewashing, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.[Pf]

2VAC5-585-180. Hand antiseptics.

A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

1. Comply with one of the following:

a. Be an approved drug that is listed in the ~~FDA publication~~ "Approved Drug Products with Therapeutic Equivalence Evaluations, 34th Edition," 2014, (U.S. Food and Drug Administration) as an approved drug based on safety and effectiveness;[Pf] or

b. Have active antimicrobial ingredients that are listed in the FDA tentative final monograph for over the counter (OTC) Health-Care Antiseptic Drug Products, 59 FR 31402-31452 (June 17, 1994) as an antiseptic handwash;[Pf] and

2. ~~Comply~~ Consist only of components that the intended use of each complies with one of the following:

a. ~~Have components that are exempted from the requirement of being listed in the federal Food Additive regulations as specified in~~ A threshold of regulation exemption under 21 CFR 170.39 ~~Threshold of regulation for substances used in food contact articles~~; ~~or~~[Pf]

~~b. Comply with and be listed in:~~

~~(1) 21 CFR Part 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use; or~~

~~(2) 21 CFR Part 182, Substances Generally Recognized as Safe; 21 CFR Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe; or 21 CFR Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food; and~~

b. 21 CFR Part 178, as regulated for use as a food additive with conditions of safe use;[Pf]

c. A determination of generally recognized as safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in 21 CFR Part 182, 21 CFR Part 184, or 21 CFR Part 186; and in FDA's Inventory of GRAS Notices;[Pf]

d. A prior sanction listed under 21 CFR Part 181;[Pf] or

e. A food contact notification that is effective;[Pf] and

3. Be applied only to hands that are cleaned as specified under 2VAC5-585-140.[Pf]

B. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under subdivision A 2 of this section, use shall be:

1. Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves;[Pf] or

2. Limited to situations that involve no direct contact with food by the bare hands.[Pf]

C. A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 ~~ppm (mg/l)~~ mg/l (ppm) chlorine ~~or above~~.[Pf]

2VAC5-585-190. Maintenance of fingernails.

A. Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.[Pf]

B. Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial nails when working with exposed food.[Pf]

2VAC5-585-200. Prohibition of jewelry.

~~While preparing food, food employees may not wear jewelry including medical information jewelry on their arms and hands. This section does not apply to a plain ring such as a wedding band.~~ Except for a plain ring such as a wedding band, while preparing food, food employees may not wear jewelry, including medical information jewelry, on their arms and hands.

Article 4
Hygienic Practices

2VAC5-585-220. Eating, drinking, or using tobacco.~~*~~

A. Except as specified in subsection B of this section, an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

B. A food employee may drink from a closed beverage container ~~with a straw~~ if the container is handled to prevent contamination of:

1. The employee's hands;

2. The container; and

3. Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

2VAC5-585-230. Discharges from the eyes, nose, and mouth.~~*~~

Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

2VAC5-585-250. Handling of animals prohibited.~~*~~

A. Except as specified in subsection B of this section, food employees may not care for or handle animals that may be present such as patrol dogs, ~~support~~ service animals, or pets that are allowed ~~in~~ as specified in subdivisions B 2 through B [~~5~~ 6] of 2VAC5-585-3310.[Pf]

B. Food employees with ~~support~~ service animals may handle or care for their ~~support~~ service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under 2VAC5-585-140 and subdivision 3 of 2VAC5-585-160.

[2VAC5-585-255. Clean-up of vomiting and diarrheal events.

A. A food establishment shall have procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment.[Pf]

B. The procedures shall address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.[Pf]]

Part III
Food

Article 1
Characteristics

2VAC5-585-260. Safe, unadulterated, and honestly presented.~~*~~

Food shall be safe, unadulterated, and, as specified under 2VAC5-585-890, honestly presented.[P]

Article 2
Sources, Specifications, and Original Containers and Records

2VAC5-585-270. Compliance with food law.~~*~~

A. Food shall be obtained from sources that comply with law.[P]

B. Food prepared in a private home may not be used or offered for human consumption in a food establishment unless the home kitchen is inspected ~~by the responsible~~ and regulated by the food regulatory authority that has jurisdiction over the private home.[P]

C. Packaged food shall be labeled as specified in law, including 21 CFR Part 101~~, Food Labeling~~; 9 CFR Part 317~~, Labeling, Marking Devices, and Containers~~; and 9 CFR Part 381, Subpart N~~, Labeling and Containers~~; and as specified under 2VAC5-585-400 and 2VAC5-585-410.[Pf]

~~D. Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified in 2VAC5-585-700 D 1 may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 2VAC5-585-730, or frozen on the premises as specified under 2VAC5-585-730, and records are retained as specified under 2VAC5-585-740.~~

D. Fish, other than those specified in 2VAC5-585-730 B, that are intended for consumption in raw or undercooked form and allowed as specified in 2VAC5-585-700 D, may be offered for sale or service if they are obtained from a supplier that freezes fish as specified under 2VAC5-585-730 A, or if they are frozen on the premises as specified under 2VAC5-585-730 A and records are retained as specified under 2VAC5-585-740.

E. Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 2VAC5-585-700 C shall be:

1. Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them to indicate that ~~they~~ the steaks meet the definition of whole-muscle, intact beef;[Pf] or

2. Deemed acceptable by the department based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef;[Pf] and

3. If individually cut in a food establishment:

a. Cut from whole-muscle, intact beef that is labeled by a food processing plant as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection;[Pf]

b. Prepared so they remain intact;[Pf] and

c. If packaged for undercooking in a food establishment, labeled ~~to indicate that they meet the definition of whole-muscle, intact beef~~ as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection.[Pf]

F. Meat and poultry that are not ~~a~~ ready-to-eat ~~food~~ foods and are in a packaged form when offered for sale or otherwise offered for consumption shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

G. ~~Shell eggs~~ Eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled to include safe

handling instructions as specified in law, including 21 CFR 101.17(h).

2VAC5-585-280. Food in a hermetically sealed container.~~*~~

Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.[P]

2VAC5-585-290. Fluid milk and milk products.~~*~~

Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law.[P]

2VAC5-585-295. Juice treated.

~~Pre-packaged~~ Prepackaged juice shall:

1. Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120;[Pf] and

2. Be obtained pasteurized or otherwise treated to attain a 5-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR 120.24~~; or~~.[P]

~~3. Bear a warning label as specified in 21 CFR 101.17(g).~~

2VAC5-585-300. Fish.~~*~~

A. Fish that are received for sale or service shall be:

1. Commercially and legally caught or harvested;[P] or

2. Approved for sale or service by a regulatory authority.[P]

B. Molluscan shellfish that are recreationally caught may not be received for sale or service.[P]

2VAC5-585-310. Molluscan shellfish.~~*~~

A. Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the ~~U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration,~~ National Shellfish Sanitation Program ~~Manual of Operations, Part II, Sanitation of the Harvesting, Processing and Distribution of Shellfish, 1995 Revision~~ (NSSP) Guide for the Control of Molluscan Shellfish, [~~2011~~ 2013] Revision, (U.S. Food and Drug Administration).[P]

B. Molluscan shellfish [~~received in interstate commerce~~] shall be from sources that are listed in the "Interstate Certified Shellfish Shippers List," updated monthly (U.S. Food and Drug Administration).[P]

2VAC5-585-320. Wild mushrooms.~~*~~

A. Except as specified in subsection B of this section, mushroom species picked in the wild shall ~~be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert~~ not be offered for sale or service by a food establishment unless the food establishment has been approved to do so.[P]

B. This section does not apply to:

1. Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or

2. Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

2VAC5-585-330. Game animals.~~*~~

A. If game animals are received for sale or service they shall be:

1. Commercially raised for food and~~: a. Raised~~ raised, slaughtered, and processed under a voluntary inspection program that is conducted by the state agency that has animal health jurisdiction~~;~~ or

~~b. Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction; and~~

~~c. Raised, slaughtered, and processed according to:~~

~~(1) Laws governing meat and poultry as determined by the agency; and~~

~~(2) Requirements that are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;~~

~~2. Under~~ under a voluntary inspection program administered by the USDA for game animals such as exotic animals ~~including animals~~ (i.e., reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR Part 352~~, Exotic Animals; Voluntary Inspection~~, or rabbits that are "inspected and certified" in accordance with 9 CFR Part 354~~, Voluntary Inspection of Rabbits and Edible Products Thereof~~;[P]

~~3.~~ 2. As allowed by law, for wild game animals that are live-caught:

a. Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction;[P]

b. Slaughtered and processed according to:

(1) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program;[P] and

(2) Requirements that are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;[P] or

~~4.~~ 3. As allowed by law for field-dressed wild game animals under a routine inspection program that ensures the animals:

a. Receive a postmortem examination by an approved veterinarian or veterinarian's designee~~, or are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program~~; ~~and~~[P]

b. Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program;[P] and

c. Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.[P]

B. A game animal may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR Part 17~~, Endangered and Threatened Wildlife and Plants~~.

2VAC5-585-340. Temperature.~~*~~

A. Except as specified in subsection B of this section, refrigerated, ~~potentially hazardous~~ time/temperature control for safety food shall be at a temperature of 41°F (5°C) or below when received.[P]

B. If a temperature other than 41°F (5°C) for a ~~potentially hazardous~~ time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk~~,~~ and molluscan shellfish, ~~and shell eggs,~~ the food may be received at the specified temperature.

C. Raw ~~shell~~ eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.[P]

D. ~~Potentially hazardous~~ Time/temperature control for safety food that is cooked to a temperature and for a time specified under 2VAC5-585-700 through 2VAC5-585-720 and received hot shall be at a temperature of 135°F (57°C) or above.[P]

E. A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.[Pf]

F. Upon receipt, ~~potentially hazardous~~ time/temperature control for safety food shall be free of evidence of previous temperature abuse.[Pf]

2VAC5-585-350. Additives.~~*~~

Food may not contain unapproved food additives or additives that exceed amounts ~~allowed~~ specified in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe or prior sanctioned substances that exceed amounts ~~allowed~~ specified in 21 CFR Parts 181-186; substances that exceed amounts specified in 9 CFR~~, Subpart C,~~ 424.21(b)~~, Approval of Substances for Use in the Preparation of Products~~; or pesticide residues that exceed provisions specified in 40 CFR Part ~~185, Tolerances for Pesticides in Food.~~ 180.[P]

2VAC5-585-360. ~~Shell eggs~~ Eggs.~~*~~

~~Shell eggs~~ Eggs shall be received clean and sound and [~~may~~ shall] not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56, effective July 20, 2000, ~~AMS 56.200 et seq., administered by the~~ (Agricultural Marketing Service of USDA).[P] [Eggs sold pursuant to § 3.2-5305 of the Code of Virginia are exempt from the restricted egg tolerances for U.S. Consumer Grade B as specified in the United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56, effective July 20, 2000, (Agricultural Marketing Service of USDA).]

2VAC5-585-370. Eggs and milk products, pasteurized.~~*~~

A. Egg products shall be obtained pasteurized.[P]

B. Fluid and dry milk and milk products shall:

1. Be obtained pasteurized;[P] and

2. Comply with Grade A standards as specified in law.[P]

C. Frozen milk products, such as ice cream, shall be obtained pasteurized ~~in accordance with~~ as specified in 21 CFR Part 135~~, Frozen Desserts~~.[P]

D. Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are ~~provided for in the Code of Federal Regulations,~~ specified in the CFR, such as 21 CFR Part 133~~, Cheeses and Related Cheese Products,~~ for curing certain cheese varieties.[P]

2VAC5-585-380. Package integrity.~~*~~

Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.[Pf]

2VAC5-585-390. Ice.~~*~~

Ice for use as a food or a cooling medium shall be made from drinking water.[P]

2VAC5-585-400. Shucked shellfish, packaging and identification.

A. Raw shucked shellfish shall be obtained in nonreturnable packages that bear a legible label that identifies the:[Pf]

1. Name, address, and certification number of the shucker, packer, or repacker of the molluscan shellfish;[Pf] and

2. The "sell by" or "best if used by" date for packages with a capacity of less than one-half gallon ~~(1.87 L)~~ (1.89 L) or the date shucked for packages with a capacity of one-half gallon ~~(1.87 L)~~ (1.89 L) or more.[Pf]

B. A package of raw shucked shellfish that does not bear a label or ~~which~~ that bears a label that does not contain all the information as specified under subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR 1240.60(d)~~, Subpart D, Specific Administrative Decisions Regarding Interstate Shipments~~.

2VAC5-585-410. Shellstock identification.~~*~~

A. Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the ~~harvester and each~~ dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish ~~(2007),~~ [~~2011~~ 2013] Revision, (U.S. Food and Drug Administration) and that list~~:~~ on each dealer's tag or label the following information in the following order:[Pf]

~~1. Except as specified under subsection C of this section, on the harvester's tag or label, the following information in the following order:~~

~~a. The harvester's identification number that is assigned by the shellfish control authority;~~

~~b. The date of harvesting;~~

~~c. The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested;~~

~~d. The type and quantity of shellfish; and~~

~~e. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; and~~

~~2. Except as specified under subsection D of this section, on each dealer's tag or label, the following information in the following order:~~

~~a.~~ 1. The dealer's name and address, and the certification number assigned by the shellfish control authority;[Pf]

~~b.~~ 2. The original shipper's certification number [~~including the abbreviation of the name of the state or country in which the shellfish are harvested~~];[Pf]

~~c. The same information as specified for a harvester's tag under subdivisions 1 b through d of this subsection; and~~ 3. The harvest date, or if depurated, the date of depuration processing, or if wet stored, the original harvest date and the final harvest date [~~, which is the date removed from wet storage~~];[Pf]

4. If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w";[Pf]

5. The harvest area including the initials of the state of harvest;[Pf]

6. The type and quantity of shellstock;[Pf]

~~d.~~ 7. The following statement in bold, capitalized type: ~~"~~ "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS";[Pf] and

8. A consumer advisory as specified in 2VAC5-585-930.

B. A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR 1240.60(d)~~, Subpart D, Specific Administrative Decisions Regarding Interstate Shipments~~ and § 28.2-801 of the Code of Virginia.

~~C. If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.~~

~~D. If the harvester's tag or label is designed to accommodate each dealer's identification as specified under subdivisions A 2 a and b of this section, individual dealer tags or labels need not be provided.~~

2VAC5-585-430. Molluscan shellfish; original container.

A. Except as specified in subsections B ~~and C~~ through D of this section, molluscan shellfish may not be removed from the container in which they ~~were~~ are received other than immediately before sale or preparation for service.

B. For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

1. The source of the shellstock on display is identified as specified under 2VAC5-585-410 and recorded as specified under 2VAC5-585-440; and

2. The shellstock are protected from contamination.

C. Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

1. The labeling information for the shellfish on display as specified under 2VAC5-585-400 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

2. The shellfish are protected from contamination.

D. Shucked shellfish may be removed from the container in which they were received and repacked in consumer self-service containers where allowed by law if:

1. The labeling information for the shellfish is on each consumer self-service container as specified under 2VAC5-585-400 and 2VAC5-585-900 A and B 1 through 5;

2. The labeling information as specified under 2VAC5-585-400 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

3. The labeling information and dates specified under subdivision 2 of this subsection are maintained for 90 days; and

4. The shellfish are protected from contamination.

2VAC5-585-440. Shellstock; maintaining identification.*~~*~~

A. Except as specified under subdivision C 2 of this section, shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty.Pf

B. The date when the last shellstock from the container is sold or served shall be recorded on the tag or label.Pf

C. The identity of the source of ~~shellfish~~ shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label as specified in subsection B of this section by:Pf

1. Using an approved recordkeeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under subsection B of this section;Pf and

2. If shellstock are removed from its tagged or labeled container:

a. Preserving source identification by using a recordkeeping system as specified under subdivision 1 of this subsection;Pf and

b. Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the consumer.Pf

Article 3
Protection from Contamination after Receiving

2VAC5-585-450. Preventing contamination from hands.*~~*~~

A. Food employees shall wash their hands as specified under 2VAC5-585-140.

B. Except when washing fruits and vegetables as specified under 2VAC5-585-510 or as specified in ~~subsection C~~ subsections D and E of this section, food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.P

C. Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.S Pf

D. Subsection B of this section does not apply to a food employee who contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to food that:

1. Contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the minimum temperatures specified in 2VAC5-585-700 A and B or 2VAC5-585-710; or

2. Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 145°F (63°C).

E. Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if:

1. The operator obtains prior approval from the ~~regulatory authority~~ department;

2. Written procedures are maintained in the food establishment and made available to the ~~regulatory authority~~ department upon request that include:

a. For each bare hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands; and

b. Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under 2VAC5-585-2230, 2VAC5-585-2280, 2VAC5-585-2310, 2VAC5-585-3020, 2VAC5-585-3030, and 2VAC5-585-3045, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

3. A written employee health policy that details how the food establishment complies with 2VAC5-585-80, 2VAC5-585-90, and 2VAC5-585-100 including:

a. Documentation that the food employees and conditional employees acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food as specified under 2VAC5-585-80 A;

b. Documentation that food employees and conditional employees acknowledge their responsibilities as specified under 2VAC5-585-80 E and F; and

c. Documentation that the person in charge acknowledges the responsibilities as specified under 2VAC5-585-80 B, C, and D, 2VAC5-585-90, and 2VAC5-585-100;

4. Documentation that the food employees acknowledge that they have received training in:

a. The risks of contacting the specific ready-to-eat foods with their bare hands,

b. Proper handwashing as specified under 2VAC5-585-140,

c. When to wash their hands as specified under 2VAC5-585-160,

d. Where to wash their hands as specified under 2VAC5-585-170,

e. Proper fingernail maintenance as specified under 2VAC5-585-190,

f. Prohibition of jewelry as specified under 2VAC5-585-200, and

g. Good hygienic practices as specified under 2VAC5-585-220 and 2VAC5-585-230;

5. Documentation that hands are washed before food preparation and as necessary to prevent cross-contamination by food employees as specified under 2VAC5-585-130, 2VAC5-585-140, 2VAC5-585-160, and 2VAC5-585-170 during all hours of operation when the specific ready-to-eat foods are prepared;

6. Documentation that food employees contacting ready-to-eat food with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:

a. Double handwashing,

b. Nail brushes,

c. A hand antiseptic after handwashing as specified under 2VAC5-585-180,

d. Incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill, or

e. Other control measures approved by the ~~regulatory authority~~ department; and

7. Documentation that corrective action is taken when subdivisions 1 through 6 of this subsection are not followed.

2VAC5-585-460. Preventing contamination when tasting.~~*~~

A food employee may not use a utensil more than once to taste food that is to be sold or served.[P]

2VAC5-585-470. Packaged and unpackaged food - separation, packaging, and segregation.~~*~~

A. Food shall be protected from cross contamination by:

1. ~~Separating~~ Except as specified in subdivision 1 c of this subsection, separating raw animal foods during storage, preparation, holding, and display from:

a. Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as fruits and vegetables; ~~and~~[P]

b. Cooked ready-to-eat food;[P] and

c. Frozen, commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food;

2. Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

a. Using separate equipment for each type ~~or arranging each type of food in equipment so that cross contamination of one type with another is prevented~~; ~~and~~ [P]

b. Arranging each type of food in equipment so that cross contamination of one type with another is prevented;[P] and

c. Preparing each type of food at different times or in separate areas;[P]

3. Cleaning equipment and utensils as specified under 2VAC5-585-1780 A and sanitizing as specified under 2VAC5-585-1900;

4. Except as specified in subdivision B 2 of 2VAC5-585-810 and subsection B of this section, storing the food in packages, covered containers, or wrappings;

5. Cleaning hermetically sealed containers of food of visible soil before opening;

6. Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

7. Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 2VAC5-585-3150; and

8. Separating fruits and vegetables before they are washed as specified under 2VAC5-585-510 from ready-to-eat food.

B. Subdivision A 4 of this section does not apply to:

1. Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;

2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;

3. Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;

4. Food being cooled as specified under 2VAC5-585-810 B 2; or

5. Shellstock.

2VAC5-585-480. Food storage containers; identified with common name of food.

~~Working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar, shall be identified with the common name of the food (in English and the common language of the food workers) except that containers holding food that can be readily and unmistakably recognized such as dry pasta need not be identified.~~ Except for containers holding food that can be readily and unmistakably recognized, such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar, shall be identified with the common name of the food.

2VAC5-585-490. Pasteurized eggs; substitute for raw ~~shell~~ eggs for certain recipes and populations.~~*~~

Pasteurized eggs or egg products shall be substituted for raw ~~shell~~ eggs in the preparation of foods such as Caesar salad,

hollandaise or béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages that are not:[P]

1. Cooked as specified under ~~subdivisions~~ subdivision A 1 or 2 of 2VAC5-585-700;[P] or

2. Included in 2VAC5-585-700 D.[P]

2VAC5-585-500. Protection from unapproved additives.~~*~~

A. Food shall be protected from contamination that may result from the addition of, as specified in 2VAC5-585-350:

1. Unsafe or unapproved food or color additives;[P] and

2. Unsafe or unapproved levels of approved food and color additives.[P]

B. A food employee may not:

1. Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin ~~B1~~ B_1;[P] or

2. Except for grapes, serve or sell food specified in subdivision 1 of this subsection that is treated with sulfiting agents before receipt by the food establishment.[P]

2VAC5-585-510. Washing fruits and vegetables.

A. ~~Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form except as specified in subsection B of this section and except that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.~~ Except as specified in subsection B of this section and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.

B. Fruits and vegetables may be washed by using chemicals as specified under 2VAC5-585-3390.

C. Devices used for onsite generation of chemicals meeting the requirements specified in 21 CFR 173.315 for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer's instructions.[Pf]

2VAC5-585-520. Ice used as exterior coolant prohibited as ingredient.

After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice may not be used as food.[P]

2VAC5-585-530. Storage or display of food in contact with water or ice.

A. Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

B. Except as specified in subsections C and D of this section, unpackaged food may not be stored in direct contact with undrained ice.

C. Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

D. Raw ~~chicken~~ poultry and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.

2VAC5-585-540. Food contact with equipment and utensils.~~*~~

Food shall only contact surfaces of:

1. Equipment and utensils that are cleaned as specified under 2VAC5-585-1770 through ~~2VAC5-595-1870~~ 2VAC5-585-1860 and sanitized as specified under ~~2VAC5-585-1890~~ 2VAC5-585-1885 through 2VAC5-585-1900; ~~or~~[P]

2. Single-service and single-use articles; or [P]

3. Linens, such as cloth napkins, as specified under 2VAC5-585-560, that are laundered as specified under 2VAC5-585-1910 through 2VAC5-585-1950.[P]

2VAC5-585-550. In-use utensils, between-use storage.

During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

1. Except as specified under subdivision 2 of this section, in the food with their handles above the top of the food and the container;

2. In food that is not ~~potentially hazardous~~ time/temperature control for safety food with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

3. On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 2VAC5-585-1780 and 2VAC5-585-1890;

4. In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

5. In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not ~~potentially hazardous~~ time/temperature control for safety food; or

6. In a container of water if the water is maintained at a temperature of at least 135°F (57°C) and the container is cleaned at a frequency specified under 2VAC5-585-1780 D 7.

2VAC5-585-560. Linens and napkins, use limitation.

Linens ~~and napkins~~, such as cloth napkins, may not be used in contact with food unless they are used to line a container

for the service of foods and the linens ~~and napkins~~ are replaced each time the container is refilled for a new ~~customer~~ consumer.

2VAC5-585-570. Wiping cloths, use limitation.

A. Cloths in use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:

1. Maintained dry; and

2. Used for no other purpose.

B. Cloths in use for wiping counters and other equipment surfaces shall be:

1. Held between uses in a chemical sanitizer solution at a concentration specified in ~~2VAC5-585-3380~~ 2VAC5-585-1700; and

2. Laundered daily as specified under 2VAC5-585-1920 D.

C. Cloths in use for wiping surfaces in contact with raw animal foods shall be kept separate from other cloths used for other purposes.

D. Dry wiping cloths and the chemical sanitizing solutions specified in subdivision B 1 of this section in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

E. Containers of chemical sanitizing solutions specified in subdivision B 1 of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of food, equipment, utensils, linens, single-service, or single-use articles.

F. Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

2VAC5-585-580. Gloves, use limitation.

A. If used, single-use gloves shall be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.[P]

B. Except as specified in subsection C of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under 2VAC5-585-700 through 2VAC5-585-765 such as frozen food or a primal cut of meat.

C. Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

D. Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under 2VAC5-585-700 through 2VAC5-585-765 such as frozen food or a primal cut of meat.

2VAC5-585-590. Using clean tableware for second portions and refills.

A. Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer to provide second portions or refills.

B. Except as specified in subsection C of this section, self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.

C. ~~Cups and glasses~~ Drinking cups and containers may be reused by self-service consumers ~~or food employees~~ if refilling is a contamination-free process as specified under subdivisions 1, 2, and 4 of 2VAC5-585-1230.

2VAC5-585-600. Refilling returnables.

A. ~~A take-home food container~~ Except as specified in subsections B through E of this section, empty containers returned to a food establishment ~~may not be refilled at a food establishment with a potentially hazardous food~~ for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.[P]

B. ~~Except as specified in subsection C of this section, a~~ A take-home food container ~~refilled with food that is not potentially hazardous shall be cleaned as specified under 2VAC5-585-1870 B.~~ returned to a food establishment may be refilled at a food establishment with food if the food container is:

1. Designed and constructed for reuse and in accordance with the requirements specified under 2VAC5-585-960 through 2VAC5-585-1435;[P]

2. One that was initially provided by the food establishment to the consumer, either empty or filled with food by the food establishment, for the purpose of being returned for reuse;

3. Returned to the food establishment by the consumer after use;

4. Subject to the following steps before being refilled with food:

a. Cleaned as specified under 2VAC5-585-1770 through 2VAC5-585-1860;

b. Sanitized as specified under 2VAC5-585-1885 through 2VAC5-585-1900;[P] and

c. Visually inspected by a food employee to verify that the container, as returned, meets the requirements specified under 2VAC5-585-960 through 2VAC5-585-1435[P].

C. ~~Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as~~

~~specified under subdivisions 1, 2 and 4 of 2VAC5-585-1230.~~ A take-home food container returned to a food establishment may be refilled at a food establishment with beverage if:

1. The beverage is not a time/temperature control for safety food;

2. The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;

3. Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and

5. The container is refilled by:

a. An employee of the food establishment; or

b. The owner of the container if the beverage system includes a contamination-free transfer process as specified under subdivisions 1, 2, and 4 of 2VAC5-585-1230 that cannot be bypassed by the container owner.

D. Consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under subdivisions 1, 2, and 4 of 2VAC5-585-1230.

E. Consumer-owned containers that are not food specific may be filled at a water vending machine or system.

2VAC5-585-620. Food storage; prohibited areas.

Food may not be stored:

1. In locker rooms;

2. In toilet rooms ~~or their vestibules~~;

3. In dressing rooms;

4. In garbage rooms;

5. In mechanical rooms;

6. Under sewer lines that are not shielded to intercept potential drips;

7. Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

8. Under open stairwells; or

9. Under other sources of contamination.

2VAC5-585-630. Vended ~~potentially hazardous~~ time/temperature control for safety food; original container.

~~Potentially hazardous~~ Time/temperature control for safety food dispensed through a vending machine shall be in the package in which it was placed at the food establishment or food processing plant at which it was prepared.

2VAC5-585-650. Food display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means.[P]

2VAC5-585-660. Condiments; protection.

A. Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

B. Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at ~~a~~ an approved location ~~that is approved by the department~~, such as the food establishment that provides food to the vending machine location, a food processing plant that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the vending machine location.

2VAC5-585-670. Consumer self-service operations.~~*~~

A. Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self-service.[P] This subsection does not apply to:

1. Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;

2. Ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or

3. Raw, frozen, shell-on shrimp or lobster.

B. Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination.[Pf]

C. Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures.[~~N~~ Pf]

2VAC5-585-680. Returned food and reservice of food.~~*~~

A. Except as specified under subsection B of this section, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption.[P]

B. Except as specified in subdivision ~~8~~ 7 of 2VAC5-585-950, a container of food that is not ~~potentially hazardous (time/temperature~~ time/temperature control for safety ~~food)~~ food may be re-served from one consumer to another if:

1. The food is dispensed so that it is protected from contamination and the container is closed between uses such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

2. The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.

Article 4
Destruction of Organisms of Public Health Concern

2VAC5-585-700. Raw animal foods.~~*~~

A. Except as specified in subsections B, C, and D of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

1. 145°F (63°C) or above for 15 seconds for:[P]

a. Raw ~~shell~~ eggs that are broken and prepared in response to a consumer's order and for immediate service;[P] and

b. Except as specified under subdivisions A 2 and 3 and subsections B and C of this section, fish and meat including game animals commercially raised for food and under a voluntary inspection program as specified under 2VAC5-585-330 A 1 ~~and game animals under a voluntary inspection program as specified under 2VAC5-585-330 A 2~~;[P]

2. 155°F (68°C) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food and under a voluntary inspection program as specified under 2VAC5-585-330 A 1~~, and game animals under a voluntary inspection program as specified under 2VAC5-585-330 A 2~~; and raw eggs that are not prepared as specified under subdivision A 1 a of this section:[P]

Minimum	
Temperature °F (°C)	Time
145 (63)	3 minutes
150 (66)	1 minute
158 (70)	<1 second (instantaneous)

3. 165°F (74°C) or above for 15 seconds for poultry, baluts, wild game animals as specified under 2VAC5-585-330 A 2 and 3, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, ~~or~~ poultry, or ratites.[P]

B. Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

1. In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature;[Pf] and

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg) or more
Still Dry	350°F (177°C) or more	250°F (121°C) or more
Convection	325°F (163°C) or more	250°F (121°C) or more
High Humidity[1]	250°F (121°C) or less	250°F (121°C) or less

[1]Relative humidity greater than 90% for at least one hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity

2. As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature.[P]

Temperature °F (°C)	Time[1] in Minutes	Temperature °F (°C)	Time[1] in Seconds
130 (54.4)	112	147 (63.9)	134
131 (55.0)	89	149 (65.0)	85
133 (56.1)	56	151 (66.1)	54
135 (57.2)	36	153 (67.2)	34
136 (57.8)	28	155 (68.3)	22
138 (58.9)	18	157 (69.4)	14
140 (60.0)	12	158 (70.0)	0
142 (61.1)	8		
144 (62.2)	5		
145 (62.8)	4		

[1]Holding time may include postoven heat rise.

C. A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

1. The food establishment serves a population that is not a highly susceptible population;

2. The steak is labeled, as specified under 2VAC5-585-270 E, to indicate that it meets the definition of "whole-muscle, intact beef"; and

3. The steak is cooked on both the top and bottom to a surface temperature of 145°F (63°C) or above and a cooked color change is achieved on all external surfaces.

D. A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare~~,~~ or a partially cooked food such as lightly cooked fish, soft cooked

eggs, or rare meat other than whole-muscle, intact beef steaks as specified in subsection C of this section~~,~~ may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:

1. As specified under subdivisions 3 a and 3 b of 2VAC5-585-950, the food establishment serves a population that is not a highly susceptible population; ~~and~~

2. The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat;[Pf] and

~~2.~~ 3. The consumer is informed as specified under 2VAC5-585-930 that to ensure its safety, the food should be cooked as specified under subsection A or B of this section; or

~~3.~~ 4. The department grants a variance from subsection A or B of this section as specified in 2VAC5-585-3540 based on a HACCP plan that:

a. Is submitted by the operator and approved as specified under 2VAC5-585-3541;

b. Documents scientific data or other information ~~that shows~~ showing that a lesser time and temperature regimen results in a safe food; and

c. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions of the variance.

2VAC5-585-710. Microwave cooking.~~*~~

Raw animal foods cooked in a microwave oven shall be:

1. Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

2. Covered to retain surface moisture;

3. Heated to a temperature of at least 165°F (74°C) in all parts of the food;[P] and

4. Allowed to stand covered for two minutes after cooking to obtain temperature equilibrium.

2VAC5-585-720. Plant food cooking for hot holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 135°F (57°C).[Pf]

2VAC5-585-725. Noncontinuous cooking of raw animal foods.

Raw animal foods that are cooked using a noncontinuous cooking process shall be:

1. Subject to an initial heating process that is no longer than 60 minutes in duration;[P]

2. Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under 2VAC5-585-800 A;[P]

3. After cooling, held frozen or cold as specified for time/temperature control for safety food under 2VAC5-585-820 A 2;[P]

4. Prior to sale or service, cooked using a process that heats all parts of the food to a temperature and for a time as designated in 2VAC5-585-700 A through C;[P]

5. Cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under 2VAC5-585-800 A if not either hot held as specified under 2VAC5-585-820 A 1, served immediately, or held using time as a public health control as specified under 2VAC5-585-850 after complete cooking;[P] and

6. Prepared and stored according to written procedures that:

a. Have obtained prior approval from the department;[Pf]

b. Are maintained in the food establishment and are available to the department upon request;[Pf]

c. Describe how the requirements specified under subdivisions 1 through 5 of this section are to be monitored and documented by the operator and the corrective actions to be taken if the requirements are not met;[Pf]

d. Describe how the foods, after initial heating but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under subdivision 4 of this section prior to being offered for sale or service;[Pf] and

e. Describe how the foods, after initial heating but prior to cooking as specified in subdivision 4 of this section, are to be separated from ready-to-eat foods as specified under 2VAC5-585-470 A.[Pf]

2VAC5-585-730. Parasite destruction.~~*~~

A. Except as specified in subsection B of this section, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:

1. Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168 hours (seven days) in a freezer;[P]

2. Frozen at -31°F (-35°C) or below until solid and stored at -31°F (-35°C) or below for a minimum of 15 hours;[P] or

3. Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a minimum of 24 hours.[P]

B. Subsection A of this section does not apply to:

1. Molluscan shellfish~~,~~;

2. A scallop product consisting only of the shucked abductor muscle;

3. Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin, Northern); ~~or~~

~~3.~~ 4. Aquacultured fish, such as salmon, that:

a. If raised in open water, are raised in net pens, or

b. Are raised in land-based operations such as ponds or tanks, and

c. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish. or

5. Fish eggs that have been removed from the skein and rinsed.

2VAC5-585-740. Records; creation and retention.

A. Except as specified in 2VAC5-585-730 B and subsection B of this section, if raw, marinated, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food establishment for 90 calendar days beyond the time of service or sale of the fish. Pf

B. If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 2VAC5-585-730 may substitute for the records specified under subsection A of this section.

C. If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in 2VAC5-585-730 B 3 4, a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 2VAC5-585-730 B 3 4 shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish. Pf

2VAC5-585-755. Preparation for immediate service.

Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

2VAC5-585-760. Reheating for hot holding.*

A. Except as specified under subsections B, C and E of this section, potentially hazardous food (time/temperature time/temperature control for safety food) food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach at least 165°F (74°C) for 15 seconds. P

B. Except as specified under subsection C of this section, potentially hazardous food (time/temperature time/temperature control for safety food) food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165°F (74°C) and the food is rotated or stirred, covered, and allowed to stand covered for two minutes after reheating. P

C. Ready-to-eat time/temperature control for safety food taken from a that has been commercially processed, hermetically sealed container, or from an intact package from and packaged in a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 135°F (57°C) when being reheated for hot holding. P

D. Reheating for hot holding as specified under subsections A, B, and C of this section shall be done rapidly and the time the food is between the temperature specified under 2VAC5-585-820-A-2 41°F (5°C) and the temperatures specified under subsections A through, B and C of this section may not exceed two hours. P

E. Remaining unsliced portions of meat roasts that are cooked as specified under 2VAC5-585-700 B may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 2VAC5-585-700 B.

2VAC5-585-765. Treating juice.

Juice packaged in a food establishment shall be:

1. Treated under a HACCP plan as specified in [subdivisions 2 through 5 of 2VAC5-585-3610 2VAC5-585-3630] to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; P or

2. Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: Pf

a. As specified under 2VAC5-585-900; Pf and

b. As specified in 21 CFR 101.17(g), with the phrase, following: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Pf

2VAC5-585-780. Potentially hazardous Time/temperature control for safety food, slacking.

Frozen potentially hazardous food (time/temperature time/temperature control for safety food) food that is slacked to moderate the temperature shall be held:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less, or at 45°F (7°C) or less as specified under 2VAC5-585-820-A-2-b; or

2. At any temperature if the food remains frozen.

2VAC5-585-790. Thawing.

A. Except as specified in subdivision 4 of this section subsection, potentially hazardous food (time/temperature time/temperature control for safety food) food shall be thawed:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less, or at 45°F (7°C) or less as specified under 2VAC5-585-820-A-2-b; or

2. Completely submerged under running water:

a. At a water temperature of 70°F (21°C) or below;

b. With sufficient water velocity to agitate and float off loose particles in an overflow; and

c. For a period of time that does not allow thawed portions of ready-to-eat food to rise above 41°F (5°C)~~, or 45°F (7°C) as specified under 2VAC5-585-820-A-2-b~~; or

d. For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under 2VAC5-585-700 A or B to be above 41°F (5°C)~~, or 45°F (7°C) as specified under 2VAC5-585-820-A-2-b,~~ for more than four hours including:

(1) The time the food is exposed to the running water and the time needed for preparation for cooking; or

(2) The time it takes under refrigeration to lower the food temperature to 41°F (5°C)~~, or 45°F (7°C) as specified under 2VAC5-585-820-A-2-b~~;

3. As part of a cooking process if the food that is frozen is:

a. Cooked as specified under 2VAC5-585-700 A or B or 2VAC5-585-710; or

b. Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

4. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

B. Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

1. Prior to its thawing under refrigeration as specified in subdivision A 1 of this section; or

2. Prior to, or immediately upon completion of, its thawing using procedures specified in subdivision A 2 of this section.

2VAC5-585-800. Cooling.~~*~~

A. Cooked ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food shall be cooled:

1. Within two hours, from 135°F (57°C) to 70°F (21°C);[P] and

2. Within a total of six hours, from 135°F (57°C) to 41°F (5°C) or less~~, or to 45°F (7°C) or less as specified under 2VAC5-585-820-A-2-b~~.[P]

B. ~~Potentially hazardous food (time/temperature~~ Time/temperature control for safety ~~food)~~ food shall be cooled within four hours to 41°F (5°C) or less~~, or to 45°F (7°C) or less as specified under 2VAC5-585-820-A-2-b~~ if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.[P]

C. Except as specified in subsection D of this section, a ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food received in compliance with laws allowing a temperature above 41°F (5°C) during shipment from the supplier as specified in 2VAC5-585-340 B, shall be cooled within four hours to 41°F (5°C) or less~~, or 45°F (7°C) or less as specified under of 2VAC5-585-820-A-2-b~~.[P]

D. Raw ~~shell~~ eggs shall be received as specified under 2VAC5-585-340 C and immediately placed in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.[P]

2VAC5-585-810. Cooling methods.

A. Cooling shall be accomplished in accordance with the time and temperature criteria specified under 2VAC5-585-800 by using one or more of the following methods based on the type of food being cooled:

1. Placing the food in shallow pans;[Pf]

2. Separating the food into smaller or thinner portions;[Pf]

3. Using rapid cooling equipment;[Pf]

4. Stirring the food in a container placed in an ice water bath;[Pf]

5. Using containers that facilitate heat transfer;[Pf]

6. Adding ice as an ingredient;[Pf] or

7. Other effective methods.[Pf]

B. When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

1. Arranged in the equipment to provide maximum heat transfer through the container walls; and

2. Loosely covered, or uncovered if protected from overhead contamination as specified under 2VAC5-585-610 A 2, during the cooling period to facilitate heat transfer from the surface of the food.

2VAC5-585-820. ~~Potentially hazardous~~ Time/temperature control for safety food; hot and cold holding.~~*~~

A. Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 2VAC5-585-850, ~~potentially hazardous food (time/temperature~~ and except as specified under subsections B and C of this section, time/temperature control for safety ~~food)~~ food shall be maintained:

1. At 135°F (57°C) or above, except that roasts cooked to a temperature and for a time specified in 2VAC5-585-700 B or reheated as specified in 2VAC5-585-760 E may be held at a temperature of 130°F (54°C) or above;[P] or

2. ~~At a temperature specified in the following:~~

~~a. 41°F (5°C) or less; or~~

~~b. 45°F (7°C) or between 45°F (7°C) and 41°F (5°C) in existing refrigeration equipment that is not capable of maintaining the food at 41°F (5°C) or less if:~~

~~(1) The equipment is in place and in use in the food establishment; and~~

~~(2) Before January 1, 2012, the equipment is upgraded or replaced to maintain food at a temperature of~~ At 41°F (5°C) or less.

B. ~~Shell eggs~~ Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.[P]

C. ~~Potentially hazardous food (time/temperature~~ Time/temperature control for safety ~~food)~~ food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified in subsection A of this section, while contained within specially designed equipment that complies with the design and construction requirements as specified under subdivision 5 of 2VAC5-585-1230.

2VAC5-585-830. ~~Ready-to-eat~~ Ready-to-eat, ~~potentially hazardous~~ time/temperature control for safety food; date marking.~~*~~

A. Except when packaging food using a reduced oxygen packaging method as specified under 2VAC5-585-870 and except as specified in subsections ~~D and~~ E and F of this section, refrigerated, ready-to-eat, ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food prepared and held in a food establishment for more than 24 hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded ~~based on the temperature and time combinations specified below. The day of preparation shall be counted as Day 1.~~

~~1. 41°F (5°C) or less for a maximum of seven days; or~~

~~2. 45°F (7°C) or between 41°F (5°C) and 45°F (7°C) for a maximum of four days in existing refrigeration equipment that is not capable of maintaining the food at 41°F (5°C) or less if:~~

~~a. The equipment is in place and in use in the food establishment; and~~

~~b. Before January 1, 2012, the equipment is upgraded or replaced to maintain food at a temperature of 41°F (5°C) or less.~~ when held at a temperature of 41°F (5°C) or less for a maximum of seven days. The day of preparation shall be counted as day one.[Pf]

B. Except as specified in subsections ~~D through~~ E, F, and G of this section, refrigerated, ready-to-eat, ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in subsection A of this section and:[Pf]

1. The day the original container is opened in the food establishment shall be counted as ~~Day 1~~ day one;[Pf] and

2. The day or date marked by the food establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety.[Pf]

C. A refrigerated, ready-to-eat ~~potentially hazardous food (time/temperature~~, time/temperature control for safety ~~food)~~ food ingredient or a portion of a refrigerated, ready-to-eat, ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient.[Pf]

D. A date marking system that meets the criteria ~~specified~~ stated in subsections A and B of this section may include:

1. Using a method approved by the ~~regulatory authority~~ department for refrigerated, ready-to-eat ~~potentially hazardous food (time/temperature~~, time/temperature control for safety ~~food)~~ food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft-serve mix or milk in a dispensing machine;

2. Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified in subsection A of this section;

3. Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date ~~of~~ or day by which the food must be consumed on the premises, sold, or discarded as specified under subsection B of this section; or

4. Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the ~~regulatory authority~~ department upon request.

E. Subsections A and B of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

F. Subsections A and B of this section do not apply to shellstock.

G. Subsection B of this section does not apply to the following foods prepared and packaged by a food processing plant inspected by a regulatory authority:

1. Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110~~, Current good manufacturing practice in manufacturing, packing, or holding human food~~;

2. Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133~~, Cheeses and related cheese products~~, such as cheddar, gruyere, parmesan and reggiano, and romano;

3. Semi-soft cheese containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR Part

133~~, Cheeses and related cheese products~~, such as blue, edam, gorgonzola, gouda, and Monterey ~~jack~~ Jack;

4. Cultured dairy products as defined in 21 CFR Part 131~~, Milk and cream~~, such as yogurt, sour cream, and buttermilk;

5. Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products as defined in 21 CFR Part 114~~, Acidified foods~~;

6. Shelf stable, dry fermented sausages, such as pepperoni and Genoa ~~salami that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317, Labeling, marking devices, and containers, and which retain the original casing on the product~~; and

7. Shelf stable salt-cured products such as prosciutto and Parma (ham) ~~that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317, Labeling, marking devices, and containers~~.

2VAC5-585-840. Ready-to-eat, ~~potentially hazardous~~ time/temperature control for safety food; disposition.~~*~~

A. A food specified in 2VAC5-585-830 A or B shall be discarded if it:

1. Exceeds ~~either of~~ the temperature and time ~~combinations~~ combination specified in 2VAC5-585-830 A, except time that the product is frozen;[P]

2. Is in a container or package that does not bear a date or day;[P] or

3. Is [~~appropriately~~ inappropriately] marked with a date or day that exceeds a temperature and time combination as specified in 2VAC5-585-830 A.[P]

B. Refrigerated, ready-to-eat, ~~potentially hazardous~~ time/temperature control for safety food prepared in a food establishment and dispensed through a vending machine with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in 2VAC5-585-830 A.[P]

2VAC5-585-850. Time as a public health control.~~*~~

A. Except as specified under subsection D of this section, if time without temperature control is used as the public health control for a working supply of ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food before cooking, or for ready-to-eat ~~potentially hazardous food (time/temperature~~, time/temperature control for safety ~~food)~~ food that is displayed or held for sale or service:

1. Written procedures shall be prepared in advance, maintained in the food establishment, and made available to the ~~regulatory authority~~ department upon request that specify:[Pf]

a. Methods of compliance with ~~subdivision~~ subdivisions B 1 ~~through 4~~, 2, and 3 or subsection C ~~1 through 5~~ of this section;[Pf] and

b. Methods of compliance with 2VAC5-585-800 for food that is prepared, cooked, and refrigerated before time is used as a public health control.[Pf]

B. If time without temperature control is used as the public health control up to a maximum of 4 hours:

1. The food shall have an initial temperature of 41°F (5°C) or less when removed from cold holding temperature control, or 135°F (57°C) or greater when removed from hot-holding temperature control;[P]

2. The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;[Pf]

3. The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control;[P] and

4. The food in unmarked containers or packages or marked to exceed a four-hour limit shall be discarded.[P]

C. If time without temperature control is used as the public health control up to a maximum of six hours:

1. The food shall have an initial temperature of 41°F (5°C) or less when removed from temperature control and the food temperature may not exceed 70°F (21°C) within a maximum time period of six hours;[P]

2. The food shall be monitored to ensure the warmest portion of the food does not exceed 70°F (21°C) during the six-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70°F (21°C) during the six-hour holding period;[Pf]

3. The food shall be marked or otherwise identified to indicate:[Pf]

a. The time when the food is removed from 41°F (5°C) or less cold holding temperature control;[Pf] and

b. The time that is six hours past the point in time when the food is removed from 41°F (5°C) or less cold holding temperature control;[Pf]

4. The food shall be:

a. Discarded if the temperature of the foods exceeds 70°F (21°C);[P] or

b. Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of six hours from the point in time when the food is removed from 41°F (5°C) or less cold holding temperature control;[P] and

5. The food in unmarked containers or packages, or marked with a time that exceeds the six-hour limit shall be discarded.[P]

D. A food establishment that serves a highly susceptible population may not use time as specified under ~~subsections~~ subsection A, B, or C of this section as the public health control for raw eggs.

2VAC5-585-860. Variance requirement.~~*~~

A food establishment shall obtain a variance from the department as specified in 2VAC5-585-3540 and 2VAC5-585-3541 before:[Pf]

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement;[Pf]

2. Curing food;[Pf]

3. Using food additives or adding components such as vinegar:[Pf]

a. As a method of food preservation rather than as a method of flavor enhancement;[Pf] or

b. To render a food so that it is not ~~potentially hazardous~~ time/temperature control for safety food;[Pf]

4. Packaging time/temperature control for safety food using a reduced oxygen packaging method except ~~as specified under 2VAC5-585-870 where a barrier to~~ where the growth of and toxin formation by Clostridium botulinum ~~in addition to refrigeration exists~~ and the growth of Listeria monocytogenes are controlled as specified under 2VAC5-585-870;[Pf]

5. Operating a molluscan shellfish life-support system display tank used to store ~~and~~ or display shellfish that are offered for human consumption;[Pf]

6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment;[Pf]

7. Sprouting seeds or beans;[Pf] or

8. Preparing food by another method that is determined by the ~~regulatory authority~~ department to require a variance.[Pf]

2VAC5-585-870. Reduced oxygen packaging without a variance; criteria.~~*~~

A. Except for a food establishment that obtains a variance as specified under 2VAC5-585-860 ~~and except as specified under subsections C and E of this section~~, a food establishment that packages ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food using a reduced oxygen packaging method shall ~~ensure that there are at least two barriers in place to~~ control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes.[P]

B. ~~A~~ Except as specified in subsection F of this section, a food establishment that packages ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food using a reduced oxygen packaging method shall ~~have~~ implement a HACCP plan that contains the ~~following~~ information specified under ~~subdivision~~ subdivisions [~~2~~ 3] and 4 of 2VAC5-585-3630 and that:[Pf]

1. Identifies food to be packaged;[Pf]

2. Except as specified in subsections C ~~and~~, D, and E ~~and as specified in subsection D~~ of this section, requires that the packaged food shall be maintained at 41°F (5°C) or less and meet at least one of the following criteria:[Pf]

a. Has an A_w of 0.91 or less,[Pf]

b. Has a pH of 4.6 or less,[Pf]

c. Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21~~, Use of food ingredients and sources of radiation,~~ and is received in an intact package,[Pf] or

d. Is a food with a high level of competing organisms such as raw meat~~, or~~ raw poultry, or raw vegetables;[Pf]

3. Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:[Pf]

a. Maintain the food at 41°F (5°C) or below,[Pf] and

b. Discard the food within ~~14~~ 30 calendar days of its packaging if it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;[Pf]

4. Limits the refrigerated shelf life to no more than ~~14~~ 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;[P]

5. Includes operational procedures that:

a. Prohibit contacting ready-to-eat food with bare hands as specified under 2VAC5-585-450 B;[Pf]

b. Identify a designated work area and the method by which:[Pf]

(1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination,[Pf] and

(2) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation;[Pf] and

c. Delineate cleaning and sanitization procedures for ~~food contact~~ food-contact surfaces; ~~and~~[Pf]

6. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:[Pf]

a. Concepts required for safe operation;[Pf]

b. Equipment and facilities;[Pf] and

c. Procedures specified under subdivision 5 of this subsection and ~~2VAC5-585-3630 D.~~ subdivisions [~~2~~ 3] and 4 of 2VAC5-585-3630;[Pf] and

7. Is provided to the department prior to implementation as specified under subsection B of 2VAC5-585-3620.

C. Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.[P]

D. Except as specified in ~~subsection~~ subsections C and F of this section, a food establishment ~~may package~~ that packages

time/temperature control for safety food using a cook-chill or ~~sous vide~~ sous vide process ~~without obtaining a variance if~~ shall:

1. ~~The food establishment implements~~ Provide to the department prior to implementation, a HACCP plan that contains the information as specified under ~~2VAC5-585-3630 D~~ subdivisions [~~2~~ 3] and 4 of 2VAC5-585-3630;[Pf]

2. ~~The~~ Ensure the food is:

a. Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the ~~bagged~~ packaged product to another business entity or the consumer;[Pf]

b. Cooked to heat all parts of the food to a temperature and for a time as specified under 2VAC5-585-700 A, B, and C;[P]

c. Protected from contamination before and after cooking as specified in 2VAC5-585-450 through ~~2VAC5-585-690~~ 2VAC5-585-765;[P]

d. Placed in a package ~~or bag~~ with an oxygen barrier and sealed before cooking, or placed in a package ~~or bag~~ and sealed immediately after cooking, and before reaching a temperature below 135°F (57°C);[P]

e. Cooled to 41°F (5°C) in the sealed package or bag as specified under 2VAC5-585-800~~,~~ and ~~subsequently;~~[P]

(1) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that temperature until consumed or discarded within 30 days after the date of ~~preparation~~ packaging;[P]

(2) ~~Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C), removed from refrigeration equipment that maintains a 34°F (1°C) food temperature and then held~~ Held at 41°F (5°C) or less for no more than ~~72 hours~~ seven days, at which time the food must be consumed or discarded;[P] or

~~(3) Cooled to 38°F (3°C) or less within 24 hours of reaching 41°F (5°C) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded; or~~

~~(4)~~ (3) Held frozen with no shelf-life restriction while frozen until consumed or used;[P]

f. Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily;[Pf]

g. If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation;[Pf] and

h. Labeled with the product name and the date packaged;[Pf] and

3. ~~The~~ Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan~~, are maintained~~ and ~~are~~:

a. ~~Made~~ Make such records available to the ~~regulatory authority~~ department upon request;[Pf] and

b. ~~Held~~ Hold such records for at least six months;[Pf] and

4. ~~Written~~ Implement written operational procedures as specified under subdivision B 5 of this section and a training program as specified under subdivision B 6 of this section ~~are implemented~~.[Pf]

E. ~~A~~ Except as specified under subsection F of this section, a food establishment ~~may package~~ that packages cheese using a reduced oxygen packaging method ~~without obtaining a variance~~ shall:

1. ~~If it limits~~ Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150, ~~Hard Cheeses,~~ 21 CFR 133.169, ~~Pasteurized process cheese,~~ or 21 CFR 133.187~~, Semi-soft cheeses~~;[P]

2. ~~If it has~~ Have a HACCP plan that contains the information specified in ~~2VAC5-585-3630 D~~ subdivisions [~~2~~ 3] and 4 of 2VAC5-585-3630 and as specified in subdivisions B 1, B 3 a, B 5, and B 6 of this section;[Pf]

~~3. Except as specified under subdivisions B 2, B 3 b, and B 4, complies with subsection B of this section;~~

~~4. If it labels~~ 3. [~~Labels~~ Label] the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever ~~comes~~ occurs first;[Pf] and

~~5. If it discards~~ 4. [~~Discards~~ Discard] the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.[Pf]

F. A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package time/temperature control for safety food that is always:

1. Labeled with the production time and date;

2. Held at 41°F (5°C) or less during refrigerated storage; and

3. Removed from its packaging in the food establishment within 48 hours after packaging.

2VAC5-585-900. Food labels.

A. Food packaged in a food establishment shall be labeled as specified in law, including 21 CFR Part 101~~, Food Labeling,~~ and 9 CFR Part 317~~, Labeling, Marking Devices, and Containers~~.

B. Label information shall include:

1. The common name of the food, or absent a common name, an adequately descriptive identity statement;

2. If made from two or more ingredients, a list of ingredients and subingredients in descending order of predominance by weight, including a declaration of artificial ~~color or flavor~~ colors, artificial flavors, and chemical preservatives, if contained in the food;

3. An accurate declaration of the net quantity of contents;

4. The name and place of business of the manufacturer, packer, or distributor;

5. The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient;[Pf]

6. Except as exempted in the Federal Food, Drug, and Cosmetic Act ~~21 USC § 343(q) (3) through (5)~~ 21 USC § 403(g)(3) through (5), nutrition labeling as specified in 21 CFR Part 101~~, Food Labeling,~~ and 9 CFR Part 317, Subpart B~~, Nutrition Labeling~~; and

7. For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

C. Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:

1. The manufacturer's or processor's label that was provided with the food; or

2. A card, sign, or other method of notification that includes the information specified under subdivisions B 1, 2, and ~~5~~ 6 of this section.

D. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:

1. A health, nutrient content, or other claim is not made;

2. There are no state or local laws requiring labeling; and

3. The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

2VAC5-585-930. Consumer advisory; consumption of animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens.*[*]

A. Except as specified in 2VAC5-585-700 C and 2VAC5-585-700 D ~~3~~ 4 and under subdivision 3 of 2VAC5-585-950, if an animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food, the ~~person in charge~~ operator shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in subsections B and C of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.[Pf]

B. Disclosure shall include:

1. A description of the animal-derived foods, such as "oysters on the half shell (raw oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)";[Pf] or

2. Identification of the animal-derived foods by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.[Pf]

C. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:

1. Regarding the safety of these items, written information is available upon request~~:~~;[Pf]

2. Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness;[Pf] or

3. Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.[Pf]

Article 7
Contaminated Food

2VAC5-585-940. Discarding or reconditioning unsafe, adulterated, or contaminated food.*[*]

A. A food that is unsafe, adulterated, or not honestly presented as specified under 2VAC5-585-260 shall be discarded or reconditioned according to an approved procedure ~~or discarded~~.[P]

B. Food that is not from an approved source as specified under 2VAC5-585-270 through 2VAC5-585-330 shall be discarded.[P]

C. Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 2VAC5-585-90 shall be discarded.[P]

D. Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.[P]

Article 8
Special Requirements for Highly Susceptible Populations

2VAC5-585-950. Pasteurized foods, prohibited reservice, and prohibited food.*[*]

In a food establishment that serves a highly susceptible population:

1. The following criteria apply to juice:

a. For the purposes of subdivision 1 of this section only, children who are age ~~9~~ nine years or ~~less~~ younger and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;

b. Prepackaged juice or a prepackaged beverage containing juice~~,~~ that bears a warning label as specified in 21 CFR 101.17(g)~~, Food Labeling,~~ or a packaged juice or beverage containing juice~~,~~ that bears a warning label as specified under subdivision 2 of 2VAC5-585-765 may not be served or offered for sale;[P] and

c. Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified in subdivisions [~~2~~ 3] through 5 of 2VAC5-585-3630 and as specified ~~under~~ in 21 CFR ~~Part 120, Hazard Analysis And Critical Control Point (HACCP) Systems, Subpart B, Pathogen Reduction,~~ 120.24~~, Process Controls~~.[P]

2. Pasteurized ~~shell~~ eggs or egg products shall be substituted for raw ~~shell~~ eggs in the preparation of:[P]

a. Foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages;[P] and

b. Except as specified in subdivision 6 of this section, recipes in which more than one egg is broken and the eggs are combined.[P]

3. The following foods may not be served or offered for sale in a ready-to-eat form:[P]

a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare;[P]

b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw ~~shell~~ eggs, and meringue;[P] and

c. Raw seed sprouts.[P]

4. Food employees may not contact ready-to-eat food as specified in 2VAC5-585-450 B and E.[P]

5. Time only, as the public health control as specified under 2VAC5-585-850 D, may not be used for raw eggs.[P]

6. Subdivision 2 b of this section does not apply if:

a. The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under 2VAC5-585-700 A 1, and served immediately, such as an omelet, soufflé, or scrambled eggs;

b. The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or

c. The preparation of the food is conducted under a HACCP plan that:

(1) Identifies the food to be prepared;

(2) Prohibits contacting ready-to-eat food with bare hands;

(3) Includes specifications and practices that ensure:

(a) Salmonella ~~enteritidis~~ Enteritidis growth is controlled before and after cooking; and

(b) Salmonella ~~enteritidis~~ Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 2VAC5-585-700 A 2;

d. Contains the information specified under subdivision 4 of 2VAC5-585-3630 including procedures that:

(1) Control cross contamination of ready-to-eat food with raw eggs; and

(2) Delineate cleaning and sanitization procedures for food-contact surfaces; and

e. Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

7. Except as specified in subdivision 8 of this section, food may be re-served as specified under 2VAC5-585-680 B 1 and 2.

8. Foods may not be re-served under the following conditions:

[~~1.~~ a.] Any food served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.

[~~2.~~ b.] Packages of food from any patients, clients, or other consumers should not be re-served to persons in protective environment isolation.

Part IV
Equipment, Utensils, and Linens

Article 1
Materials for Construction and Repair

2VAC5-585-960. Multiuse, characteristics.~~*~~

Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be:[P]

1. Safe;[P]

2. Durable, corrosion-resistant, and nonabsorbent;[N]

3. Sufficient in weight and thickness to withstand repeated warewashing;[N]

4. Finished to have a smooth, easily cleanable surface;[N] and

5. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.[N]

2VAC5-585-980. Lead use limitation.

A. Ceramic, china, and crystal utensils, and decorative utensils such as hand-painted ceramic or china that are used

in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:[P]

Utensil Category	Ceramic Article Description	Maximum Lead (mg/L)
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls ~~>~~≥1.1 Liter (1.16 Quart)	1.0
Small Hollowware (excluding cups and mugs)	Bowls <1.1 Liter (1.16 Quart)	2.0
Flat Tableware	Plates, Saucers	3.0

B. Pewter alloys containing lead in excess of 0.05% may not be used as a ~~food-contact~~ food-contact surface.[P]

C. Solder and flux containing lead in excess of 0.2% may not be used as a ~~food-contact~~ food-contact surface.

2VAC5-585-990. Copper, use limitation.~~*~~

A. Except as specified in subsections B and C of this section, copper and copper alloys such as brass may not be used in contact with a food that has a pH below ~~6~~ 6.0 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.[P]

B. Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below ~~6~~ 6.0 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

C. Copper and copper alloys may be used in contact with apple butter and molasses that have a pH below ~~6~~ 6.0 during the typical processing times (i.e., mixing, cooking, and cooling) for these products, as long as laboratory analysis does not reveal excessive levels of copper or other heavy metals in the finished product. Apple butter and molasses may not be held or stored in copper or copper alloys for time periods any longer than the typical processing times for these products.

2VAC5-585-1000. Galvanized metal, use limitation.~~*~~

Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.[P]

2VAC5-585-1070. Single-service and single-use, characteristics.~~*~~

Materials that are used to make single-service and single-use articles:

1. May not:

a. Allow the migration of deleterious substances;[P] or

b. Impart colors, odors, or tastes to food.[N]

2. Shall be:

a. Safe;[P] and

b. Clean.[N]

2VAC5-585-1090. Food temperature measuring devices.~~*~~

Food temperature measuring devices may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.[P]

2VAC5-585-1100. Food-contact surfaces; cleanability.~~*~~

A. Multiuse food-contact surfaces shall be:

1. Smooth;[Pf]

2. Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;[Pf]

3. Free of sharp internal angles, corners, and crevices;[Pf]

4. Finished to have smooth welds and joints;[Pf] and

5. ~~Accessible~~ Except as specified in subsection B of this section, accessible for cleaning and inspection by one of the following methods:

a. Without being disassembled;[Pf]

b. By disassembling without the use of tools;[Pf] or

c. By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.[Pf]

B. Subdivision A 5 of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

2VAC5-585-1110. CIP equipment.

A. CIP equipment shall meet the characteristics specified under 2VAC5-585-1100 and shall be designed and constructed so that:

1. Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces;[Pf] and

2. The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.

B. CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

2VAC5-585-1120. "V" threads, use limitation.

Except for hot oil cooking or filtering equipment, "V" type threads may not be used on food-contact surfaces. ~~This section does not apply to hot oil cooking or filtering equipment.~~

2VAC5-585-1180. Temperature measuring devices; food.

A. Food temperature measuring devices that are scaled only in Fahrenheit or dually scaled in Fahrenheit and Celsius shall

be scaled in 2°F increments and accurate to ±2°F in the intended range of use.[Pf]

B. Food temperature measuring devices that are scaled only in Celsius shall be scaled in 1°C increments accurate to ±1°C in the intended range of use.[Pf]

2VAC5-585-1190. Temperature measuring devices; ambient air and water.

A. Ambient air and water temperature measuring devices that are scaled in Fahrenheit or dually scaled in Fahrenheit and Celsius and shall be designed to be easily readable and scaled in 3°F increments and accurate to ±3°F in the intended range of use.[Pf]

B. Ambient air and water temperature measuring devices that are scaled only in Celsius shall be scaled in 1.5°C increments and accurate to ±1.5°C in the intended range of use.[Pf]

2VAC5-585-1230. Dispensing equipment, protection of equipment and food.

In equipment that dispenses or vends liquid food or ice in unpackaged form:

1. The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food.

2. The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed.

3. The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

a. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

b. Available for self-service during hours when it is not under the full-time supervision of a food employee.

4. The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

5. Dispensing equipment in which ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food in homogenous liquid form is maintained outside of the temperature control requirements as specified in 2VAC5-585-820 ~~C~~ A shall:

a. Be specifically designed and equipped to maintain the commercial sterility of aseptically packaged food in a homogenous liquid form for a specified duration from the time of opening the packaging within the equipment;[P] and

b. Conform to the requirements for this equipment as specified in NSF/ANSI ~~18-2006~~ 18-2012 Manual Food and Beverage Dispensing Equipment, 2012, (NSF International).[P]

2VAC5-585-1240. Vending machine, vending stage closure.

The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not ~~potentially hazardous~~ time/temperature control for safety food such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

1. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

2. Available for self-service during hours when it is not under the full-time supervision of a food employee.

2VAC5-585-1300. Molluscan shellfish tanks.

A. Except as specified under subsection B of this section, molluscan shellfish life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to consumers that the shellfish are for display only.[P]

B. Molluscan shellfish life-support system display tanks that are used to store ~~and~~ or display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the department as specified in 2VAC5-585-3540 and a HACCP plan that:[Pf]

1. Is submitted by the ~~person in charge~~ operator and approved as specified under 2VAC5-585-3541;[Pf] and

2. Ensures that:

a. Water used with fish other than molluscan shellfish does not flow into the molluscan tank;[Pf]

b. The safety and quality of the shellfish as they were received are not compromised by the use of the tank;[Pf] and

c. The identity of the source of the shellstock is retained as specified under 2VAC5-585-440.[Pf]

2VAC5-585-1310. Vending machines, automatic shutoff.~~*~~

A. A machine vending ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food shall have an automatic control that prevents the machine from vending food:

1. If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that cannot maintain food temperatures as specified under Part III (2VAC5-585-260 et seq.) of this chapter;[P] and

2. If a condition specified under subdivision 1 of this subsection occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under Part III.[P]

B. When the automatic shutoff within a machine vending ~~potentially hazardous food (time/temperature~~ time/temperature control for safety ~~food)~~ food is activated:

1. In a refrigerated vending machine, the ambient temperature may not exceed 41°F (5°C) ~~or 45°F (7°C) as specified under 2VAC5-585-820 A 2~~ for more than 30 minutes immediately after the machine is filled, serviced, or restocked;[P] or

2. In a hot holding vending machine, the ambient temperature may not be less than 135°F (57°C) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.[P]

2VAC5-585-1320. Temperature measuring devices.

A. In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

B. Except as specified in subsection C of this section, cold or hot holding equipment used for ~~potentially hazardous~~ time/temperature control for safety food shall be designed to include and shall be equipped with at least one integral or affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

C. Subsection B of this section does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

D. Temperature measuring devices shall be designed to be easily readable.

E. Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than 2°F or 1°C in the intended range of use.[Pf]

2VAC5-585-1330. Warewashing machine, data plate operating specifications.

A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and ~~operating~~ operation specifications including the:

1. Temperatures required for washing, rinsing, and sanitizing;

2. Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and

3. Conveyor speed for conveyor machines or cycle time for stationary rack machines.

2VAC5-585-1350. Warewashing machines, temperature measuring devices.

A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

1. In each wash and rinse tank;[Pf] and

2. As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.[Pf]

2VAC5-585-1360. Manual warewashing equipment, heaters and baskets.

If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

1. Designed with an integral heating device that is capable of maintaining water at a temperature not less than 171°F (77°C);[Pf] and

2. Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.[Pf]

2VAC5-585-1370. Warewashing machines, automatic dispensing of detergents and sanitizers.

~~A.~~ A warewashing machine ~~that is installed after the adoption of this regulation by the board~~ shall be equipped to:

1. Automatically dispense detergents and sanitizers;[Pf] and

2. Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles.[Pf]

~~B. Before January 1, 2012, existing warewashing equipment shall be upgraded or replaced to meet the requirements of subsection A of this section.~~

2VAC5-585-1435. Food equipment, certification and classification.

Food equipment that is certified or classified for sanitation by an American National Standards Institute accredited certification program is deemed to comply with the requirements of Articles 1 (2VAC5-585-960 et seq.) and 2 (2VAC5-585-1080 et seq.) of this part.

Article 3
Numbers and Capacities

2VAC5-585-1450. Cooling, heating, and holding capacities.

Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity ~~and capable of providing~~ to provide food temperatures as specified under Part III (2VAC5-585-260 et seq.) of this chapter.[Pf]

2VAC5-585-1460. Manual warewashing, sink compartment requirements.

A. Except as specified in subsection C of this section, a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.[Pf]

B. Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in subsection C of this section shall be used.[Pf]

C. Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:

1. High-pressure detergent sprayers;

2. Low-pressure or line-pressure spray detergent foamers;

3. Other task-specific cleaning equipment;

4. Brushes or other implements;

5. Two-compartment sinks as specified under subsections D and E of this section; or

6. Receptacles that substitute for the compartments of a multicompartment sink.

D. Before a two-compartment sink is used:

1. The operator shall have its use approved; and

2. The ~~person in charge~~ operator shall limit the number of kitchenware items cleaned and sanitized in the two-compartment sink, ~~and~~ shall limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and shall:

a. Make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use; and

b. Use a detergent-sanitizer to sanitize and apply the detergent-sanitizer in accordance with the manufacturer's label instructions and as specified under 2VAC5-585-1710; or

c. Use a hot water sanitization immersion step as specified under subdivision 3 of 2VAC5-585-1860.

E. A two-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

2VAC5-585-1500. Utensils, consumer self-service.

A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar.[Pf]

2VAC5-585-1510. Food temperature measuring devices.

A. Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under Part III (2VAC5-585-260 et seq.) of this chapter.[Pf]

B. A temperature measuring device with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish fillets.[Pf]

2VAC5-585-1520. Temperature measuring devices, manual and mechanical warewashing.

A. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.[Pf]

B. In hot water mechanical warewashing operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the utensil surface temperature.[Pf]

2VAC5-585-1530. Sanitizing solutions, testing devices.

A test kit or other device that accurately measures the concentration in mg/L (ppm) of sanitizing solutions shall be provided ~~and readily accessible for use~~.[Pf]

[2VAC5-585-1535. Cleaning agents and sanitizers; availability.

A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6 (2VAC5-585-1770 et seq.) of this part shall be provided and available for use during all hours of operation.

B. Except for chemical sanitizers that are generated on site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under Article 7 (2VAC5-585-1885 et seq.) of this part shall be provided and available for use during all hours of operation.]

Article 4
Location and Installation

2VAC5-585-1540. Equipment, clothes washers and dryers, and storage cabinets, contamination prevention.

A. Except as specified in subsection B of this section, equipment, ~~cabinets~~ a cabinet used for the storage of food, or ~~cabinets~~ a cabinet used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located:

1. In locker rooms;

2. In toilet rooms ~~or vestibules~~;

3. In garbage rooms;

4. In mechanical rooms;

5. Under sewer lines that are not shielded to intercept potential drips;

6. Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

7. Under open stairwells; or

8. Under other sources of contamination.

B. A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

C. If a mechanical clothes washer or dryer is provided, it shall be located ~~only where there is no exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; and~~ (i) so that the washer or dryer is protected from contamination and (ii) only where there is no exposed food; clean equipment, utensils, and linens; or unwrapped single-service and single-use articles.

2VAC5-585-1550. Fixed equipment, spacing or sealing.

A. Equipment that is fixed because it is not easily movable shall be installed so that it is:

1. Spaced to allow access for cleaning along the sides, behind, and above the equipment;

2. Spaced from adjoining equipment, walls, and ceilings a distance of not more than 1/32 inch or one millimeter; or

3. Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

B. Counter-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

1. Sealed ~~to the table~~; or

2. Elevated on legs as specified under 2VAC5-585-1560 D.

2VAC5-585-1560. Fixed equipment, elevation or sealing.

A. Except as specified in subsections B and C of this section, floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a six-inch [(15-centimeter) ~~(15-centimeter)~~] clearance between the floor and the equipment.

B. If no part of the floor under the floor-mounted equipment is more than six inches (15 centimeters) from the point of cleaning access, the clearance space may be only four inches (10 centimeters).

C. This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

D. Except as specified in subsection E of this section, counter-mounted equipment that is not easily movable shall be elevated on legs that provide at least a four-inch [(10-centimeter) ~~(10-centimeter)~~] clearance between the table and the equipment.

E. The clearance space between the table and counter-mounted equipment may be:

1. Three inches (7.5 centimeters) if the horizontal distance of the table top under the equipment is no more than 20 inches (50 centimeters) from the point of access for cleaning; or

2. Two inches (5 centimeters) if the horizontal distance of the table top under the equipment is no more than three inches (7.5 centimeters) from the point of access for cleaning.

Article 5
Maintenance and Operation

2VAC5-585-1570. Good repair and proper adjustment.

A. Equipment shall be maintained in a state of repair and condition that meets the requirements specified under Articles 1 (2VAC5-585-960 et seq.) and 2 (2VAC5-585-1080 et seq.) of this part. ~~Unused or nonfunctioning equipment shall be removed from the premises.~~

B. Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

C. Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

2VAC5-585-1630. Warewashing equipment, cleaning agents.

When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 2VAC5-585-1460 C, shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.[Pf]

2VAC5-585-1650. Manual warewashing equipment, wash solution temperature.

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 110°F (43°C) or the temperature specified on the cleaning agent manufacturer's label instructions.[Pf]

2VAC5-585-1660. Mechanical warewashing equipment, wash solution temperature.

A. The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:

1. For a stationary rack, single temperature machine, 165°F (74°C);[Pf]

2. For a stationary rack, dual temperature machine, 150°F (66°C);[Pf]

3. For a single tank, conveyor, dual temperature machine, 160°F (71°C);[Pf] or

4. For a multitank, conveyor, multitemperature machine, 150°F (66°C).[Pf]

B. The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 120°F (49°C).[Pf]

2VAC5-585-1670. Manual warewashing equipment, hot water sanitization temperatures.~~*~~

If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 171°F (77°C) or above.[P]

2VAC5-585-1680. Mechanical warewashing equipment, hot water sanitization temperatures.

A. Except as specified in subsection B of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 194°F (90°C), or less than:[Pf]

1. For a stationary rack, single temperature machine, 165°F (74°C);[Pf] or

2. For all other machines, 180°F (82°C).[Pf]

B. The maximum temperature specified under subsection A of this section does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

2VAC5-585-1700. Manual and mechanical warewashing equipment, chemical sanitization - temperature, pH, concentration, and hardness.~~*~~

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at ~~exposure~~ contact times specified under subdivision 3 of 2VAC5-585-1900 shall ~~be listed in 40 CFR 180.940, Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food-Contact Surface Sanitizing Solutions), shall be used in accordance with the EPA-approved manufacturer's label use instructions,~~ meet the criteria specified under 2VAC5-585-3380, shall be used in accordance with the EPA-registered label use instructions,[P] and shall be used as follows:

1. A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;[P]

Minimum Concentration	Minimum Temperature	
mg/L (ppm)	pH 10 or less °F (°C)	pH ~~8~~ 8.0 or less °F (°C)
25-49	120 (49)	120 (49)
50-99	100 (38)	75 (24)
100	55 (13)	55 (13)

2. An iodine solution shall have a:

a. Minimum temperature of ~~75°F (24°C)~~ 68°F (20°C);[P]

b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective;[P] and

c. Concentration between 12.5 mg/L(ppm) and 25 mg/L (ppm);[P]

3. A quaternary ammonium compound solution shall:

a. Have a minimum temperature of 75°F (24°C);[P]

b. Have a concentration as specified under 2VAC5-585-3380 and as indicated by the manufacturer's use directions included in the labeling;[P] and

c. Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the ~~manufacturer's label~~ EPA-registered label use instructions;[P]

4. If another solution of a chemical specified under subdivisions 1 through 3 of this section is used, the ~~person in charge~~ operator shall demonstrate to the department that the solution achieves sanitization and the use of the solution shall be approved;[P] or

5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the ~~manufacturer's use directions included in the labeling.~~ EPA-registered label use instructions;[P] and

6. If a chemical sanitizer is generated by a device located on site at the food establishment, it shall be used as specified in subdivisions 1 through 4 of this section and shall be produced by a device that:

a. Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 USC § 136(q)(1) and 7 USC § 136j);[P]

b. Complies with 40 CFR 152.500 and 40 CFR 156.10;[P]

c. Displays the EPA device manufacturing facility registration number on the device;[Pf] and

d. Is operated and maintained in accordance with manufacturer's instructions.[Pf]

2VAC5-585-1720. Warewashing equipment, determining chemical sanitizer concentration.

Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.[Pf]

2VAC5-585-1730. Good repair and calibration.

A. Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under Articles 1 (2VAC5-585-960 et seq.) and 2 (2VAC5-585-1080 et seq.) of this part or shall be discarded.

B. Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.[Pf]

C. Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.

2VAC5-585-1740. Single-service and single-use articles, required use.*~~*~~

A food establishment without facilities specified under Articles 6 (2VAC5-585-1770 et seq.) and 7 ~~(2VAC5-585-1880~~ (2VAC5-585-1885 et seq.) of this part for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.P

Article 6
Cleaning of Equipment and Utensils

2VAC5-585-1770. Equipment, food-contact surfaces, nonfood-contact surfaces, and utensils.*~~*~~

A. Equipment food-contact surfaces and utensils shall be clean to sight and touch.Pf

B. The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.~~N~~

C. Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.~~N~~

2VAC5-585-1780. Equipment food-contact surfaces and utensils.*~~*~~

A. Equipment food-contact surfaces and utensils shall be cleaned:

1. Except as specified in subsection B of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry;P

2. Each time there is a change from working with raw foods to working with ready-to-eat foods;P

3. Between uses with raw fruits and vegetables and with ~~potentially hazardous~~ time/temperature control for safety food;P

4. Before using or storing a food temperature measuring device;P and

5. At any time during the operation when contamination may have occurred.P

B. Subdivision A 1 of this section does not apply if the ~~food contact~~ food-contact surface or utensil is in contact with a succession of different ~~raw animal foods~~ types of raw meat and poultry each requiring a higher cooking temperature as specified under 2VAC5-585-700 than the previous ~~food, such as preparing raw fish followed by cutting raw poultry on the same cutting board~~ type.

C. Except as specified in subsection D of this section, if used with ~~potentially hazardous~~ time/temperature control for safety food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every four hours.P

D. Surfaces of utensils and equipment contacting ~~potentially hazardous~~ time/temperature control for safety food may be cleaned less frequently than every four hours if:

1. In storage, containers of ~~potentially hazardous~~ time/temperature control for safety food and their contents are maintained at temperatures specified under Part III (2VAC5-585-260 et seq.) of this chapter and the containers are cleaned when they are empty;

2. Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:

a. The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature; and

Temperature	Cleaning Frequency
41°F (5.0°C) or less	24 hours
>41°F - 45°F (>5.0°C - 7.2°C)	20 hours
>45°F - 50°F (>7.2°C - 10.0°C)	16 hours
>50°F - 55°F (>10.0°C - 12.8°C)	10 hours

b. The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.

3. Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat ~~potentially hazardous~~ time/temperature control for safety food that is maintained at the temperatures specified under Part III, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;

4. Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Part III;

5. Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues; ~~or~~

6. The cleaning schedule is approved based on consideration of:

a. Characteristics of the equipment and its use;

b. The type of food involved;

c. The amount of food residue accumulation; and

d. The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or

7. In-use utensils are intermittently stored in a container of water in which the water is maintained at 135°F (57°C) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

E. Except when dry cleaning methods are used as specified under 2VAC5-585-1810, surfaces of utensils and equipment contacting food that is not ~~potentially hazardous~~ time/temperature control for safety food shall be cleaned:[N]

1. At any time when contamination may have occurred;

2. At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;

3. Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers; and

4. ~~Equipment~~ In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:

a. At a frequency specified by the manufacturer; or

b. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

2VAC5-585-1790. Cooking and baking equipment.

A. The food-contact surfaces of ~~in use~~ cooking and baking equipment shall be cleaned at least every 24 hours. This section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in 2VAC5-585-1780 D 6.

B. The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

2VAC5-585-1810. Dry cleaning.

A. If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not ~~potentially hazardous~~ time/temperature control for safety food.

B. Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose.

2VAC5-585-1870. ~~Returnables, cleaning for refilling.*~~ (Repealed.)

~~A. Except as specified in subsections B and C of this section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.~~

~~B. A food-specific container for beverages may be refilled at a food establishment if:~~

~~1. Only a beverage that is not a potentially hazardous food is used as specified under 2VAC5-585-600 A;~~

~~2. The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;~~

~~3. Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;~~

~~4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and~~

~~5. The container is refilled by:~~

~~a. An employee of the food establishment; or~~

~~b. The owner of the container if the beverage system includes a contamination-free transfer process that cannot be bypassed by the container owner.~~

~~C. Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.~~

Article 7
Sanitization of Equipment and Utensils

2VAC5-585-1885. Food-contact surfaces and utensils.

Equipment food-contact surfaces and utensils shall be sanitized.

2VAC5-585-1890. Before use after cleaning.*

Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.[P]

2VAC5-585-1900. Hot water and chemical.*

After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:

1. Hot water manual operations by immersion for at least 30 seconds as specified under 2VAC5-585-1670;[P]

2. Hot water mechanical operations by being cycled through equipment that is set up as specified under 2VAC5-585-1610, 2VAC5-585-1680, and 2VAC5-585-1690 and achieving a utensil surface temperature of 160°F (71°C) as measured by an irreversible registering temperature indicator;[P] or

3. Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 2VAC5-585-1700. Contact times shall be consistent with those on EPA-registered label use instructions by providing:

a. Except as specified under subdivision 3 b of this section, ~~an exposure~~ a contact time of at least 10 seconds for a chlorine solution specified under subdivision 1 of 2VAC5-585-1700;[P]

b. ~~An exposure~~ A contact time of at least ~~7~~ seven seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 100°F (38°C) or a pH of ~~8~~ 8.0 or less and a temperature of at least 75°F (24°C);[P]

c. ~~An exposure~~ A contact time of at least 30 seconds for other chemical sanitizing solutions;[P] or

d. ~~An exposure~~ A contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in 2VAC5-585-40.[P]

2VAC5-585-1920. Specifications.

A. Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.

B. Cloth gloves used as specified in 2VAC5-585-580 D shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork, ~~and~~ fish, or poultry.

C. Linens ~~and napkins~~ that are used as specified under 2VAC5-585-560 and cloth napkins shall be laundered between each use.

D. Wet wiping cloths shall be laundered daily.

E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

Article 9
Protection of Clean Items

2VAC5-585-1960. Equipment and utensils, air-drying required.

After cleaning and sanitizing, equipment and utensils:

1. Shall be air dried or used after adequate draining as specified in ~~40 CFR 180.9401~~ the first paragraph of 40 CFR 180.940 before contact with food; and

2. May not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

2VAC5-585-2000. Equipment, utensils, linens, and single-service and single-use articles.

A. Except as specified in subsection D of this section, cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored:

1. In a clean, dry location;

2. Where they are not exposed to splash, dust, or other contamination; and

3. At least six inches (15 ~~cm)~~ centimeters) above the floor.

B. Clean equipment and utensils shall be stored as specified under subsection A of this section and shall be stored:

1. In a self-draining position that allows air drying; and

2. Covered or inverted.

C. Single-service and single-use articles shall be stored as specified under subsection A of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

D. Items that are kept in closed packages may be stored less than six inches (15 ~~cm)~~ centimeters) above the floor on dollies, pallets, racks, and skids that are designed as provided under 2VAC5-585-1420.

2VAC5-585-2010. Prohibitions.

A. Except as specified in subsection B of this section, cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored:

1. In locker rooms;

2. In toilet rooms ~~or vestibules~~;

3. In garbage rooms;

4. In mechanical rooms;

5. Under sewer lines that are not shielded to intercept potential drips;

6. Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

7. Under open stairwells; or

8. Under other sources of contamination.

B. Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

2VAC5-585-2040. Preset tableware.

A. ~~Tableware~~ Except as specified in subsection B of this section, tableware that is preset shall be protected from contamination by being wrapped, covered, or inverted.

~~B. When tableware is preset, exposed, unused settings shall be:~~

~~1. Removed when a consumer is seated; or~~

~~2. Cleaned and sanitized before further use if the settings are not removed when a consumer is seated.~~

B. Preset tableware may be exposed if:

1. Unused settings are removed when a consumer is seated; or

2. Settings not removed when a consumer is seated are cleaned and sanitized before further use.

2VAC5-585-2045. Rinsing equipment and utensils after cleaning.

After being cleaned and sanitized, equipment and utensils shall not be rinsed before air drying or use unless:

1. The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under 2VAC5-585-1210 through 2VAC5-585-1430 and 2VAC5-585-1570 through 2VAC5-585-1720; and

2. The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA-registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

Part V
Water, Plumbing, and Waste

Article 1
Water

2VAC5-585-2050. Approved system.[*]

[~~Drinking~~ Pure] water shall be obtained from an approved [~~source that is~~ water system defined as]:

1. A [~~public water system~~ waterworks constructed, maintained, and operated in compliance with 12VAC5-590];[P] or

2. A [~~nonpublic water system that is constructed, maintained, and operated according to law~~ private well constructed, maintained, and operated in compliance with 12VAC5-630].[P]

2VAC5-585-2060. System flushing and disinfection.[*]

[~~A drinking water~~ An approved water] system shall be flushed and disinfected [~~before being placed in service~~] after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. [A sample shall be collected from the water system and the results of the analysis shall be total coliform negative prior to placing the water system into service.][P]

2VAC5-585-2070. Bottled drinking water.[*]

Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR Part 129~~, Processing and Bottling of Bottled Drinking Water~~.[P]

2VAC5-585-2080. [~~Quality~~ Pure water] standards.[*]

Except as specified under 2VAC5-585-2090:

1. Water from a [~~public water system~~ waterworks] shall meet [~~the applicable~~ water quality and quantity] standards [~~found in 40 CFR Part 141 and the Virginia Waterworks Regulations (12VAC5-590)~~ in accordance with 12VAC5-590].[P]

2. Water from a [~~nonpublic water system~~ private well] shall meet ~~state drinking water quality standards~~ [~~the bacteriological standards found in the Virginia Waterworks Regulations (12VAC5-590)~~ water quality and quantity standards in accordance with 12VAC5-630-370].[P]

2VAC5-585-2090. [~~Nondrinking~~ Nonpotable] water.[*]

A. A [~~nondrinking~~ nonpotable] water supply shall be used only if its use is approved.[P]

B. [~~Nondrinking~~ Nonpotable] water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, and fire protection~~, and irrigation~~.[P]

2VAC5-585-2100. Sampling.

[~~Except when used as specified under 2VAC5-585-2090, water~~ A. Water] from a [~~nonpublic water system~~ private well] shall be sampled and tested at least annually [~~and as required by state water quality regulations~~ for nitrate and total coliform]. [[Pf]]

[B. If nitrate, which is reported as "N" on the test results, exceeds 10 mg/L, the operator shall notify the department by the end of the day the operator is notified of the test result. Additional sampling may be required.[Pf]

C. If a sample is total coliform positive, the positive culture medium shall be further analyzed to determine if E. coli is present. The operator shall notify the department within two days from when the operator is notified of the coliform-positive test result. [Pf]

D. If E. coli is present, the operator shall notify the department by the end of the day the operator is notified of the test result.[Pf]]

[2VAC5-585-2110. Sample report.

~~The most recent~~ All sample ~~report~~ reports for the ~~nonpublic water system~~ private well shall be retained on file in the food establishment ~~or the report shall be maintained as specified by state water quality regulations~~ for a minimum of five years and be made available to the department upon request.]

2VAC5-585-2120. Capacity.[*]

A. The water source and system shall be of sufficient capacity to meet the [~~peak~~ maximum daily] water demands [and the peak hourly water demands] of the food establishment.[Pf]

B. Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food establishment.[Pf]

2VAC5-585-2130. Pressure.

Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under subdivisions 1 and 2 of 2VAC5-585-2160 to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure.[Pf]

2VAC5-585-2150. Distribution, delivery, and retention system.

Water shall be received from the source through the use of:

1. An approved public water main;[Pf] or

2. One or more of the following that shall be constructed, maintained, and operated according to law:[Pf]

a. Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances;[Pf]

b. Water transport vehicles; ~~and~~[Pf] or

c. Water containers.[Pf]

2VAC5-585-2160. Alternative water supply.

Water meeting the requirements specified under 2VAC5-585-2050 through 2VAC5-585-2130 shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

1. A supply of containers of commercially bottled drinking water;[Pf]

2. One or more closed portable water containers;[Pf]

3. An enclosed vehicular water tank;[Pf]

4. An on-premises water storage tank;[Pf] or

5. Piping, tubing, or hoses connected to an adjacent approved source.[Pf]

Article 2
Plumbing System

2VAC5-585-2170. Approved materials.[*]

A. A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law.[P]

B. A water filter shall be made of safe materials.[P]

2VAC5-585-2180. Approved system and cleanable fixtures.[*]

A. A plumbing system shall be designed, constructed, and installed according to law.[P]

B. A plumbing fixture such as a handwashing ~~lavatory~~ sink, toilet, or urinal shall be easily cleanable.[N]

2VAC5-585-2190. Handwashing sink, water temperature, and flow.

A. A handwashing sink shall be equipped to provide water at a temperature of at least 100°F (38°C) through a mixing valve or combination faucet.[Pf]

B. A steam mixing valve may not be used at a handwashing sink.

C. A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

D. If an automatic handwashing facility is installed, it shall be installed in accordance with manufacturer's instructions.

2VAC5-585-2200. Backflow prevention, air gap.[*]

An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than one inch (25 mm).[P]

2VAC5-585-2210. Backflow prevention device, design standard.

A backflow or backsiphonage prevention device installed on a water supply system shall comply with the Virginia Uniform Statewide Building Code (13VAC5-63) for construction, installation, maintenance, inspection, and testing for that specific application and type of device.[P]

2VAC5-585-2230. Handwashing sinks, numbers and capacities.[*]

A. Except as specified in subsections B and C of this section, at least one handwashing sink, or the number of handwashing sinks necessary for their convenient use by employees in areas specified under 2VAC5-585-2280, and not fewer than the number of handwashing sinks required by law shall be provided.[Pf]

B. If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing sinks in a food establishment that has at least one handwashing sink.

C. If approved, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically-treated towelettes for handwashing.

2VAC5-585-2240. Toilets and urinals.[*]

At least one toilet and not fewer than the toilets required by law shall be provided. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in law.

2VAC5-585-2250. Service sink.

A. At least one service sink or one curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

B. Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.

2VAC5-585-2260. Backflow prevention device, when required.[*]

A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb ~~(threaded faucet)~~ if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law by:

1. Providing an air gap as specified under 2VAC5-585-2200;[P] or

2. Installing an approved backflow prevention device as specified under 2VAC5-585-2210.[P]

2VAC5-585-2270. Backflow prevention device, carbonator.[*]

A. If not provided with an air gap as specified under 2VAC5-585-2200, a double check valve with an intermediate vent preceded by a screen of not less than 100 mesh to one inch (100 mesh to 25.4mm) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.[P]

B. A ~~single or double~~ dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under subsection A of this section.

2VAC5-585-2280. Handwashing sinks, locations.[*]

A handwashing sink shall be located:

1. To ~~be readily accessible for~~ allow convenient use by employees in food preparation, food dispensing, and warewashing areas;[Pf] and

2. In, or immediately adjacent to, toilet rooms.[Pf]

2VAC5-585-2310. Using a handwashing sink.

A. A handwashing sink shall be maintained so that it is accessible at all times for employee use.[Pf]

B. A handwashing sink may not be used for purposes other than handwashing.[Pf]

C. An automatic handwashing sink shall be used in accordance with manufacturer's instructions.[Pf]

2VAC5-585-2320. Prohibiting a cross connection.~~*~~

A. ~~Except as specified in 9 CFR 308.3(d) for firefighting, a~~ A person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.[P]

B. The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.~~N~~ [Pf]

2VAC5-585-2330. Scheduling inspection and service for a water system device.

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.[Pf]

2VAC5-585-2340. Water reservoir of fogging devices, cleaning.~~*~~

A. A reservoir that is used to supply water to a device such as a produce fogger shall be:

1. Maintained in accordance with manufacturer's specifications;[P] and

2. Cleaned in accordance with manufacturer's specifications or according to the procedures specified under subsection B of this section, whichever is more stringent.[P]

B. Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

1. Draining and complete disassembly of the water and aerosol contact parts;[P]

2. Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;[P]

3. Flushing the complete system with water to remove the detergent solution and particulate accumulation;[P] and

4. Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L (ppm) hypochlorite solution.[P]

2VAC5-585-2350. System maintained in good repair.~~*~~

A plumbing system shall be:

1. Repaired according to law;[P] and

2. Maintained in good repair.~~S~~

Article 3
Mobile Water Tank and Mobile Food Establishment Water Tank

2VAC5-585-2360. Approved materials.

Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

1. Safe;[P]

2. Durable, corrosion resistant, and nonabsorbent; and

3. Finished to have a smooth, easily cleanable surface.

2VAC5-585-2420. Hose, construction and identification.

A hose used for conveying [~~drinking~~ potable] water from a water tank shall be:

1. Safe;[P]

2. Durable, corrosion resistant, and nonabsorbent;

3. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;

4. Finished with a smooth interior surface; and

5. Clearly and durably identified as to its use if not permanently attached.

2VAC5-585-2430. Filter, compressed air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and [~~drinking~~ potable] water system when compressed air is used to pressurize the water tank system.[P]

2VAC5-585-2460. System flushing and disinfection.~~*~~

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.[P]

2VAC5-585-2490. Tank, pump, and hoses, dedication.

A. Except as specified in subsection B of this section, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.[P]

B. Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

2VAC5-585-2505. Establishment drainage system.

Food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under 2VAC5-585-2180 A.

2VAC5-585-2520. Backflow prevention.~~*~~

A. Except as specified in subsections B, C, and D of this section, a direct connection may not exist between the sewage

system and a drain originating from equipment in which food, portable equipment, or utensils are placed.[P]

B. Subsection A of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

C. If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within five feet (1.5 meters) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

D. If allowed by law, a warewashing or culinary sink may have a direct connection.

2VAC5-585-2540. Conveying sewage.~~*~~

Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.[P]

2VAC5-585-2550. Removing mobile food establishment wastes.

Sewage and other liquid wastes shall be removed from a mobile food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created.[Pf]

2VAC5-585-2570. Approved sewage disposal system.~~*~~

Sewage shall be disposed through an approved facility that is:

1. A public sewage treatment plant;[P] or

2. An individual sewage disposal system that is sized, constructed, maintained, and operated ~~according to law~~ in accordance with the regulations promulgated pursuant to Chapter 6 (§ 32.1-163 et seq.) of Title 32.1 of the Code of Virginia.[P]

2VAC5-585-2595. Indoor storage area.

If located within the food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under 2VAC5-585-2790, 2VAC5-585-2810 through 2VAC5-585-2880, 2VAC5-585-2930, and 2VAC5-585-2940.

2VAC5-585-2840. Floor carpeting, restrictions and installation.

A. A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing ~~lavatories~~ sinks, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

B. If carpeting is installed as a floor covering in areas other than those specified under subsection A of this section, it shall be:

1. Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

2. Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

2VAC5-585-2930. Outer openings, protected.

A. Except as specified in subsections B through E of this section, outer openings of a food establishment shall be protected against the entry of insects and rodents by:

1. Filling or closing holes and other gaps along floors, walls and ceilings;

2. Closed, tight-fitting windows; and

3. Solid self-closing, tight-fitting doors.

B. Subsection A of this section does not apply if a food establishment opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

C. Exterior doors used as exits need not be self-closing if they are:

1. Solid and tight-fitting;

2. Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the food establishment; and

3. ~~Restricted~~ Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

D. Except as specified in subsections B and E of this section, if the windows or doors of a food establishment, or of a larger structure within which a food establishment is located, are kept open for ventilation or other purposes, or a temporary food establishment is not provided with windows and doors as specified in subsection A of this section, the openings shall be protected against the entry of insects and rodents by:

1. 16 mesh to one-inch (16 mesh to 25.4-mm) screens;

2. Properly designed and installed air curtains to control flying insects; or

3. Other effective means.

E. Subsection D of this section does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.

2VAC5-585-2990. Private homes and living or sleeping quarters, use prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting food establishment operations.[P]

2VAC5-585-3000. Living or sleeping quarters, separation.

~~Sleeping~~ Living or sleeping quarters located on the premises of a food establishment such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for food establishment operations by complete partitioning and solid self-closing doors.

2VAC5-585-3020. Handwashing cleanser, availability.

Each handwashing sink or group of two adjacent handwashing sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap.[Pf]

2VAC5-585-3030. Hand drying provision.

Each handwashing sink or group of adjacent handwashing sinks shall be provided with:

1. Individual, disposable towels;[Pf]

2. A continuous towel system that supplies the user with a clean towel; ~~or~~[Pf]

3. A heated-air hand drying device;[Pf] or

4. A hand-drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures.[Pf]

2VAC5-585-3040. Handwashing aids and devices, use restrictions.

A sink used for food preparation or utensil washing or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes may not be provided with the handwashing aids and devices required for a handwashing sink as specified under 2VAC5-585-2650 C, 2VAC5-585-3020, and 2VAC5-585-3030 ~~and 2VAC5-585-2650 C~~.

2VAC5-585-3047. Disposable towels, waste receptacle.

A handwashing sink or group of adjacent handwashing sinks that is provided with disposable towels shall be provided with a waste receptacle as specified under 2VAC5-585-2650 C.

2VAC5-585-3070. Toilet tissue, availability.

A supply of toilet tissue shall be available at each toilet.[Pf]

2VAC5-585-3130. Toilet rooms, convenience and accessibility.

Toilet rooms shall be conveniently located and accessible to employees during all hours of operation. ~~Toilet rooms intended for use by customers shall not necessitate travel through food preparation or handling areas.~~

2VAC5-585-3150. Distressed merchandise, segregation and location.

Products that are held by the ~~person in charge~~ operator for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles.[Pf]

2VAC5-585-3210. Cleaning maintenance tools, preventing contamination.~~*~~

Food preparation sinks, handwashing ~~lavatories~~ sinks, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.[Pf]

2VAC5-585-3240. Cleaning of plumbing fixtures.

Plumbing fixtures such as handwashing sinks, toilets, and urinals shall be cleaned as often as necessary to keep them clean ~~and maintained and used as specified under 2VAC5-585-2310~~.

2VAC5-585-3250. Closing toilet room doors.

~~Toilet room doors as specified under 2VAC5-585-2920 shall be kept closed except during cleaning and maintenance operations unless otherwise required by other regulations or law.~~ Except during cleaning and maintenance operations, toilet room doors as specified under 2VAC5-585-2920 shall be kept closed.

2VAC5-585-3270. Controlling pests.~~*~~

The ~~presence~~ premises shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to ~~minimize~~ eliminate their presence on the premises by:

1. Routinely inspecting incoming shipments of food and supplies;[N]

2. Routinely inspecting the premises for evidence of pests;[N]

3. Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 2VAC5-585-3360, 2VAC5-585-3440, and 2VAC5-585-3450;[Pf] and

4. Eliminating harborage conditions.[N]

2VAC5-585-3310. Prohibiting animals.~~*~~

A. Except as specified in subsections B and C of this section, live animals may not be allowed on the premises of a food establishment.[Pf]

B. Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:

1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

2. Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

3. In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled

employee or person, if a health or safety hazard will not result from the presence or activities of the service animal;

4. Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

a. Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas;

b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present; and

c. Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; [~~and~~]

5. In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly ~~restricted~~ confined, such as in a variety store that sells pets or a tourist park that displays animals [; and

6. Dogs in outdoor dining areas if:

a. The outdoor dining area is not fully enclosed with floor to ceiling walls and is not considered a part of the interior physical facility.

b. The outdoor dining area is equipped with an entrance that is separate from the main entrance to the food establishment, and the separate entrance serves as the sole means of entry for patrons accompanied by dogs.

c. A sign stating that dogs are allowed in the outdoor dining area is posted at each entrance to the outdoor dining area in such a manner as to be clearly observable by the public.

d. A sign within the outdoor dining area stating the requirements as specified in subdivisions 6 e, f, and g of this subsection is provided in such a manner as to be clearly observable by the public.

e. Food and water provided to dogs is served using equipment that is not used for the service of food to a person or is served in single-use articles.

f. Dogs are not allowed on chairs, seats, benches, or tables.

g. Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.

h. The establishment provides effective means for cleaning up dog vomitus and fecal matter].

C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result.

Part VII
Poisonous or Toxic Materials

Article 1
Labeling and Identification

2VAC5-585-3320. Original containers - identifying information, prominence.*

Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label.[Pf]

2VAC5-585-3330. Working containers - common name.*

Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material.[Pf]

Article 2
Operational Supplies and Applications

2VAC5-585-3340. Storage, separation.*

Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

1. Separating the poisonous or toxic materials by spacing or partitioning;[S P] and

2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This subsection does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles~~; and~~.[P]

~~3. Detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes and other chemicals shall be stored separately from insecticides and rodenticides.~~

2VAC5-585-3350. Presence and use restriction.*

A. Only those poisonous or toxic materials that are required for the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food establishment.[S Pf]

B. Subsection A of this section does not apply to packaged poisonous or toxic materials that are for retail sale.

2VAC5-585-3360. Conditions of use.*

A. Poisonous or toxic materials shall be:

1. Used according to:

a. Law and this chapter;

b. Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment;[P]

c. The conditions of certification, if certification is required, for use of the pest control materials;[P] and

d. Additional conditions that may be established by the department; and

2. Applied so that:

a. A hazard to employees or other persons is not constituted;[P] and

b. Contamination including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:[P]

(1) Removing the items;[P]

(2) Covering the items with impermeable covers;[P] or

(3) Taking other appropriate preventive actions;[P] and

(4) Cleaning and sanitizing equipment and utensils after the application.[P]

B. A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC § 136(e); §§ 3.2-3929, 3.2-3930, and 3.2-3931 of the Code of Virginia (Virginia Pesticide Control Act); or a person under the direct supervision of a certified applicator.[Pf]

2VAC5-585-3370. Poisonous or toxic material containers.~~*~~

A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food.[P]

2VAC5-585-3380. Sanitizers, criteria.~~*~~

Chemical sanitizers, including chemical sanitizing solutions generated on site, and other chemical antimicrobials applied to food-contact surfaces shall ~~meet the requirements specified in 40 CRF 180.940.~~:

1. Meet the requirements specified in 40 CFR 180.940;[P] or

2. Meet the requirements as specified in 40 CFR 180.2020.[P]

2VAC5-585-3390. Chemicals for washing fruits and vegetables, criteria.~~*~~

A. Chemicals, including those generated on site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in ~~21 CFR 173.315~~ 40 CFR Part 156 and shall:[P]

1. Be an approved food additive listed for this intended use in 21 CFR Part 173;[P]

2. Be generally recognized as safe for this intended use;[P] or

3. Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification).[P]

B. Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368.[P]

2VAC5-585-3400. Boiler water additives, criteria.~~*~~

Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310.[P]

2VAC5-585-3410. Drying agents, criteria.~~*~~

Drying agents used in conjunction with sanitization shall:

1. Contain only components that are listed as one of the following:

a. Generally recognized as safe for use in food as specified in 21 CFR Part 182~~, Substances Generally Recognized as Safe,~~ or 21 CFR Part 184~~, Direct Food Substances Affirmed as Generally Recognized as Safe~~;[P]

b. Generally recognized as safe for the intended use as specified in 21 CFR Part 186~~, Indirect Food Substances Affirmed as Generally Recognized as Safe~~;[P]

c. Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to food as described in 21 CFR 170.30;[P]

d. Subject of an effective food contact notification as described in § 409(h) of the Federal Food, Drug, and Cosmetic Act (21 USC § 348(h));[P]

e. Approved for use as a drying agent under a prior sanction ~~specified in 21 CFR Part 181, Prior-Sanctioned Food Ingredients~~ as described in § 201(s)(4) of the Federal Food, Drug, and Cosmetic Act (21 USC § 321(s)(4));[P]

~~d.~~ f. Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts ~~175-178~~ 174-178;[P] or

~~e.~~ g. Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39~~, Threshold of Regulation for Substances Used in Food-Contact Articles~~;[P] and

2. When sanitization is with chemicals, the approval required under ~~subdivisions 1 c or~~ subdivision 1 e or 1 g of this section or the ~~regulation~~ chapter as an indirect food additive required under subdivision 1 ~~d~~ f of this section~~,~~ shall be specifically for use with chemical sanitizing solutions.[P]

2VAC5-585-3420. Lubricants - incidental food contact, criteria.~~*~~

Lubricants shall meet the requirements specified in 21 CFR 178.3570 if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.[P]

2VAC5-585-3430. Restricted use pesticides, criteria.~~*~~

Restricted use pesticides specified under subsection B of 2VAC5-585-3360 shall meet the requirements specified in 40 CFR Part 152, Subpart I~~, Classification of Pesticides~~.[P]

2VAC5-585-3440. Rodent bait stations.~~*~~

Rodent bait shall be contained in a covered, tamper-resistant bait station.[P]

2VAC5-585-3450. Tracking powders, pest control and monitoring.~~*~~

A. ~~A~~ Except as specified in subsection B of this section, a tracking powder pesticide may not be used in a food establishment.[P]

B. If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.[N]

2VAC5-585-3460. Medicines - restriction and storage.~~*~~

A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment.[Pf]

B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 2VAC5-585-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.[P]

2VAC5-585-3470. Refrigerated medicines, storage.~~*~~

Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

1. Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines;[P] and

2. Located so they are inaccessible to children.[P]

2VAC5-585-3480. First aid supplies, storage.~~*~~

First aid supplies that are in a food establishment for the employees' use shall be:

1. Labeled as specified under 2VAC5-585-3320;~~S~~ [Pf] and

2. Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles.~~S~~ [P]

Article 3
Stock and Retail Sale

2VAC5-585-3500. Storage and display, separation.~~*~~

Poisonous or toxic materials shall be stored and displayed for retail sale so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

1. Separating the poisonous or toxic materials by spacing or partitioning;~~S~~ [P] and

2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.[P]

Part VIII
Compliance and Enforcement

Article 1
Applicability of Chapter

2VAC5-585-3510. Public health protection.

A. The department shall apply this ~~regulation~~ chapter to promote its underlying purpose, as specified in 2VAC5-585-20, of safeguarding public health and ensuring that food is safe ~~and~~, unadulterated, and honestly presented when offered to the consumer.

B. In enforcing the provisions of this ~~regulation~~ chapter, the department shall assess existing facilities or equipment that were in use before the effective date of this ~~regulation~~ chapter based on the following considerations:

1. Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;

2. Whether food-contact surfaces comply with 2VAC5-585-960 through 2VAC5-585-1060;

3. Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 2VAC5-585-1450; and

4. The existence of a documented agreement with the establishment operator that the facilities or equipment will be replaced or upgraded as specified in ~~the following:~~ subdivision 6 of 2VAC5-585-3660.

~~a. Except as specified under subdivision B 4 b of this section, replace existing facilities and equipment specified in this section with facilities and equipment that comply with this regulation if:~~

~~(1) The department directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted;~~

~~(2) The department directs the replacement of the facilities and equipment because of a change of ownership; or~~

~~(3) The facilities and equipment are replaced in the normal course of operation;~~

~~b. Upgrade or replace refrigeration equipment as specified under 2VAC5 585 820 A 2 b, if the circumstances specified under subdivision B 4 a of this section do not occur first.~~

2VAC5-585-3541. Documentation of proposed variance and justification.

Before a variance from a requirement of this ~~regulation~~ chapter is approved, the information that shall be provided by the person requesting the variance and retained in the department's file on the food establishment includes:

1. A statement of the proposed variance of the regulation requirement citing relevant regulation section numbers;[Pf]

2. An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant regulation sections will be alternatively addressed by the proposal;[Pf] and

3. A HACCP plan if required as specified under 2VAC5-585-3620 A that includes the information specified under 2VAC5-585-3630 as it is relevant to the variance requested.[Pf]

2VAC5-585-3542. Conformance with approved procedures.~~*~~

If the department grants a variance as specified in 2VAC5-585-3540, or a HACCP plan is otherwise required as specified under 2VAC5-585-3620, the operator shall:

1. Comply with the HACCP plans and procedures that are submitted as specified under 2VAC5-585-3630 and approved as a basis for the modification or waiver;[P] and

2. Maintain and provide to the department, upon request, records specified under subdivisions 4 and 5 [c] of 2VAC5-585-3630 that demonstrate that the following are routinely employed:

a. Procedures for monitoring critical control points;[Pf]

b. Monitoring of the critical control points;[Pf]

c. Verification of the effectiveness of an operation or process;[Pf] and

d. Necessary corrective actions if there is failure at a critical control point.[Pf]

Article 2
Plan Submission and Approval

2VAC5-585-3600. Facility and operating plans - when plans are required.

An operator shall submit to the department properly prepared plans and specifications for review and approval ~~when appropriate or when requested by the department. Such instances shall include~~ before:

1. The construction of a food establishment;[Pf]

2. The conversion of an existing structure for use as a food establishment;[Pf] or

3. The remodeling of a food establishment or a change of type of food establishment or food operation if the department determines that plans and specifications are necessary to ensure compliance with this ~~regulation~~ chapter.[Pf]

2VAC5-585-3620. When a HACCP plan is required.

A. Before engaging in an activity that requires a HACCP plan, an operator shall submit to the department for approval a properly prepared HACCP plan as specified under 2VAC5-585-3630 and the relevant provisions of this chapter if:

1. Submission of a HACCP plan is required according to law;

2. A variance is required as specified under 2VAC5-585-700 D 4, 2VAC5-585-860, or 2VAC5-585-1300 B~~, or subdivision 2VAC5-585-700 D 3~~; or

3. The department determines that a food preparation or processing method requires a variance based on a plan submittal specified under 2VAC5-585-3610, an inspectional finding, or a variance request.

B. ~~An operator shall have a properly prepared HACCP plan~~ Before engaging in reduced oxygen packaging without a variance as specified under 2VAC5-585-870, an operator shall submit a properly prepared HACCP plan to the department.

2VAC5-585-3630. Contents of a HACCP plan.

For a food establishment that is required under 2VAC5-585-3620 to have a HACCP plan, the [~~plan and specifications shall indicate~~ operator shall submit to the department a properly prepared HACCP plan that includes]:

1. [General information such as the name of the operator, the food establishment address, and contact information;

2.] A categorization of the types of ~~potentially hazardous~~ time/temperature control for safety foods that are [~~specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the department~~ to be controlled under the HACCP plan];[Pf]

[~~2.~~ 3.] A flow diagram [~~by specific food or category type identifying critical control points and providing information on the following~~ or chart for each specific food or category type that identifies]:

a. [~~Ingredients, materials, and equipment used in the preparation of that food~~ Each step in the process];[Pf] [~~and~~]

b. [~~Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved~~ The hazards and controls for each step in the flow diagram or chart];[Pf]

[c. The steps that are critical control points;[Pf]

d. The ingredients, materials, and equipment used in the preparation of that food;[Pf] and

e. The formulations or recipe that delineates methods and procedural control measures that address the food safety concerns involved;[Pf]]

[~~3. Food employee and supervisory training plan that addresses the food safety issues of concern;~~[Pf]]

4. [~~A statement of standard operating procedures for the plan under consideration including clearly identifying~~ A critical control points summary for each specific food category type that clearly identifies]:

a. Each critical control point;[Pf]

b. The critical limits for each critical control point;[Pf]

c. The method and frequency for monitoring and controlling each critical control point by the [designated] food employee [~~designated by~~ or] the person in charge;[Pf]

d. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;[Pf]

e. Action to be taken by the [designated food employee or] person in charge if the critical limits for each critical control point are not met;[Pf] and

f. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;[Pf] [~~and~~]

5. [~~Additional scientific data or other information, as required by the department, supporting the determination that food safety is not compromised by the proposal.~~[Pf] Supporting documents such as:

a. Food employee and supervisory training plan that addresses the food safety issues of concern;[Pf]

b. Copies of blank record forms that are necessary to implement the HACCP plan;[Pf]

c. Additional scientific data or other information, as required by the department, supporting the determination that food safety is not compromised by the proposal;[Pf]and

6. Any other information required by the department.]

2VAC5-585-3655. Responsibilities of the department.

A. At the time of the initial inspection, the department shall provide to the operator a copy of this chapter so that the operator is notified of the compliance requirements and the conditions of retention, as specified under 2VAC5-585-3660, that are applicable to the food establishment.

B. Failure to provide the information specified in subsection A of this section does not prevent the department from taking authorized action or seeking remedies if the operator fails to comply with this chapter or an order, warning, or directive of the department.

2VAC5-585-3660. Responsibilities of the operator.

The operator shall:

1. Comply with the provisions of this chapter including the conditions of a granted variance as specified under 2VAC5-585-3542 and approved plans as specified under 2VAC5-585-3610;

2. If a food establishment is required under 2VAC5-585-3620 to operate under a HACCP plan, comply with the plan as specified under 2VAC5-585-3542;

3. Immediately contact the department to report an illness of a food employee or conditional employee as specified under 2VAC5-585-80 B;

4. Immediately discontinue operations and notify the department if an imminent health hazard may exist as specified under 2VAC5-585-3910;

5. Allow authorized representatives of the commissioner access to the food establishment as specified under 2VAC5-585-3820;

6. Replace existing facilities and equipment specified in 2VAC5-585-3510 with facilities and equipment that comply with this chapter if:

a. The department directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted;

b. The department directs the replacement of the facilities and equipment because of a change of ownership; or

c. The facilities and equipment are replaced in the normal course of operation;

7. Comply with directives of the department including timeframes for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the department in regard to the operator's food establishment or in response to community emergencies;

8. Accept notices issued and served by the department according to law;

9. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this chapter or a directive of the department, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives; and

10. Notify customers that a copy of the most recent establishment inspection report is available upon request by posting a sign or placard in a location in the food establishment that is conspicuous to customers or by another method acceptable to the department.

Article 4
Inspection and Correction of Violations

2VAC5-585-3800. Frequency, establishing inspection interval.

~~Food establishments shall be inspected by the designee of the commissioner. Inspections of food establishments shall be performed as often as necessary for the enforcement of this part in accordance with the following:~~

~~1.~~ A. Except as specified in ~~subdivisions 2 and 3~~ subsections B and C of this section, the department shall inspect a food establishment at least once every six months.

~~2.~~ B. The department may increase the interval between inspections beyond six months if:

~~a.~~ 1. The food establishment is fully operating under an approved and validated HACCP plan as specified under ~~2VAC5-585-3630 and~~ subdivisions 1 and 2 of 2VAC5-585-3542 and 2VAC5-585-3630.

~~b.~~ 2. The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction.

~~c.~~ 3. The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not ~~potentially hazardous~~ time/temperature control for safety food such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.

~~3.~~ C. The department shall periodically inspect a temporary food establishment that prepares, sells, or serves unpackaged ~~potentially hazardous~~ time/temperature control for safety food and that:

~~a.~~ 1. Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or

~~b.~~ 2. Has inexperienced food employees.

2VAC5-585-3810. Performance-based and risk-based inspections.

Within the parameters specified in 2VAC5-585-3800, the department shall prioritize, and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this chapter and the establishment's potential as a vector of foodborne illness by evaluating:

1. Past performance for nonconformance with this chapter or HACCP plan requirements that are ~~critical~~ priority items or priority foundation items;

2. Past performance for numerous or repeat violations of this chapter or HACCP plan requirements that are ~~noncritical~~ core items;

3. Past performance for complaints investigated and found to be valid;

4. The hazards associated with the particular foods that are prepared, stored, or served;

5. The type of operation including the methods and extent of food storage, preparation, and service;

6. The number of people served; and

7. Whether the population served is a highly susceptible population.

[2VAC5-585-3815. Competency of ~~personnel~~ inspectors.

A. An authorized representative of the commissioner who inspects a food establishment or conducts plan review for compliance with this regulation shall have the knowledge, skills, and ability to adequately perform the required duties.

B. The department shall ensure that authorized representatives who inspect a food establishment or conduct plan review for compliance with this chapter have access to training and continuing education as needed to properly identify violations and apply the chapter.]

2VAC5-585-3820. Access allowed at reasonable times.

After the authorized representative of the commissioner presents official credentials and ~~identifies~~ provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the authorized representative to determine if the food establishment is in compliance with this chapter by allowing access to the establishment, allowing inspection, and providing information and records specified in this chapter and to which the department is entitled according to law, during the food establishment's hours of operation and other reasonable times.

2VAC5-585-3830. Refusal, notification of right to access, and final request for access.

If a person denies access to the authorized representative of the commissioner, the authorized representative shall:

1. Inform the person that:

a. The person is required to allow access to the authorized representative as specified under 2VAC5-585-3820;

b. ~~If access is denied, the~~ The department will refer the matter to the Commonwealth's Attorney for handling in accordance with applicable sections of the Code of Virginia; and

2. Make a final request for access.

2VAC5-585-3840. Refusal, reporting.

If after the authorized representative of the commissioner presents credentials and ~~identifies the purpose of and the intent to conduct an inspection~~ provides notice as specified under 2VAC5-585-3820, explains the authority upon which access is requested, and makes a final request for access as specified in 2VAC5-585-3830, the person in charge continues to refuse access, the authorized representative shall provide details of the denial of access on an inspection report form.

2VAC5-585-3860. Documenting information and observations.

The authorized representative of the commissioner shall document on an inspection report form:

1. Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation, inspection date, and other information such as type of water supply and sewage disposal, and personnel certificates that may be required; and

2. Specific factual observations of violative conditions or other deviations from this chapter that require correction by the establishment operator including:

a. Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this chapter specified under 2VAC5-585-60;

b. Failure of food employees, conditional employees, and the person in charge ~~to demonstrate their knowledge of their responsibility~~ to report a disease or medical condition as specified under 2VAC5-585-80 B and D;

c. Nonconformance with ~~critical items~~ priority items and priority foundation items of this chapter;

d. Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the department as specified under ~~2VAC5-585-60~~ 2VAC5-585-3542;

e. Failure of the person in charge to provide records required by the department for determining conformance with a HACCP plan as specified under subdivision 4 f of 2VAC5-585-3630; and

f. Nonconformance with critical limits of a HACCP plan.

2VAC5-585-3910. Imminent health hazard, ceasing operations and reporting.

A. Except as specified in subsection B of this section, an operator shall immediately discontinue operations and notify the department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.P

B. An operator need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

2VAC5-585-3930. ~~Critical violation~~ Priority or priority foundation item, timely correction.

A. Except as specified in subsection B of this section, an operator or person in charge shall at the time of inspection correct a ~~critical~~ violation of a priority item or priority foundation item of this chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.Pf

B. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the department may agree to or specify a longer time frame, not to exceed ~~10 calendar days after the inspection, for the operator or person in charge to correct critical violations or HACCP plan deviations.~~:

1. 72 hours after the inspection, for the operator to correct violations of a priority item; or

2. 10 calendar days after the inspection, for the operator to correct violations of a priority foundation item or HACCP plan deviations.

2VAC5-585-3940. Verification and documentation of correction.

A. After observing at the time of inspection a correction of a ~~critical~~ violation ~~or~~ of a priority item or priority foundation item or a HACCP plan deviation, the authorized representative of the commissioner shall enter the violation and information about the corrective action on the inspection report.

B. As specified under 2VAC5-585-3930 B, after receiving notification that the operator has corrected a violation of a priority item or priority foundation item or HACCP plan deviation, or at the end of the specified period of time, the authorized representative shall verify correction of the ~~critical~~ violation or deviation during the next scheduled inspection of the establishment and shall document the information on an inspection report, and enter the report in the department's records.

2VAC5-585-3950. ~~Noncritical violation~~ Core items, ~~time frame for~~ timely correction.

A. Except as specified in subsection B of this section, the operator or person in charge shall correct ~~noncritical violations~~ core items by a date and time agreed to or specified by the department but no later than 90 calendar days after the inspection.

B. The department may approve a compliance schedule that extends beyond the time limits specified under subsection A of this section if a written schedule of compliance is submitted by the operator and no health hazard exists or will result from allowing an extended schedule for compliance.

Article 5
Prevention of Foodborne Disease Transmission by Employees

2VAC5-585-4040. Investigation and control, obtaining information: personal history of illness, medical examination, and specimen analysis.

The department shall act when it has reasonable cause to believe that a food employee or conditional employee has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound, or acute respiratory infection, by:

1. Securing a confidential medical history of the food employee or conditional employee suspected of transmitting disease or making other investigations as deemed appropriate; and

2. Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected food employee ~~and other employees~~ or conditional employee.

2VAC5-585-4050. Restriction or exclusion of food employee.

Based on the findings of an investigation related to a food employee or conditional employee who is suspected of being infected or diseased, the department may ~~request that~~ issue an order to the suspected food employee, ~~or~~ conditional employee, or operator ~~institute~~ instituting one or more of the following control measures:

1. Restricting the food employee or conditional employee; ~~or~~

2. Excluding the food employee or conditional employee; or

3. Closing the food establishment in accordance with law.

2VAC5-585-4060. Restriction or exclusion request: information required.

Based on the findings of the investigation as specified in 2VAC5-585-4040 and to control disease transmission, the department may ~~make a request~~ issue an order of restriction or exclusion to the suspected food employee or the operator ~~regarding restriction or exclusion if the request~~ without prior warning, notice of hearing, or a hearing if the order:

1. States the reasons for the restriction or exclusion that is ~~requested~~ ordered;

2. States the evidence that the food employee or operator shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;

3. States that the suspected food employee or the operator may request an appeal hearing by submitting a timely request as provided in law; and

4. Provides the name and address of the authorized representative of the commissioner to whom a request for appeal hearing be made.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (2VAC5-585)

~~Food Safety and Security Program, Inspection Report~~

~~Food Safety and Security Program, Record of Complaint~~

~~Food Safety and Security Program, Record of Complaint, FBI~~

~~Food Safety and Security Program, Sample Collection Report~~

Food Safety and Security Program, Retail Inspection Report, ODF-FSSP-10001 (rev. 9/14)

Food Safety and Security Program, Complaint Report, ODF-FSSP-10004 (rev. 12/13)

Food Safety and Security Program, Foodborne Illness Complaint Report, ODF-FSSP-10003 (rev. 12/13)

Food Safety and Security Program, Sample Collection Report, ODF-FSSP-10002 (rev. 12/13)

DOCUMENTS INCORPORATED BY REFERENCE (2VAC5-585)

~~Approved Drug Products with Therapeutic Equivalence Evaluations (updated daily), 25th Edition, available from the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs at http://www.fda.gov/cder/ob/default.htm.~~

~~Grade "A" Pasteurized Milk Ordinance, 2003 Revision, published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835.~~

~~Grade "A" Condensed and Dry Milk Ordinance, 1995 Revision, published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835~~

Approved Drug Products with Therapeutic Equivalence Evaluations, 34th Edition, 2014, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs at http://www.fda.gov/cder/ob/default.htm

Grade "A" Pasteurized Milk Ordinance, 2013 Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835

Interstate Certified Shellfish Shippers List (updated monthly), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood (HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835~~.~~

~~National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (2007), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood (HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835.~~

~~NSF/ANSI 18-2006 Manual Food and Beverage Dispensing Equipment, American National Standard, published by NSF International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, Michigan 48113-0140.~~

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, [~~2011~~ 2013] Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood

(HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835

NSF/ANSI 18-2012 Manual Food and Beverage Dispensing Equipment, 2012, NSF International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, MI 48113-0140, www.nsf.org

Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, Conference for Food Protection, 30 Elliott Court, Martinsville, IN 46151-1331

United States Standards, Grades, and Weight Classes for Shell Eggs, AMS-56, effective July 20, 2000, U.S. Department of Agriculture, Agricultural Marketing Service, Poultry Programs, STOP 0259, Room 3944-South, 1400 Independence Avenue, SW, Washington, DC 20250-0259

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TITLE 12. HEALTH

STATE BOARD OF HEALTH

Final Regulation

REGISTRAR'S NOTICE: The State Board of Health is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 22 of the Code of Virginia, which excludes the board in promulgating regulations pursuant to § 35.1-14 C of the Code of Virginia that incorporate the federal Food and Drug Administration's Food Code pertaining to restaurants or food service. In addition, § 35.1-14 E provides that the provisions of the Administrative Process Act shall not apply to the adoption of any regulation pursuant to § 35.1-14 C if the Board of Agriculture and Consumer Services adopts the same edition of the Food Code, or the same portions thereof, pursuant to § 3.2-5121 B of the Code of Virginia and the regulations adopted by the State Board of Health and the Board of Agriculture and Consumer Services have the same effective date.

Title of Regulation: **12VAC5-421. Food Regulations (amending 12VAC5-421-10, 12VAC5-421-50 through 12VAC5-421-210, 12VAC5-421-220, 12VAC5-421-250 through 12VAC5-421-410, 12VAC5-421-430 through 12VAC5-421-520, 12VAC5-421-540 through 12VAC5-421-580, 12VAC5-421-600, 12VAC5-421-630, 12VAC5-421-650, 12VAC5-421-670, 12VAC5-421-680, 12VAC5-421-700 through 12VAC5-421-765, 12VAC5-421-780 through 12VAC5-421-880, 12VAC5-421-900, 12VAC5-421-930 through 12VAC5-421-960, 12VAC5-421-980, 12VAC5-421-990, 12VAC5-421-1000, 12VAC5-421-1070, 12VAC5-421-1090, 12VAC5-421-1100, 12VAC5-421-1110, 12VAC5-421-1180, 12VAC5-421-1190, 12VAC5-421-1230, 12VAC5-421-1240, 12VAC5-421-1300, 12VAC5-421-1310, 12VAC5-421-1320, 12VAC5-421-1350, 12VAC5-421-1360, 12VAC5-421-1370, 12VAC5-421-1450, 12VAC5-421-1460, 12VAC5-421-1500 through 12VAC5-421-1530, 12VAC5-421-1630, 12VAC5-421-1650 through 12VAC5-421-1680, 12VAC5-421-1700, 12VAC5-421-1720, 12VAC5-421-1730, 12VAC5-421-1740, 12VAC5-421-1770, 12VAC5-421-1780, 12VAC5-421-1810, 12VAC5-421-1890, 12VAC5-421-1900, 12VAC5-421-1920, 12VAC5-421-2040, 12VAC5-421-2050 through 12VAC5-421-2130, 12VAC5-421-2160 through 12VAC5-421-2210, 12VAC5-421-2230, 12VAC5-421-2250 through 12VAC5-421-2280, 12VAC5-421-2310 through 12VAC5-421-2360, 12VAC5-421-2420, 12VAC5-421-2430, 12VAC5-421-2460, 12VAC5-421-2490, 12VAC5-421-2520, 12VAC5-421-2540, 12VAC5-421-2550, 12VAC5-421-2570, 12VAC5-421-2990, 12VAC5-421-3020, 12VAC5-421-3030, 12VAC5-421-3070, 12VAC5-421-3150, 12VAC5-421-3210, 12VAC5-421-3270, 12VAC5-421-3310 through 12VAC5-421-3500, 12VAC5-421-3590, 12VAC5-421-3600, 12VAC5-421-3620, 12VAC5-421-3630, 12VAC5-421-3670, 12VAC5-421-3700, 12VAC5-421-3770, 12VAC5-421-3780, 12VAC5-421-3800, 12VAC5-421-3810, 12VAC5-421-3815, 12VAC5-421-3860, 12VAC5-421-3910, 12VAC5-421-3930 through 12VAC5-421-3980, 12VAC5-421-4000; adding 12VAC5-421-55, 12VAC5-421-65, 12VAC5-421-255, 12VAC5-421-725, 12VAC5-421-750, 12VAC5-421-755, 12VAC5-421-1435, 12VAC5-421-1535, 12VAC5-421-1885, 12VAC5-421-2045; repealing 12VAC5-421-1870, 12VAC5-421-2150, 12VAC5-421-3990).**

Statutory Authority: §§ 35.1-11 and 35.1-14 of the Code of Virginia.

Effective Date: July 12, 2016.

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Summary:

The Food Regulations (12VAC5-421) establish minimum sanitary standards for operating a food establishment. Those standards include the safe and sanitary maintenance, storage, operation, and use of equipment; the safe preparation, handling, protection, and preservation of food, including necessary refrigeration and heating methods, and procedures for vector and pest control; requirements for toilet and cleansing facilities for employees and customers; requirements for appropriate lighting and ventilation; requirements for an approved water supply and sewage disposal system; personal hygiene standards for employees, particularly those engaged in food handling; and the appropriate use of precautions to prevent the transmission of communicable diseases. The regulations also inform a potential food establishment owner or operator how to obtain a permit from the Virginia Department of Health (VDH) to operate a food establishment.

The current regulation is based on the U.S. Food and Drug Administration (FDA) 2005 Food Code and the 2005 Food Code Supplement. The existing regulation is being amended to be consistent with the current 2013 FDA Food Code and the Supplement to the 2013 FDA Food Code. Many of the proposed changes simply refine and provide further clarity to existing regulations.

The amendments include (i) food establishments must refrigerate cut leafy greens to ensure that the product is safe to consume; (ii) food establishments must have employees who are fully informed regarding food allergens and their dangers; (iii) food establishment employees must be aware of their responsibility to inform management of any health or illness issue that might affect the safety of food products; (iv) the establishment must have procedures in place for addressing vomitus or fecal matter discharge on surfaces in the food establishment; (v) wild mushrooms cannot be sold unless the establishment has been approved to do so by the regulatory authority; (vi) bare hand contact with ready-to-eat food ingredients is allowed in certain instances; (vii) game animals that are sold must be raised, slaughtered, and processed under a voluntary inspection program that is conducted by the U.S. Department of Agriculture or the state agency that has animal health jurisdiction; (viii) the food establishment must discontinue operations and notify VDH if an imminent health hazard exists at the establishment; (ix) the establishment must immediately contact VDH to report a food employee illness due to nontyphoidal Salmonella if it is determined that the illness is of a nature that can be transmitted through food; (x) the establishment must correct all priority item violations within 72 hours and all priority foundation item violations within 10 days; (xi) the food establishment must have at least one supervisor who is a certified food protection manager, with some exceptions; (xii) changes in the requirements for water supplies; and (xiii) changes regarding the presence of dogs in food establishments under certain conditions, which were modified at the final stage.

Other changes made at the final stage were in the 2013 FDA Food Code Supplement and include (i) requiring food allergy awareness as a component of employee training; (ii) clarifying that certain cooked and refrigerated foods prepared for immediate service may be served for immediate service and do not need to be heated to a specific temperature; (iii) requiring food labels to include sub-ingredients and astaxanthin as an additional color additive in salmonid fish; (iv) clarifying the requirements for processing apple butter and molasses in copper and copper alloy containers; (v) requiring a permit applicant or holder to submit a properly prepared hazard analysis critical control point plan to the regulatory authority before engaging in reduced oxygen packaging without a variance; and (vi) clarifying that chemicals may be used to wash or assist in the peeling process of fruits and vegetables if done so in accordance with federal regulation and the manufacturer's instructions.

The amendments are adopted concurrently with the Virginia Department of Agriculture and Consumer Services action adopting certain changes based on the 2013 FDA Food Code and Supplement, also published in this issue of the Virginia Register of Regulations.

Part I

Definitions, Purpose and Administration

12VAC5-421-10. Definitions.

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

"Accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards that certify individuals. "Accredited program" refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, recertification, discipline and grievance procedures; and test development and administration. "Accredited program" does not refer to training functions or educational programs.

"Additive" means either a (i) "food additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR ~~Part 170~~ 170.3(e)(1) or (ii) "color additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR ~~Part 70~~ 70.3(f).

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

"Agent" means a legally authorized representative of the owner.

"Agent of the commissioner" means the district or local health director, unless otherwise stipulated.

"Approved" means acceptable to the department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

"Approved water ~~supply"~~ system" means a permitted waterworks constructed, maintained, and operated pursuant to 12VAC5-590; or a private well constructed, maintained, and operated pursuant to 12VAC5-630. ~~which has a valid waterworks operation permit from the department or a nonpublic water supply which is evaluated, tested and if found in reasonable compliance with the construction standards of the Private Well Regulations (12VAC5-630) and the bacteriological water quality standards of the Virginia Waterworks Regulations (12VAC5-590), accepted and approved by the director or the director's designee.~~

"Asymptomatic" means without obvious symptoms; not showing or producing ~~indication~~ indications of a disease or

other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice. Asymptomatic includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

"a_w" means water activity ~~which~~ that is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.

"Balut" means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

"Bed and breakfast" means a tourist home that serves meals.

"Beverage" means a liquid for drinking, including water.

"Board" means the State Board of Health.

"Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption [, including bottled mineral water].

"Building official" means a representative of the Department of Housing and Community Development.

"Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

"Catering operation" means a person who contracts with a client to prepare a specific menu and amount of food in an approved and permitted food establishment for service to the client's guests or customers at a service location different from the permitted food establishment. Catering may also include cooking or performing final preparation of food at the service location.

"Catering operation" does not include:

1. A private chef or cook who, as the employee of a consumer, prepares food solely in the consumer's home.

2. Delivery service of food by an approved and permitted food establishment to an end consumer.

"Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

"CFR" means Code of Federal Regulations. Citations in this chapter to the CFR refer sequentially to the title, part, and section number, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

"CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. CIP does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

~~"CFR" means Code of Federal Regulations. Citations in these regulations to the CFR refer sequentially to the title, part, and section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.~~

~~"Code of Federal Regulations" means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which:~~

~~1. Is published annually by the U.S. Government Printing Office; and~~

~~2. Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40 CFR, and Wildlife and Fisheries Rules in 50 CFR.~~

"Commingle" means:

1. To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or

2. To combine shucked shellfish from containers with different container codes or different shucking dates.

"Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing. "Comminuted" includes (i) fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage~~;~~ and (ii) a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

"Commissary" means a catering establishment, ~~restaurant~~ food establishment, or any other place in which food, food containers, or supplies are kept, handled, prepared, packaged, or stored for distribution to satellite operations.

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

"Conditional employee" means a potential food employee to whom a job offer is made~~, conditional on~~ with employment dependent upon responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative organism or chemical and epidemiological analysis implicates the food as the source of the illness.

"Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

"Core item" means a provision in this chapter that is not designated as a priority item or a priority foundation item. Core item includes an item that usually relates to general sanitation, operational controls, sanitation standard operating

procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

"Corrosion-resistant materials" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

"Counter-mounted equipment" means equipment that is not [~~easily movable~~ portable] and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

~~"Critical item" means a provision of these regulations that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental degradation.~~

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

"Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula, and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

"Dealer" means a person who is authorized by a shellfish control authority for the activities of a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan shellfish according to the provisions of the National Shellfish Sanitation Program and is listed in the U.S. Food and Drug Administration's Interstate Certified Shellfish Shippers List, updated monthly (U.S. Food and Drug Administration).

"Delicatessen" means a store where ready to eat products such as cooked meats, prepared salads, etc. are sold for off-premises consumption.

"Department" means the ~~State Health~~ Virginia Department of Health.

"Director" means the district or local health director.

"Disclosure" means a written statement that clearly identifies the animal [derived] foods that are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens in their entirety, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

~~"Drinking water" means water that meets the water quality standards for bacteria of the Virginia Waterworks Regulations (12VAC5-590). Drinking water is traditionally known as "potable water." Drinking water includes the term water except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.~~

"Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not ~~potentially hazardous~~ time/temperature control for safety food and dry goods such as single-service items.

"Easily cleanable" means a characteristic of a surface that:

1. Allows effective removal of soil by normal cleaning methods;

2. Is dependent on the material, design, construction, and installation of the surface; and

3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

"Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified above to different situations in which varying degrees of cleanability are required such as:

1. The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

2. The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

"Easily movable" means:

1. Portable [~~(weighing 30 pounds or less)~~]; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

2. Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

"Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ~~ratites~~ ratite, or turkey. Egg does not include a balut; egg of the reptile species such as alligator; or an egg product.

"Egg product" means all, or a portion of, the contents found inside eggs separated from the shell and pasteurized in a food processing plant, with or without added ingredients, intended for human consumption, such as dried, frozen, or liquid eggs. Egg product does not include food that contains eggs only in a relatively small proportion such as cake mixes.

"Employee" means the permit holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment.

~~"Enterohemorrhagic *Escherichia coli* (EHEC)" means *E.coli* that cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with *E.coli* that have the capacity to produce Shiga toxins and to cause attaching and effacing lesion in the intestine. EHEC is a subset of STEC, whose members produce additional virulence factors. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: *E.coli* O157:H7; *E.coli* O157:NM; *E.coli* O26:H11; *E.coli* O145:NM; *E.coli* O103:H2; or *E.coli* O111:NM. Also see Shiga toxin producing *E.coli*.~~

"EPA" means the U.S. Environmental Protection Agency.

"Equipment" means an article that is used in the operation of a food establishment. "Equipment" includes, but is not limited to, items such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine. Equipment does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

"Exclude" means to prevent a person from working as [~~a food~~ an] employee in a food establishment or entering a food establishment as an employee.

"°F" means degrees Fahrenheit.

"FDA" means the U.S. Food and Drug Administration.

"Fish" means~~:~~ fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals~~;~~ and all mollusks, if such animal life is intended for human consumption~~;~~ and~~,~~ includes any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner.

"Food" means (i) a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption or (ii) chewing gum.

"Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

"Food-contact surface" means a surface of equipment or a utensil with which food normally comes into contact, or a surface of equipment or a utensil from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.

"Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

"Food establishment" means an operation that (i) stores, prepares, packages, serves, or vends food directly to the consumer or otherwise provides food to the public for human consumption ~~(i),~~ such as a restaurant~~;~~, satellite or catered feeding location~~;~~, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people~~;~~, market~~;~~, vending location~~;~~, conveyance used to transport people~~;~~, institution~~;~~, or food bank~~;~~, and (ii) ~~that~~ relinquishes possession of food to a consumer directly~~;~~ or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

"Food establishment" includes ~~(a)~~ (i) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location; ~~(b)~~ (ii) an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location~~;~~ where consumption is on or off the premises~~;~~ and regardless of whether there is a charge for the food; and ~~(c)~~ (iii) a facility that does not meet the exemption criteria identified in subdivision 6 of this definition or a facility that meets the exemption requirements but chooses to be regulated under ~~these regulations~~ this chapter.

For the purpose of implementing this chapter, the following places are also included in the definition of a "food establishment" as defined in subdivision 9 of § 35.1-1 of the Code of Virginia:

1. Any place where food is prepared for service to the public on or off the premises, or any place where food is served. Examples of such places include but are not limited to lunchrooms, short order places, cafeterias, coffee shops, cafes, taverns, delicatessens, dining accommodations of public or private clubs, kitchen facilities of hospitals and nursing homes, dining accommodations of public and private schools and colleges, and kitchen areas of local correctional facilities subject to standards adopted under § 53.1-68 of the Code of Virginia.

2. Any place or operation that prepares or stores food for distribution to persons of the same business operation or of a related business operation for service to the public. Examples of such places or operations include but are not limited to operations preparing or storing food for catering services, push cart operations, hotdog stands, and other mobile points of service. Such mobile points of service are also deemed to be restaurants unless the point of service and of consumption is in a private residence.

"Food establishment" does not include:

1. An establishment that offers only prepackaged ~~foods that are not potentially hazardous~~ food that is not time/temperature control for safety food;

2. A produce stand that only offers whole, uncut fresh fruits and vegetables;

3. A food processing plant~~;~~, including those that are located on the premises of a food establishment;

4. A kitchen in a private home if only food that is not ~~potentially hazardous~~ time/temperature control for safety food is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority;

5. An area where food that is prepared as specified in subdivision 4 ~~above~~ of this definition is sold or offered for human consumption;

6. A kitchen in a private home, such as, but not limited to, a family day-care provider or a home for adults, serving 12 or fewer recipients; or a bed-and-breakfast operation that prepares and offers food only to guests if the premises of the home is owner or owner-agent occupied, ~~the number of available guest bedrooms does not exceed six,~~ breakfast is the only meal offered, the number of guests served does not exceed 18, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is, by ~~these regulations~~ this chapter, exempt from this chapter; ~~or~~

7. A private home that receives catered or home-delivered food~~.~~; or

8. Places manufacturing packaged or canned foods that are distributed to grocery stores or other similar food retailers for sale to the public.

For the purpose of implementing this chapter, the following are also exempt from the definition of a "food establishment" in this chapter, as defined in §§ 35.1-25 and 35.1-26 of the Code of Virginia:

1. Boarding houses that do not accommodate transients;

2. Cafeterias operated by industrial plants for employees only;

3. Churches, fraternal, school and social organizations and volunteer fire departments and rescue squads that hold dinners and bazaars not more than one time per week and not in excess of two days duration at which food prepared in homes of members or in the kitchen of the church or organization and is offered for sale to the public;

4. Grocery stores, including the delicatessen that is a part of a grocery store, selling exclusively for off-premises consumption and places manufacturing or selling packaged or canned goods;

5. Churches that serve meals for their members as a regular part of their religious observance; and

6. Convenience stores or gas stations that are subject to the State Board of Agriculture and Consumer Services' Retail Food Establishment Regulations (2VAC5-585) or any regulations subsequently adopted and that (i) have 15 or fewer seats at which food is served to the public on the premises of the convenience store or gas station and (ii) are not associated with a national or regional restaurant chain. Notwithstanding this exemption, such convenience stores or gas stations shall remain responsible for collecting any applicable local meals tax.

"Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and provides food for sale or distribution to other business entities such as food processing plants or food establishments. Food processing plant does not include a food establishment.

"Game animal" means an animal, the products of which are food, that is not classified as~~: cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Part 301 Definitions, as poultry in 9 CFR Part 381 Poultry Products Inspection Regulations, or as Fish as defined in this section~~ (i) livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2; (ii) poultry; or (iii) fish.

"Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat and nonaquatic reptiles such as land snakes.

"Game animal" does not include ratites such as ostrich, emu, and rhea.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175.

"Grade A standards" means the requirements of the ~~USPHS/FDA "Grade~~ [~~A~~] Grade "A" Pasteurized Milk Ordinance~~" and "Grade A Condensed and Dry Milk Ordinance"~~, 2013 Revision, (U.S. Food and Drug Administration), with which certain fluid and dry milk and milk products comply.

"HACCP Plan" means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

"Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a plumbing fixture especially placed for use in personal hygiene and designed for the washing of hands. Handwashing sink includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a nurse practitioner, physician assistant, or similar medical [~~profession~~ professional].

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to

maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are:

1. Immunocompromised, preschool age children, or older adults; and

2. Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

~~"Hot water" means water at a temperature of 100°F or higher unless otherwise stated.~~

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury.

"Injected" means ~~tenderizing a meat with deep penetration or injecting the meat such as with juices which may be referred to as "injecting," "pinning," or "stitch pumping." During injection infectious or toxigenic microorganisms may be introduced from its surface to its interior.~~ manipulating meat to which a solution has been introduced into its interior by processes such as "injecting," "pump marinating," or "stitch pumping."

"Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or purée. Juice does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

"Kitchenware" means food preparation and storage utensils.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

"Major food allergen" means milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or a food ingredient that contains protein derived from one of these foods. Major food allergen does not include any highly refined oil derived from a major food allergen in this definition and any ingredient derived from such highly refined oil~~;~~ or any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 [(P. (~~Pub.~~] L. 108-282).

"Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified under 12VAC5-421-330 [A 2 and] A 3 [~~and 4~~].

"Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles, or any mechanical device. "Mechanically tenderized" does not include processes by which solutions are injected into meat.

"mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Mobile food unit" means a food establishment ~~that is~~ mounted on wheels ~~that is~~ (excluding boats in the water) readily moveable from place to place at all times during operation and shall include, but not be limited to, pushcarts, trailers, trucks, or vans. ~~There is no size limit to mobile food units but they must be mobile at all times during operation and must be on wheels (excluding boats in the water) at all times.~~ The unit, all operations, and all equipment must be integral to and be within or attached to the unit.

"Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

"Noncontinuous cooking" means the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service. "Noncontinuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

"Occasional" means not more than one time per week, and not in excess of two days duration.

~~"Organization" means any one of the following:~~

~~1. A volunteer fire department or rescue squad or auxiliary unit thereof which has been recognized in accordance with § 15.2-955 of the Code of Virginia by an ordinance or resolution of the political subdivision where the volunteer fire department or rescue squad is located as being a part of the safety program of such political subdivision;~~

~~2. An organization operated exclusively for religious, charitable, community or educational purposes;~~

~~3. An association of war veterans or auxiliary units thereof organized in the United States;~~

~~4. A fraternal association or corporation operating under the lodge system;~~

~~5. A local chamber of commerce; or~~

~~6. A nonprofit organization that raises funds by conducting raffles which generate annual gross receipts of less than $75,000, provided such gross receipts from the raffle, less~~

~~expenses and prizes, are used exclusively for charitable, educational, religious or community purposes.~~

"Packaged" means bottled, canned, cartoned, [~~securely~~] bagged, or [~~securely~~] wrapped, whether packaged in a food establishment or a food processing plant. Packaged does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

"Permit" means a license issued by the regulatory authority that authorizes a person to operate a food establishment.

"Permit holder" means the entity that is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person, and possesses a valid permit to operate a food establishment.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

"Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance. Personal care items include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7.0 indicate acidity and values between 7.0 and 14 indicate alkalinity. The value for pure distilled water is 7.0, which is considered neutral.

"Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

"Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

1. Cleaners and sanitizers, ~~which~~ that include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

2. Pesticides ~~which~~, except sanitizers, that include substances such as insecticides and rodenticides;

3. Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants, paints, and personal care items that may be deleterious to health; and

4. Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

~~"Potentially hazardous food (time/temperature control for safety food)" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation:~~

~~1. Potentially hazardous food (time/temperature control for safety food) includes an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut tomatoes, or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support pathogenic microorganism growth or toxin formation; and except as specified in subdivision 2 of this definition, a food that because of the interaction of its A_w and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:~~

~~Table A. Interaction of pH and Aw for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.~~

~~Aw values~~	~~pH values~~		
	~~4.6 or less~~	~~>4.6-5.6~~	~~>5.6~~
~~≤0.92~~	~~non-PHF*/non-TCS food**~~	~~non-PHF/non-TCS food~~	~~non-PHF/non-TCS food~~
~~> 0.92-0.95~~	~~non-PHF/non-TCS food~~	~~non-PHF/non-TCS food~~	~~PA***~~
~~>0.95~~	~~non-PHF/non-TCS food~~	~~PA~~	~~PA~~

~~*PHF means Potentially Hazardous Food~~

~~**TCS means Time/Temperature Control for Safety Food~~

~~***PA means Product Assessment required~~

Table B. Interaction of pH and Aw for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged.

Aw values	pH values			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
<0.88	non-PHF*/ non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food
0.88 – 0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
>0.90 – 0.92	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA	PA
>0.92	non-PHF/ non-TCS food	PA	PA	PA

*PHF means Potentially Hazardous Food

**TCS means Time/Temperature Control for Safety Food

***PA means Product Assessment required

2. Potentially hazardous food (time/temperature control for safety food) does not include:

a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable *Salmonellae;*

b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

c. A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;

d. A food that is designated as Product Assessment required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or

(3) A combination of intrinsic and extrinsic factors; or

e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"Potable water" means water fit for human consumption that is obtained from an approved water supply and that is (i) sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii) adequate in quantity and quality for the minimum health requirements of the persons served (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia). Potable water is traditionally known as drinking water and excludes such nonpotable forms as "boiler water, "mop water," "rainwater," "wastewater," and "nondrinking" water.

"Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, ~~or guineas)~~ guineas, ratites, or squabs), whether live or dead, as defined in ~~9 CFR Part 381~~ 9 CFR 381.1, ~~Poultry Products Inspection Regulations,~~ and any migratory waterfowl, game bird, ~~or squab such as~~ pheasant, partridge, quail, grouse, ~~guineas,~~ or pigeon ~~or squab~~ whether live or dead, as defined in ~~9 CFR Part 362, Voluntary Poultry Inspection Regulations~~ 9 CFR 362.1. ~~"Poultry" does not include ratites.~~

"Premises" means the physical facility, its contents, and the contiguous land or property under the control of the permit holder; or the physical facility, its contents, and the land or property which are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, if a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank or veal breast.

"Priority foundation item" means a provision in this chapter whose application supports, facilitates, or enables one or more priority items. "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment, or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record

keeping, and labeling and is denoted in this regulation with a superscript P^{f}.

"Priority item" means a provision in this chapter whose application contributes directly to the elimination, prevention or reduction to an acceptable level of hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard. "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, and handwashing and is denoted in this chapter with a superscript P^{p}.

"Private well" means any water well constructed for a person on land that is owned or leased by that person and is usually intended for household, groundwater source heat pump, agricultural use, industrial use, or other nonpublic water well.

~~"Public water system" has the meaning stated in 40 CFR Part 141, National Primary Drinking Water Regulations.~~

"Pure water" means potable water fit for human consumption that is (i) sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii) adequate in quantity and quality for the minimum health requirements of the persons served (see § 32.1-176.1 and 32.1-167 of the Code of Virginia and 12VAC5-590 and 12VAC5-630-370. Potable water is traditionally known as drinking water, and excludes such nonpotable forms as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking water."

"Pushcart" means any wheeled vehicle or device other than a motor vehicle or trailer that may be moved with or without the assistance of a motor and that does not require registration by the department of motor vehicles. ~~A pushcart is limited to the sale and/or service of hot dogs and frankfurter-like foods.~~

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

"Ready-to-eat food" means food that:

1. Is in a form that is edible without additional preparation to achieve food safety, as specified under 12VAC5-421-700 A ~~through~~, B, and C, 12VAC5-421-710 [~~,~~] or 12VAC5-421-730;

2. Is a raw or partially cooked animal food and the consumer is advised as specified under 12VAC5-421- 700 D 1 and ~~2~~ 3; or

3. Is prepared in accordance with a variance that is granted as specified under 12VAC5-421-700 D ~~1 and 2~~ 4.

Ready-to-eat food may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

"Ready-to-eat food" includes:

1. Raw animal food that is cooked as specified under 12VAC5-421-700, or 12VAC5-421-710 or frozen as specified under 12VAC5-421-730;

2. Raw fruits and vegetables that are washed as specified under 12VAC5-421-510;

3. Fruits and vegetables that are cooked for hot holding as specified under 12VAC5-421-720;

4. All ~~potentially hazardous food~~ time/temperature control for safety food that is cooked to the temperature and time required for the specific food under 12VAC5-421-700 and cooled as specified in 12VAC5-421-800;

5. Plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present, are removed;

6. Substances derived from plants such as spices, seasonings, and sugar;

7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

8. The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for [~~pathogen~~ pathogens]: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

9. Food manufactured according to 21 CFR Part 113~~, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers~~.

"Reduced oxygen packaging" means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and a process as specified in this definition that involves a food for which the hazards Clostridium botulinum or Listeria monocytogenes require control in the final packaged form. Reduced oxygen packaging includes:

1. Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

2. Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

3. Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained,

such as by using oxygen scavengers or a combination of total replacement oxygen, nonrespiring food, and impermeable packaging material;

4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

5. Sous vide packaging, in which raw or partially cooked food is [~~placed in a hermetically sealed,~~ vacuum packaged in an] impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"Refuse" means solid waste not carried by water through the sewage system.

"Regulatory authority" means the Virginia Department of Agriculture and Consumer Services, the Virginia Department of Health or their authorized representative having jurisdiction over the food establishment.

"Reminder" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Reservice" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

"Restrict" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, and unwrapped single-service or single-use articles.

"Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR Part 590.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 ~~(pesticides classified for restricted use)~~ and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

"Safe material" means an article manufactured from or composed of materials that shall not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food; an additive that is used as specified in § 409 ~~or 706~~ of the Federal Food, Drug, and Cosmetic Act (21 USC § 348); or other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned ~~food contact~~ food-contact surfaces that, when evaluated for efficacy, yield a reduction of five logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that permit the entry or passage of moisture.

"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution. Sewage includes water-carried and non-water-carried human excrement or kitchen, laundry, shower, bath, or lavatory waste separately or together with such underground surface, storm, or other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments, or other places.

"Shellfish control authority" means a state, federal, foreign, tribal or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce such as the Virginia Department of Health Division of Shellfish Sanitation.

"Shellstock" means raw, in-shell molluscan shellfish.

"Shiga toxin-producing Escherichia coli" ~~(STEC)~~ or "STEC" means any E. coli capable of producing Shiga toxins (also called ~~verocytotoxins or "Shiga-like" toxins)~~ verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild nonbloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea) to hemolytic uremic syndrome (HUS), which is a type of kidney failure). Examples of serotypes of STEC include ~~both O157 and non-O157 E.coli. Also see Enterohemorrhagic Escherichia coli.~~ E. coli 0157:H7, E. coli 0157:NM, E. coli 026:H11; E. coli 0145NM, E. coli 0103:H2, and E. coli 0111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic E. coli) or as EHEC (Enterohemorrhagic E. coli). EHEC are a subset of STEC that can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means molluscan shellfish that have one or both shells removed.

"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

"Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded. Single-use articles includes items such as wax

paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength and cleanability specifications contained in 12VAC5-421-960, 12VAC5-421-1080, and 12VAC5-421-1100 for multiuse utensils.

"Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -10°F (-23°C) to 25°F (-4°C) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as ~~spinach~~ shrimp.

"Smooth" means a food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number three stainless steel; a ~~nonfood-contact~~ non-food-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and a floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Substantial compliance" ~~shall mean that details of~~ means equipment or structure design or construction ~~and/or;~~ food preparation, handling, storage, transportation ~~and/or;~~ or cleaning procedures that will not substantially affect health consideration or performance of the facility or ~~its~~ the employees.

"Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

"Temporary food establishment" means a food establishment that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

"Time/temperature control for safety food" or "TCS food" means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation:

1. TCS food includes an animal food that is raw or heat treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes, or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and except as specified in subdivision 2 d of this definition, a food that because of the interaction of its A_w and pH values is designated as product assessment required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_w for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.

A_w values	pH values		
	4.6 or less	>4.6-5.6	>5.6
≤0.92	non-TCS food*	non-TCS food	non-TCS food
>0.92-0.95	non-TCS food	non-TCS food	PA**
>0.95	non-TCS food	PA	PA

*TCS food means time/temperature control for safety food

**PA means product assessment required

Table B. Interaction of pH and A_w for control of vegetative cells and spores in food not heat treated or heat treated but not packaged.

A_w values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
<0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88-0.90	non-TCS food	non-TCS food	non-TCS food	PA**
>0.90-0.92	non-TCS food	non-TCS food	PA	PA
>0.92	non-TCS food	PA	PA	PA

*TCS food means time/temperature control for safety food

**PA means product assessment required

2. TCS food does not include:

a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

c. A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-TCS food in Table A or B of this definition;

d. A food that is designated as PA in Table A or B of this definition and has undergone a product assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

(2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf-life and use, or temperature range of storage and use; or

(3) A combination of intrinsic and extrinsic factors; or

e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single service, or single use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices and probe-type price or identification tags used in contact with food.

"Variance" means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage ~~and servicing areas on the premises that are used in conjunction with the vending machines~~ areas and areas on the premises that are used to service and maintain the vending machines.

"Warewashing" means the cleaning and sanitizing of [utensils and] food-contact surfaces of equipment [~~and utensils~~].

"Waterworks" means a system that serves piped water for human consumption to at least 15 service connections or 25 or more individuals for at least 60 days out of the year. "Waterworks" includes all structures, equipment and appurtenances used in the storage, collection, purification, treatment, and distribution of potable water except the piping and fixtures inside the building where such water is delivered (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Part II
Management and Personnel

Article 1
Supervision

12VAC5-421-50. Assignment of responsibility.

A. Except as specified in subsection B of this section, the permit holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the food establishment during all hours of operation.[Pf]

B. In a food establishment with two or more separately permitted departments that are the legal responsibility of the same permit holder and that are located on the same premises, the permit holder may, during specific time periods when food is not being prepared, packaged, or served, designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately permitted food establishment on the premises.[Pf]

12VAC5-421-55. Certified food protection manager.

A. At least one employee with supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager, demonstrating proficiency of required knowledge and information through passing a test that is part of an accredited program.

B. This section does not apply to food establishments that serve only non-temperature control for safety food and food establishments where food handling does not exceed reheating, cold holding, and hot holding of commercially processed and packaged ready-to-eat foods.

C. For purposes of enforcement, this section will take effect on July 1, 2018.

12VAC5-421-60. Demonstration of knowledge.

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, and the requirements of ~~these regulations~~ this chapter. The person in charge shall demonstrate this knowledge by:

1. Complying with ~~the Food Regulations~~ this chapter by having no violations of ~~critical~~ priority items during the current inspection;[Pf]

2. Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program;[Pf] or

3. Responding correctly to the environmental health specialist's questions as they relate to the specific food operation. The areas of operation may include:

a. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;[Pf]

b. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;[Pf]

c. Describing the symptoms associated with the diseases that are transmissible through food;[Pf]

d. Explaining the significance of the relationship between maintaining the time and temperature of ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food and the prevention of foodborne illness;[Pf]

e. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;[Pf]

f. Stating the required food temperatures and times for safe cooking of ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food including meat, poultry, eggs, and fish;[Pf]

g. Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food;[Pf]

h. Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(1) Cross contamination,[Pf]

(2) Hand contact with ready-to-eat foods,[Pf]

(3) Handwashing,[Pf] and

(4) Maintaining the food establishment in a clean condition and in good repair;[Pf]

i. Describing the foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction;[Pf]

j. Explaining the relationship between food safety and providing equipment that is:

(1) Sufficient in number and capacity,[Pf] and

(2) Properly designed, constructed, located, installed, operated, maintained, and cleaned;[Pf]

k. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;[Pf]

l. Identifying the source of water used and measures taken to ensure that ~~it~~ the water supply remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;[Pf]

m. Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;[Pf]

n. Identifying critical control points in the operation from purchasing through sale or service that [when not controlled] may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this chapter;[Pf]

o. Explaining the details of how the person in charge and food employees comply with a HACCP plan if such a plan is required by the law, this chapter, or a voluntary agreement between the regulatory authority and the food establishment; ~~and~~[Pf]

p. Explaining the responsibilities, rights, and authorities assigned by this chapter to the:

(1) Food employee,[Pf]

(2) Conditional employee,[Pf]

~~(2)~~ (3) Person in charge,[Pf] and

~~(3)~~ (4) Regulatory authority;[Pf] and

q. Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and the exclusion or restriction of food employees.[Pf]

12VAC5-421-65. Food protection manager certification.

A. A person in charge who demonstrates knowledge by being a food protection manager who is certified by a food protection manager certification program that is evaluated by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with subdivision 2 of 12VAC5-421-60.

B. A food establishment that has an employee who is certified by a food protection certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with 12VAC5-421-55.

12VAC5-421-70. Duties of person in charge.

The person in charge shall ensure that:

1. Food establishment operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under 12VAC5-421-2990;[Pf]

2. Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination;[Pf]

3. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with ~~these regulations~~ this chapter;[Pf]

4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;[Pf]

5. Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;[Pf]

6. Employees are verifying that foods delivered to the food establishment during non-operating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented [~~.~~ ;][Pf]

~~6.~~ 7. Employees are properly cooking ~~potentially hazardous food~~ [~~TCS~~ time/temperature control for safety] food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under 12VAC5-421-1180 and 12VAC5-421-1730 B;[Pf]

~~7.~~ 8. Employees are using proper methods to rapidly cool ~~potentially hazardous foods~~ time/temperature control for safety food that ~~are~~ is not held hot or ~~are~~ is not for consumption within four hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling;[Pf]

9. Employees are properly maintaining the temperatures of time/temperature control for safety food during hot and cold holding through daily oversight of the employees routine monitoring of food temperatures [~~.~~ ;][Pf]

~~8.~~ 10. Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under 12VAC5-421-930 that the food is not cooked sufficiently to ensure its safety;[Pf]

~~9.~~ 11. Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing;[Pf]

~~10.~~ 12. Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets;[Pf]

~~11.~~ 13. Except when approval is obtained from the regulatory authority as specified in 12VAC5-421-450 ~~B~~ E, employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; [Pf]

~~12.~~ 14. Employees are properly trained in food safety [, including food allergy awareness,] as it relates to their assigned duties;[Pf] ~~and~~

~~13.~~ 15. Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food, as specified under 12VAC5-421-80~~.~~ [Pf]; and

16. Written procedures and plans, where specified by this chapter and as developed by the food establishment, are maintained and implemented as required.[Pf]

Article 2
Employee Health

12VAC5-421-80. Responsibility of permit holder, person in charge, and conditional employees.

A. The permit holder shall require food employees and conditional employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food. A food employee or conditional employee shall report the information in a manner that allows the person in charge to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the food employee or conditional employee:

1. Has any of the following symptoms:

a. Vomiting;[P]

b. Diarrhea;[P]

c. Jaundice;[P]

d. Sore throat with fever;[P] or

e. A lesion containing pus such as a boil or infected wound that is open or draining and is:

(1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;[P]

(2) On exposed portions of the arms, unless the lesion is protected by an impermeable cover;[P] or

(3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;[P]

2. Has an illness diagnosed by a health practitioner due to:

a. Norovirus;[P]

b. Hepatitis A virus;[P]

c. Shigella spp.;[P]

d. [~~Enterohemorrhagic or~~] ~~Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli; ~~or~~ [P]

e. Typhoid fever (caused by Salmonella [~~Typhi)~~ typhi)];[P] or

f. Salmonella (nontyphoidal) [~~,~~;][P]

3. Had ~~a previous illness~~ [~~Typhoid~~ typhoid] fever, diagnosed by a health practitioner, within the past three months ~~due to Salmonella Typhi~~, without having received antibiotic therapy, as determined by a health practitioner;[P]

4. Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the food employee or conditional employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:

a. Norovirus within the past 48 hours of the last exposure; [P]

b. ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days of the last exposure;[P]

c. Typhoid fever (caused by Salmonella [~~Typhi~~ typhi]) within the past 14 days of the last exposure;[P] or

d. Hepatitis A virus within the past 30 days of the last exposure;[P] or

5. Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about an individual who works or attends a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, and individual diagnosed with an illness caused by:

a. Norovirus within the past 48 hours of exposure;[P]

b. ~~Enterohemorragic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli or Shigella spp. within the past three days of the last exposure;[P]

c. Typhoid fever (caused by Salmonella [~~Typhi~~ typhi]) within the past 14 days of the last exposure;[P] or

d. Hepatitis A virus within the past 30 days of the last exposure.[P]

B. The person in charge shall notify the regulatory authority when a food employee is:

1. Jaundiced;[Pf] or

2. Diagnosed with an illness due to a pathogen as specified under [~~subdivision~~ subdivisions] A 2 a through ~~e~~ f of this section.[Pf]

C. The person in charge shall ensure that a conditional employee:

1. Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under ~~subdivision A 2 a through e~~ subdivisions A 1, 2, and 3 of this section, is prohibited from becoming a food employee until the conditional employee meets the criteria for the specific symptoms or diagnosed illness as specified under 12VAC5-421-100;[P] and

2. Who will work as a food employee in a food establishment that serves a highly susceptible population and reports a history of exposure as specified under ~~subdivision~~ subdivisions A 4 ~~through~~ and 5 of this section, is prohibited from becoming a food employee until the conditional employee meets the criteria specified under subdivision ~~9~~ 10 of 12VAC5-421-100.[P]

D. The person in charge shall ensure that a food employee who exhibits or reports a symptom, or who reports a diagnosed illness or history of exposure as specified under ~~subdivision~~ subdivisions A 1 through 5 of this section is:

1. Excluded as specified under subdivisions 1 ~~through~~, 2, and 3 of 12VAC5-421-90, and subdivisions ~~D 1, E 1, F 1, or G 1~~ 4 a, 5 a, 6 a, 7, or 8 a of 12VAC5-421-90 and in compliance with the provisions specified under ~~subdivision~~ subdivisions 1 through ~~7~~ 8 of 12VAC5-421-100;[P] or

2. Restricted as specified under ~~subdivisions~~ subdivision 4 b, 5 b, 6 b, or ~~7~~ 8 b of 12VAC5-421-90, or ~~subdivisions 8 or~~ subdivision 9 or 10 of 12VAC5-421-90 and in compliance with the provisions specified under subdivisions 4 through ~~9~~ 10 of 12VAC5-421-100.[P]

E. A food employee or conditional employee shall report to the person in charge the information as specified under subsection A of this section.[Pf]

F. A food employee shall:

1. Comply with an exclusion as specified under subdivisions 1 ~~through~~, 2, and 3 of 12VAC5-421-90 and ~~subdivisions~~ subdivision 4 a, 5 a, 6 a, ~~or~~ 7, or 8 a of 12VAC5-421-90 and with the provisions specified under subdivisions 1 through ~~7~~ 8 of 12VAC5-421-100;[P] or

2. Comply with a restriction as specified under subdivisions 4 b, 5 b, 6 b, ~~or~~ 7, or 8 b of 12VAC5-421-90, or ~~subdivisions~~ subdivision 8, 9, or ~~9~~ 10 of 12VAC5-421-90 and comply with the provisions specified under subdivisions 4 through ~~9~~ 10 of 12VAC5-421-100.[P]

12VAC5-421-90. Exclusions and restrictions.

The person in charge shall exclude or restrict a food employee from a food establishment in accordance with the following:

1. Except when the symptom is from a noninfectious condition, exclude a food employee if the food employee is:

a. Symptomatic with vomiting or diarrhea;[P] or

b. Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, Shigella spp., Salmonella (nontyphoidal), or ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli.[P]

2. Exclude a food employee who is:

a. Jaundiced and the onset of jaundice occurred within the last seven calendar days, unless the food employee provides to the person in charge written medical documentation from a health practitioner specifying that the jaundice is not caused by Hepatitis A virus or other fecal-orally transmitted infection;[P]

b. Diagnosed with an infection from Hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within seven calendar days of the onset of jaundice;[P] or

c. Diagnosed with an infection from Hepatitis A virus without developing symptoms.[P]

3. Exclude a food employee who is diagnosed with ~~an infection from Salmonella Typhi~~ [~~Typhoid~~ typhoid] fever, or reports ~~a previous infection with Salmonella Typhi~~ having had [~~Typhoid~~ typhoid] fever within the past three months as specified in 12VAC5-421-80 A 3.[P]

4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

5. If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

6. If a food employee is diagnosed with an infection from ~~Enterohemorrhagic or Shiga toxin-producing E.coli~~ Shiga toxin-producing Escherichia coli, and is asymptomatic:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

7. If a food employee is diagnosed with an infection from Salmonella (nontyphoidal) and is asymptomatic, restrict the food employee who works in a food establishment:

a. Serving a highly susceptible population,[P] or

b. Not serving a highly susceptible population.[P]

~~7.~~ 8. If a food employee is ill with symptoms of acute onset of sore throat with fever:

a. Exclude the food employee who works in a food establishment serving a highly susceptible population;[P] or

b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.[P]

~~8.~~ 9. If a food employee is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under 12VAC5-421-80 A 1 e, restrict the food employee.[P]

~~9.~~ 10. If a food employee is exposed to a foodborne pathogen as specified under 12VAC5-421-80 A 4 or 5, restrict the food employee who works in a food establishment serving a highly susceptible population.[P]

12VAC5-421-100. Removal, adjustment, or retention of exclusions and restrictions.

The person in charge shall adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee:

1. Except when a food employee is diagnosed with [~~Typhoid~~ typhoid] fever or an infection from Hepatitis A virus ~~or Salmonella Typhi~~:

a. Reinstate a food employee who was excluded as specified under subdivision 1 a of 12VAC5-421-90 if the food employee:

(1) Is asymptomatic for at least 24 hours;[P] or

(2) Provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition.[P]

b. If a food employee was diagnosed with an infection from Norovirus and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population until the conditions for reinstatement as specified in subdivision 4 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 4 a or b of this section are met.[P]

c. If a food employee was diagnosed with an infection from Shigella spp. and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee, who is asymptomatic, for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in subdivision 5 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 5 a or b, or 5 a and 1 c (1) of this section are met.[P]

d. If a food employee was diagnosed with an infection from ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-producing Escherichia coli and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in subdivision 6 a or b of this section are met;[P] or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 6 a or b are met.[P]

e. If a food employee was diagnosed with an infection from Salmonella (nontyphoidal) and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee who is asymptomatic for at least 30 days until conditions for reinstatement as specified under subdivision 7 a or 7 b of this section are met;[P] or

(2) Retain the exclusion for the food employee who is symptomatic, until conditions for reinstatement as specified under subdivision 7 a or 7 b of this section are met.

2. Reinstate a food employee who was excluded as specified under subdivision 2 of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The food employee has been jaundiced for more than seven calendar days;[P]

b. The anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days;[P] or

c. The food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Hepatitis A virus infection.[P]

3. Reinstate a food employee who was excluded as specified under subdivision 3 of 12VAC5-421-90 if:

a. The person in charge obtains approval from the regulatory authority;[P] and

b. The food employee provides to the person in charge written medical documentation from a health practitioner that states the employee is free from ~~S. Typhi infection~~ [~~Typhoid~~ typhoid] fever.[P]

4. Reinstate a food employee who was excluded as specified under subdivision 1 b or 4 a of 12VAC5-421-90, who was restricted under subdivision 4 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection;[P]

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the food employee became symptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed.[P]

5. Reinstate a food employee who was excluded as specified under subdivision 1 b or 5 a of 12VAC5-421-90 or who was restricted under subdivision 5 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Shigella spp. infection based on test results showing two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics,[P] and

(2) At least 24 hours apart;[P]

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than seven calendar days have passed since the food employee became asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than seven calendar days have passed since the food employee was diagnosed.[P]

6. Reinstate a food employee who was excluded or restricted as specified under subdivision 1 b or 6 a of 12VAC5-421-90 or who was restricted under subdivision 6 b of 12VAC5-421-90 if the person in charge obtains

approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from ~~Enterohemorrhagic or Shiga toxin producing~~ Shiga toxin-producing Escherichia coli based on test results that show two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after the discontinuance of antibiotics;[P] and

(2) At least 24 hours apart;[P]

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than seven calendar days have passed since the employee became asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than seven days have passed since the employee was diagnosed.[P]

7. Reinstate a food employee who was excluded as specified under subsection 1 a of 12VAC5-421-90 or who was restricted as specified under subsection 7 of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority[P] and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a [~~nontyphoida~~] Salmonella [(nontyphoidal)] infection based on test results showing two consecutive negative stool specimen cultures that are taken;

(1) Not earlier than 48 hours after discontinuance of antibiotics;[P] and

(2) At least 24 hours apart;[P]

b. The food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the food employee became asymptomatic;[P] or

c. The food employee was excluded or restricted and did not develop symptoms and more than 30 days have passed since the food employee was diagnosed.[P]

~~7.~~ 8. Reinstate a food employee who was excluded or restricted as specified under subdivision ~~7~~ 8 a or b of 12VAC5-421-90 if the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

a. Has received antibiotic therapy for Streptococcus pyogenes infection for more than 24 hours;[P]

b. Has at least one negative throat specimen culture for Streptococcus pyogenes infection;[P] or

c. Is otherwise determined by a health practitioner to be free of Streptococcus pyogenes infection.[P]

~~8.~~ 9. Reinstate a food employee who was restricted as specified under subdivision ~~8~~ 9 of 12VAC5-421-90 if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

a. An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;[P]

b. An impermeable cover on the arm if the infected wound or pustular boil is on the arm;[P] or

c. A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.[P]

~~9.~~ 10. Reinstate a food employee who was restricted as specified under subdivision ~~9~~ 10 of 12VAC5-421-90 and was exposed to one of the following pathogens as specified under 12VAC5-421-80 A 4 or 5:

a. Norovirus and one of the following conditions is met:

(1) More than 48 hours have passed since the last day the food employee was potentially exposed;[P] or

(2) More than 48 hours have passed since the food employee's household contact became asymptomatic.[P]

b. Shigella spp. or [~~Enterohemorrhagic or~~] ~~Shiga-toxin producing~~ Shiga toxin-producing Escherichia coli and one of the following conditions is met:

(1) More than three calendar days have passed since the last day the food employee was potentially exposed;[P] or

(2) More than three calendar days have passed since the food employee's household contact became asymptomatic.[P]

c. ~~S. Typhi~~ Typhoid fever (caused by Salmonella [~~Typhi)~~ typhi)] and one of the following conditions is met:

(1) More than 14 calendar days have passed since the last day the food employee was potentially exposed;[P] or

(2) More than 14 calendar days have passed since the food employee's household contact became asymptomatic.[P]

d. Hepatitis A virus and one of the following conditions is met:

(1) The food employee is immune to Hepatitis A virus infection because of prior illness from Hepatitis A;[P]

(2) The food employee is immune to Hepatitis A virus infection because of vaccination against Hepatitis A;[P]

(3) The food employee is immune to Hepatitis A virus infection because of IgG administration;[P]

(4) More than 30 calendar days have passed since the last the food employee was potentially exposed;[P]

(5) More than 30 calendar days have passed since the food employee's household contact became jaundiced;[P] or

(6) The food employee does not use an alternative procedure that allows bare hand contact with ready-to-eat food until at least 30 days after the potential exposure, as specified in subdivisions ~~9~~ 10 d (4) and (5) of this section, and the food employee receives additional training about:

(a) Hepatitis A symptoms and preventing the transmission of infection;[P]

(b) Proper handwashing procedures;[P] and

(c) Protecting ready-to-eat food from contamination introduced by bare hand contact.[P]

Article 3
Personal Cleanliness

12VAC5-421-130. Clean condition of hands and arms.

Food employees shall keep their hands and exposed portions of their arms clean.[P]

12VAC5-421-140. Cleaning procedure of hands and arms.

A. Except as specified in subsection D of this section, food employees shall clean their hands and exposed portions of their arms ~~(or surrogate prosthetic devices for hands or arms) for at least 20 seconds~~ or surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a lavatory that is equipped as specified under 12VAC5-421-2190 ~~A~~.[P]

B. Food employees shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

1. Rinse under clean, running warm water;[P]

2. Apply an amount of cleaning compound recommended by the cleaning compound manufacturer;[P]

3. Rub together vigorously for at least 10 to 15 seconds while:

a. Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure;[P] and

b. Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;[P]

4. Thoroughly rinsing under clean, running warm water;[P] and

5. Immediately follow the cleaning procedure with thorough drying using a method as specified under 12VAC5-421-3030.[P]

C. To avoid recontaminating their hands or surrogate prosthetic devices, food employees may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a handwashing sink or the handle of a restroom door.

D. If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands or surrogate prosthetic devices.

12VAC5-421-160. When to wash.

Food employees shall clean their hands and exposed portions of their arms as specified under 12VAC5-421-140 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles[P] and:

1. After touching bare human body parts or hair other than clean hands and clean, exposed portions of arms;[P]

2. After using the toilet room;[P]

3. After caring for or handling ~~support~~ service animals or aquatic animals as allowed under 12VAC5-421-250 B;[P]

4. Except as specified in 12VAC5-421-220 B, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;[P]

5. After handling soiled equipment or utensils;[P]

6. During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;[P]

7. When switching between working with raw foods and working with ready-to-eat foods;[P]

8. Before donning gloves [~~for~~ to initiate a task that involves] working with foods;[P] and

9. After engaging in other activities that contaminate the hands.[P]

12VAC5-421-170. Where to wash.

Food employees shall clean their hands in a handwashing ~~lavatory~~ sink or approved automatic handwashing facility and shall not clean their hands (i) in a sink used for food preparation or utensil washing or (ii) in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.[Pf]

12VAC5-421-180. Hand antiseptics.

A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

1. Comply with one of the following:

a. Be an approved drug that is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," 34th Edition, 2014, (U.S. Food and Drug Administration) as an approved drug based on safety and effectiveness;[Pf] or

b. Have active antimicrobial ingredients that are listed in the FDA monograph for OTC (over the counter) Health-Care Antiseptic Drug Products as an antiseptic handwash;[Pf] and

2. [~~Comply~~ Consist only of components which the intended use of each complies] with one of the following:

a. [~~Have components that are exempted from the requirement of being listed in the federal Food Additive regulations as specified in 21 CFR 170.39~~] ~~Threshold of regulation for substances used in food contact articles~~ [A threshold of regulation exemption under 21 CFR 170.39];[Pf] [~~or~~]

b. [~~Comply with and be listed in (i)~~] 21 CFR Part 178 ~~Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers~~, as regulated for use as a food additive with conditions of safe use;[Pf] [~~or~~]

[~~(ii)~~ c. A determination of generally recognized as safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in] 21 CFR Part 182 ~~Substances Generally Recognized as Safe~~, 21 CFR 184 ~~Direct Food Substances Affirmed as Generally Recognized as Safe~~, or 21 CFR Part 186 ~~Indirect Food Substances Affirmed as Generally Recognized as Safe~~ for use in contact with food [and in FDA's Inventory of GRAS Notices;[Pf] [~~and~~

d. A prior sanction listed under 21 CFR 181;[Pf] or

e. A Food Contact Notification that is effective;[Pf] and]

3. Be applied only to hands that are cleaned as specified under 12VAC5-421-140.[Pf]

B. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified in subdivision A 2 of this section, use shall be:

1. Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves;[Pf] or

2. Limited to situations that involve no direct contact with food by the bare hands.[Pf]

C. A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to 100 ppm (mg/l) chlorine or above.[Pf]

12VAC5-421-190. Maintenance of fingernails.

Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.[Pf] Unless wearing intact gloves in good repair, a food employee shall not wear fingernail polish or artificial nails when working with exposed food.[Pf]

12VAC5-421-200. Prohibition of jewelry.

~~While preparing food, food employees shall not wear jewelry on their arms and hands. This section does not apply to a plain ring such as a wedding band.~~ Except for a plain ring such as a wedding band, while preparing food, food employees shall not wear jewelry, including medical information jewelry on their arms and hands.

12VAC5-421-210. Clean condition of outer clothing.

Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

[Article 4
Hygienic Practices

12VAC5-421-220. Eating, drinking, or using tobacco.

A. Except as specified in subsection B of this section, an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

B. A food employee may drink from a closed beverage container ~~with a straw~~ if the container is handled to prevent contamination of:

1. The employee's hands;

2. The container; and

3. Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.]

12VAC5-421-250. Handling of animals prohibited.

A. Except as specified in subsection B of this section, food employees shall not care for or handle animals that may be present such as patrol dogs, ~~support~~ service animals, or pets that are allowed under 12VAC5-421-3310 B 2 ~~through~~, 3, and 4.[Pf]

B. Food employees with ~~support~~ service animals may handle or care for their ~~support~~ service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under 12VAC5-421-140 and subdivision 3 of 12VAC5-421-160.

12VAC5-421-255. Clean-up of vomiting and diarrheal events.

A food establishment shall have procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. The procedures shall address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.[Pf]

Part III
Food

Article 1
Characteristics

12VAC5-421-260. Safe and unadulterated.

Food shall be safe and unadulterated.[Pf]

Article 2

Sources, Specifications, and Original Containers and Records

12VAC5-421-270. Compliance with food law.

A. Food shall be obtained from sources that comply with law.[P]

B. Food prepared in a private home shall not be used or offered for human consumption in a food establishment unless the home kitchen is inspected and [~~approved~~ regulated] by the Virginia Department of Agriculture and Consumer Services.[P]

C. Packaged food shall be labeled as specified in law, including 21 CFR Part 101~~, Food Labeling;~~, 9 CFR Part 317~~, Labeling, Marking Devices, and Containers;~~, and Subpart N of 9 CFR Part 381~~, Subpart N Labeling and Containers;~~, and as specified under 12VAC5-421-400 and 12VAC5-421-410.[Pf]

~~D. Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified under 12VAC5-421-700 D 1 may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 12VAC5-421-730, or frozen on the premises as specified under 12VAC5-421-730, and records are retained as specified under 12VAC5-421-740.~~

D. Fish, other than those specified in 12VAC5-421-730 B, that are intended for consumption in raw or undercooked form and allowed as specified in 12VAC5-421-700 D, may be offered for sale or service if they are obtained from a supplier that freezes fish as specified under 12VAC5-421-730 A; or if they are frozen on premises as specified under 12VAC5-421-730 A and records are retained as specified under 12VAC5-421-740.

E. Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 12VAC5-421-700 C shall be:

1. Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef;[Pf] or

2. Deemed acceptable by the regulatory authority based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef;[Pf] and

3. If individually cut in a food establishment:

a. Cut from whole-muscle intact beef that is labeled by a food processing plant as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection;[Pf]

b. Prepared so they remain intact;[Pf] and

c. If packaged for undercooking in a food establishment, labeled ~~to indicate that they meet the definition of whole-muscle, intact beef.~~ as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection.[Pf]

F. Meat and poultry that are not a ready-to-eat food and are in a packaged form when offered for sale or otherwise offered for consumption shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

G. Shell eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

12VAC5-421-280. Food in a hermetically sealed container.

Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.[P]

12VAC5-421-290. Fluid milk and milk products.

Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law.[P]

12VAC5-421-295. Juice treated.

Prepackaged juice shall:

1. Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120;[Pf]

2. Be obtained pasteurized or otherwise treated to attain a five-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR 120.24~~; or~~.[P]

~~3. Bear a warning label as specified in 12VAC5-421-765 and 21 CFR 101.17(g).~~

12VAC5-421-300. Fish.

A. Fish that are received for sale or service shall be:

1. Commercially and legally caught or harvested;[P] or

2. Approved for sale or service by a regulatory ~~authority~~ agency of competent jurisdiction.[P]

B. Molluscan shellfish that are recreationally caught shall not be received for sale or service.[P]

12VAC5-421-310. Molluscan shellfish.

A. Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program ~~Manual of Operations, Part II, Sanitation of the Harvesting, Processing and Distribution of Shellfish, 1995 Revision~~ (NSSP) Guide for the Control of Molluscan Shellfish, 2013 Revision, (U.S. Food and Drug Administration).[P]

B. Molluscan shellfish ~~received in interstate commerce~~ shall be from sources that are listed in the "Interstate Certified Shellfish Shippers List," updated monthly (U.S. Food and Drug Administration).[P]

12VAC5-421-320. Wild mushrooms.

A. Except as specified in subsection B of this section, mushroom species picked in the wild shall ~~be obtained from~~

~~sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert~~ not be offered for sale or service by a food establishment unless the food establishment has been approved to do so.[P]

B. This section does not apply to:

1. Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or

2. Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

12VAC5-421-330. Game animals.

A. If game animals are received for sale or service they shall be:

1. Commercially raised for food and~~: a. Raised~~ raised, slaughtered, and processed under a voluntary inspection program that is conducted by the state agency that has animal health jurisdiction~~;~~ or

~~b. Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction; and~~

~~c. Raised, slaughtered, and processed according to:~~

~~(1) Laws governing meat and poultry as determined by the agency; and~~

~~(2) Requirements that are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;~~

~~2. Under~~ under a voluntary inspection program administered by the USDA for game animals such as exotic animals ~~including animals~~ (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR Part 352~~, Exotic Animals; Voluntary Inspection,~~ or rabbits that are "inspected and certified" in accordance with 9 CFR Part 354~~, Voluntary Inspection of Rabbits and Edible Products Thereof~~;

~~3.~~ 2. As allowed by law, wild game animals that are live-caught [~~are~~]:

a. Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction;[P]

b. Slaughtered and processed according to:

(1) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program;[P] and

(2) Requirements that are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;[P] or

~~4.~~ 3. As allowed by law for field-dressed wild game animals under a routine inspection program that ensures the animals:

a. Receive a postmortem examination by an approved veterinarian or veterinarian's designee~~,~~ or ~~are~~

b. Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program[P] and

~~b.~~ c. Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.[P]

B. A game animal shall not be received for sale or service if it is a species of wildlife that is listed in 50 CFR Part 17~~, Endangered and Threatened Wildlife and Plants~~.

12VAC5-421-340. Temperature.

A. Except as specified in subsection B of this section, refrigerated, ~~potentially hazardous food~~ time/temperature control for safety food shall be at a temperature of 41°F (5°C) or below when received.[P]

B. If a temperature other than 41°F (5°C) for a ~~potentially hazardous food~~ time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk~~,~~ and molluscan shellfish, ~~and shell eggs,~~ the food may be received at the specified temperature.

C. Raw shell eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.[P]

D. ~~Potentially hazardous food~~ [~~time/temperature~~ Time/temperature] control for safety food that is cooked to a temperature and for a time specified under 12VAC5-421-700 ~~through~~, 12VAC5-421-710, and 12VAC5-421-720 and received hot shall be at a temperature of 135° (57°C) or above.[P]

E. A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.[Pf]

F. Upon receipt, ~~potentially hazardous food~~ time/temperature control for safety food shall be free of evidence of previous temperature abuse.[Pf]

12VAC5-421-350. Additives.

Food shall not contain unapproved food additives or additives that exceed amounts allowed in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe (GRAS) or prior sanctioned substances that exceed amounts allowed in 21 CFR Parts 181-186; substances that exceed

amounts specified in 9 CFR 424.21(b), Subpart C~~, Approval of Substances for Use in the Preparation of Products~~; or pesticide residues that exceed provisions specified in 40 CFR Part 185 [~~,~~] ~~Tolerances for Pesticides in Food~~ [~~,~~] and exceptions.[P]

12VAC5-421-360. ~~Shell eggs~~ Eggs.

~~Shell eggs~~ Eggs shall be received clean and sound and shall not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 et seq., administered by the Agricultural Marketing Service of USDA. Eggs sold pursuant to § 3.2-5305 of the Code of Virginia are exempt from the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56, effective July 20, 2000, (Agricultural Marketing Service of USDA).[P]

12VAC5-421-370. Eggs and milk products, pasteurized.

A. Egg products shall be obtained pasteurized.[P]

B. Fluid and dry milk and milk products shall:

1. Be obtained pasteurized;[P] and

2. Comply with Grade A standards as specified in law.

C. Frozen milk products, such as ice cream, shall be obtained pasteurized in accordance with 21 CFR Part 135~~, Frozen Desserts~~.[P]

D. Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are ~~provided for~~ specified in the ~~Code of Federal Regulations~~ CFR, such as 21 CFR Part 133~~, Cheeses and Related Cheese Products, for curing certain cheese varieties~~.[P]

12VAC5-421-380. Package integrity.

Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.[Pf]

12VAC5-421-390. Ice.

Ice for use as a food or a cooling medium shall be made from [~~drinking~~ pure] water.[P]

12VAC5-421-400. Shucked shellfish, packaging, and identification.

A. Raw shucked shellfish shall be obtained in nonreturnable packages that bear a legible label that identifies the:[Pf]

1. Name, address, and certification number of the shucker, packer, or repacker of the molluscan shellfish;[Pf] and

2. The "sell by" or "best if used by" date for packages with a capacity of less than one-half gallon ~~(1.87~~ (1.89 L) or the date shucked for packages with a capacity of one-half gallon ~~(1.87~~ (1.89 L) or more.[Pf]

B. A package of raw shucked shellfish that does not bear a label or ~~which~~ that bears a label which does not contain all the information as specified under subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR 1240.60(d), Subpart D~~, Specific Administrative Decisions Regarding Interstate Shipments~~.

12VAC5-421-410. Shellstock identification.

A. Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by ~~the harvester and each~~ a dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, 2013 Revision, (U.S. Food and Drug Administration) and that ~~list~~ include the following information:[Pf]

~~1. Except as specified under subsection C of this section, on the harvester's tag or label, the following information in the following order:~~

~~a. The harvester's identification number that is assigned by the shellfish control authority,~~

~~b. The date of harvesting,~~

~~c. The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested,~~

~~d. The type and quantity of shellfish, and~~

~~e. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; and~~

~~2. Except as specified under subsection D of this section, on each dealer's tag or label, the following information in the following order:~~

~~a.~~ 1. The dealer's name and address, and the certification number assigned by the shellfish control authority~~,~~.[Pf]

~~b.~~ 2. The original shipper's certification number ~~including the abbreviation of the name of the state or country in which the shellfish are harvested,~~ assigned by the shellfish control authority.[Pf]

~~c. The same information as specified for a harvester's tag under subdivisions 1 b through d of this subsection, and~~ 3. The harvest date, or if depurated, the date of depuration processing, or if wet stored, the original harvest date and the final harvest date.[Pf]

4. If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w."[Pf]

5. The harvest area, including the initials of the state of harvest.[Pf]

6. The type and quantity of shellstock.[Pf]

~~d.~~ 7. The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL

CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS."[Pf]

8. All shellstock intended for raw consumption shall include a consumer advisory using the statement from 12VAC5-421-930 C, or an equivalent statement.

B. A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR 1240.60(d), Subpart D~~, Specific Administrative Decisions Regarding Interstate Shipments~~.

~~C. If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.~~

~~D. If the harvester's tag or label is designed to accommodate each dealer's identification as specified under subdivisions A 2 a and b of this section, individual dealer tags or labels need not be provided.~~

12VAC5-421-430. Molluscan shellfish; original container.

A. Except as specified in subsections B ~~and,~~ C, and D of this section, molluscan shellfish shall not be removed from the container in which they were received other than immediately before sale or preparation for service.

B. For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

1. The source of the shellstock on display is identified as specified under 12VAC5-421-410 and recorded as specified under 12VAC5-421-440; and

2. The shellstock are protected from contamination.

C. Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

1. The labeling information for the shellfish on display as specified under 12VAC5-421-400 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

2. The shellfish are protected from contamination.

D. Shucked shellfish may be removed from the container in which they were received and repacked in consumer self-service containers where allowed by law if:

1. The labeling information for the shellfish is on each consumer self-service container as specified under 12VAC5-421-400 and 12VAC5-421-900 A and B 1 through 5;

2. The labeling information as specified under 12VAC5-421-400 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

3. The labeling information and dates specified under subdivision D 2 of this section are maintained for 90 days; and

4. The shellfish are protected from contamination.

12VAC5-421-440. Shellstock; maintaining identification.

A. Except as specified under subdivision C 2 of this section, shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty.[Pf]

B. The date when the last shellstock from the container is sold or served shall be recorded on the tag or label.[Pf]

C. The identity of the source of ~~shellfish~~ shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label as specified in subsection B of this section, by:[Pf]

1. Using an approved recordkeeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under subsection B of this section;[Pf] and

2. If shellstock are removed from its tagged or labeled container:

a. Preserving source identification by using a recordkeeping system as specified under subdivision C 1 of this section,[Pf] and

b. Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer.[Pf]

Article 3
Protection from Contamination after Receiving

12VAC5-421-450. Preventing contamination.

A. Food employees shall wash their hands as specified under 12VAC5-421-140.

B. Except when washing fruits and vegetables as specified under 12VAC5-421-510 or as specified in ~~subsection~~ subsections D and E of this section, food employees shall not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.[P]

C. Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.[Pf]

D. Subsection B of this section does not apply to a food employee who contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to food that:

1. Contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the

minimum temperatures specified in [subsection A or B of] 12VAC5-421-700 or [in] 12VAC5-421-710; or

2. Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 145°F (63°C).

~~D.~~ E. Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if:

1. The permit holder obtains prior approval from the regulatory authority;

2. Written procedures are maintained in the food establishment and made available to the regulatory authority upon request that include:

a. For each bare hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands~~.~~;

b. Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under 12VAC5-421-2230, 12VAC5-421-2280, 12VAC5-421-2310, 12VAC5-421-3020, 12VAC5-421-3030, and 12VAC5-421-3045 are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

3. A written employee health policy that details how the food establishment complies with 12VAC5-421-80, 12VAC5-421-90, and 12VAC5-421-100 including:

a. Documentation that the food employees and conditional employees acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food as specified under 12VAC5-421-80 A~~.~~;

b. Documentation that food employees and conditional employees acknowledge their responsibilities as specified under 12VAC5-421-80 E and F~~.~~; and

c. Documentation that the person in charge acknowledges the responsibilities as specified under 12VAC5-421-80 B, C, and D, and 12VAC5-421-90 and 12VAC5-421-100;

4. Documentation that the food employees acknowledge that they have received training in:

a. The risks of contacting the specific ready-to-eat foods with their bare hands~~.~~;

b. Proper handwashing as specified under 12VAC5-421-140~~.~~;

c. When to wash their hands as specified under 12VAC5-421-160~~.~~;

d. Where to wash their hands as specified under 12VAC5-421-170~~.~~;

e. Proper fingernail maintenance as specified under 12VAC5-421-190~~.~~;

f. Prohibition of jewelry as specified under 12VAC5-421-200~~.~~; and

g. Good hygienic practices as specified under 12VAC5-421-220 and 12VAC5-421-230;

5. Documentation that hands are washed before food preparation and as necessary to prevent cross-contamination by food employees as specified under 12VAC5-421-130~~, 12VAC5-421-140, 12VAC5-421-160, and~~ through 12VAC5-421-170 during all hours of operation when the specific ready-to-eat foods are prepared;

6. Documentation that food employees contacting ready-to-eat food with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:

a. Double handwashing~~.~~;

b. Nail brushes~~.~~;

c. A hand antiseptic after handwashing as specified under 12VAC5-421-180~~.~~;

d. Incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill~~.~~; or

e. Other control measures approved by the regulatory authority; and

7. Documentation that corrective action is taken when ~~subdivision D~~ subdivisions 1 through 6 of this ~~section~~ subsection are not followed.

12VAC5-421-460. Preventing contamination when tasting.

A food employee shall not use a utensil more than once to taste food that is to be sold or served.[P]

12VAC5-421-470. Packaged and unpackaged food - separation, packaging, and segregation.

A. Food shall be protected from cross contamination by:

1. ~~Separating~~ Except as specified in subdivision 1 c of this subsection, separating raw animal foods during storage, preparation, holding, and display from:

a. Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as [fruits and] vegetables,[P] and

b. Cooked ready-to-eat food~~.~~;[P]

c. Frozen, commercially processed, and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.

2. Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

a. Using separate equipment for each type,[P] or ~~arranging~~

b. Arranging each type of food in equipment so that cross contamination of one type with another is prevented,[P] and

~~b.~~ c. Preparing each type of food at different times or in separate areas;[P]

3. Cleaning equipment and utensils as specified under 12VAC5-421-1780 A and sanitizing as specified under 12VAC5-421-1900;

4. Except as specified in subsection B of this section and 12VAC5-421-810 B 2, storing the food in packages, covered containers, or wrappings;

5. Cleaning hermetically sealed containers of food of visible soil before opening;

6. Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

7. Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 12VAC5-421-3150; and

8. Separating fruits and vegetables, before they are washed as specified under 12VAC5-421-510 from ready-to-eat food.

B. Subdivision A 4 of this section does not apply to:

1. Whole, uncut, raw fruits and vegetables and nuts in the shell~~,~~ that require peeling or hulling before consumption;

2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;

3. Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;

4. Food being cooled as specified under 12VAC5-421-810 B 2; or

5. Shellstock.

12VAC5-421-480. Food storage containers; identified with common name of food.

~~Working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar, shall be identified with the common name of the food (in English and the common language of the food workers) except that containers holding food that can be readily and unmistakably recognized such as dry pasta need not be identified.~~ Except for containers holding food that can be readily and unmistakably recognized such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the food.

12VAC5-421-490. Pasteurized eggs; substitute for ~~shell~~ raw eggs for certain recipes and populations.

Pasteurized eggs or egg products shall be substituted for raw ~~shell~~ eggs in the preparation of foods such as Caesar salad, hollandaise or [~~bearnaise~~ béarnaise] sauce, mayonnaise, meringue, [eggnog, ice cream,] and egg-fortified beverages that are not:[P]

1. Cooked as specified in 12VAC5-421-700 A 1 or 2;[P] or

2. Included in 12VAC5-421-700 D.[P]

12VAC5-421-500. Protection from unapproved additives.

A. Food, as specified in 12VAC5-421-350, shall be protected from contamination that may result from the addition of:

1. Unsafe or unapproved food or color additives;[P] and

2. Unsafe or unapproved levels of approved food and color additives.[P]

B. A food employee shall not:

1. Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B_1;[P] or

2. Except for grapes, serve or sell food specified under subdivision B 1 of this section that is treated with sulfiting agents before receipt by the food establishment.[P]

12VAC5-421-510. Washing fruits and vegetables.

A. ~~Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form except as specified in subsection B of this section and except that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.~~ Except as specified in subsection B of this section and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.

B. Fruits and vegetables may be washed by using chemicals as specified under 12VAC5-421-3390.

C. Devices used for onsite generation of chemicals meeting the requirements specified in 21 CFR 173.315 shall be used in accordance with the manufacturer's instructions.[Pf]

12VAC5-421-520. Ice used as exterior coolant, prohibited as ingredient.

After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice shall not be used as food.[P]

12VAC5-421-540. Food contact with equipment and utensils.

Food shall only contact surfaces of:

1. Equipment and utensils that are cleaned as specified under 12VAC5-421-1770 through 12VAC5-421-1870 [~~,~~] and sanitized as specified under ~~12VAC5-421-1880 through~~ [12VAC5-421-1885,] 12VAC5-421-1890 and 12VAC5-421-1900;[P] ~~or~~

2. Single-service and single-use articles~~.~~;[P] or

3. Linens, such as cloth napkins, as specified under 12VAC5-421-560 that are laundered as specified under 12VAC5-421-1920 C.[P]

12VAC5-421-550. In-use utensils, between-use storage.

During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

1. Except as specified under subdivision 2 of this section, in the food with their handles above the top of the food and the container;

2. In food that is not ~~potentially hazardous~~ time/temperature control for safety food with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

3. On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 12VAC5-421-1780 and 12VAC5-421-1890;

4. In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

5. In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not ~~potentially hazardous~~ time/temperature control for safety food; or

6. In a container of water if the water is maintained at a temperature of at least 135°F (57°C) and the container is cleaned at a frequency specified under 12VAC5-421-1780 D 7.

[12VAC5-421-560. Linens and napkins, use limitation.

Linens ~~and~~, such as cloth napkins, shall not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new customer.]

12VAC5-421-570. Wiping cloths; ~~used for one purpose~~ use limitation.

A. Cloths in-use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:

1. Maintained dry; and

2. Used for no other purpose.

B. Cloths in-use for wiping counters and other equipment surfaces shall be:

1. Held between uses in a chemical sanitizer solution at a concentration specified in 12VAC5-421-3380; and

2. Laundered daily as specified under 12VAC5-421-1920 D.

C. Cloths in-use for wiping surfaces in contact with raw animal foods shall be kept separate from other cloths used for other purposes.

D. Dry wiping cloths and the chemical sanitizing solutions specified in subdivision B 1 of this section in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

E. Containers of chemical sanitizing solutions specified in subdivision B 1 of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of food, equipment, utensils, linens, single-service, or single-use articles.

F. Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

12VAC5-421-580. Gloves; use limitation.

A. If used, single-use gloves shall be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.[P]

B. Except as specified in subsection C of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under 12VAC5-421-700 through 12VAC5-421-760 such as frozen food or a primal cut of meat.

C. Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

D. Cloth gloves shall not be used in direct contact with food unless the food is subsequently cooked as required under 12VAC5-421-700 through 12VAC5-421-760 such as frozen food or a primal cut of meat.

12VAC5-421-600. Refilling returnables.

[A. Except as specified in subsections B through E of this section, empty containers returned to a food establishment for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.[P]

~~A.~~ B.] A take-home food container returned to a food establishment [~~shall not~~ may] be refilled at a food establishment with ~~a potentially hazardous~~ [~~time/temperature control for safety~~] food [~~.~~ if the food container is:

1. Designed and constructed for reuse and in accordance with the requirements specified in 12VAC5-421-960 through 12VAC5-421-1435;[P]

2. One that was initially provided by the food establishment to the consumer, either empty or filled with food by the establishment, for the purpose of being returned for reuse;

3. Returned to the food establishment by the consumer after use;

4. Subject to the following steps before being refilled with food;

a. Cleaned as specified in 12VAC5-421-1770 through 12VAC5-421-1860,

b. Sanitized as specified in 12VAC5-421-1885, 12VAC5-421-1890, and 12VAC5-421-1900;[P] and

c. Visually inspected by a food employee to verify that the container, as returned, meets the requirements specified in 12VAC5-421-960 through 12VAC5-421-1435;[P] and

C. A take-home food container returned to a food establishment may be refilled at a food establishment with beverage if:

1. The beverage is not a time/temperature control for safety food;

2. The design of the container, the rinsing equipment, and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;

3. Facilities before rinsing or refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and

5. The container is refilled by:

a. An employee of the food establishment; or

b. The owner of the container if the beverage system includes a contamination-free transfer process as specified in subdivisions 1, 2, and 4 of 12VAC5-421-1230.]

[~~B. Except as specified in subsection C of this section, a take-home food container refilled with food that is not~~] ~~potentially hazardous~~ [~~time/temperature control for safety food shall be cleaned as specified under 12VAC5-421-1870.~~

~~C. Personal~~ D. Consumer-owned, personal] take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under subdivisions 1, 2, and 4 of 12VAC5-421-1230.

[E. Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.]

12VAC5-421-630. Vended ~~potentially hazardous~~ time/temperature control for safety food; original container.

~~Potentially hazardous~~ Time/temperature control for safety food dispensed through a vending machine shall be in the package in which it was placed at the food establishment or food processing plant at which it was prepared.

12VAC5-421-650. Food display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means.[P]

12VAC5-421-670. Consumer self-service operations.

A. Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish shall not be offered for consumer self-service.[P] This subsection does not apply to:

1. Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;

2. Ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or

3. Raw, frozen, shell-on shrimp or lobster.

B. Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination.[Pf]

C. Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures.[Pf]

12VAC5-421-680. Returned food and reservice of food.

A. Except as specified under subsection B of this section, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer shall not be offered as food for human consumption.[P]

B. Except as specified in subdivision 8 of 12VAC5-421-950, a container of food that is not ~~potentially hazardous (time/temperature control for safety food)~~ time/temperature control for safety food may be re-served from one consumer to another if:

1. The food is dispensed so that it is protected from contamination and the container is closed between uses such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

2. The food, such as crackers, salt, or pepper, is in an unopened original package and maintained in sound condition.

Article 4
Destruction of Organisms of Public Health Concern

12VAC5-421-700. Raw animal foods.

A. Except as specified in subsections B, C, and D of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

1. 145°F (63°C) or above for 15 seconds for:[P]

a. Raw ~~shell~~ eggs that are broken and prepared in response to a consumer's order and for immediate service;[P] and

b. Except as specified under subdivisions A 2 and 3 and ~~subsection~~ subsections B and C of this section, fish and meat, including game animals commercially raised for food ~~as specified under 12VAC5-421-330 A 1~~ and game animals under a voluntary inspection program as specified under 12VAC5-421-330 A ~~2~~ 1;[P]

2. 155°F (68°C) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and ~~injected meats,~~ mechanically tenderized meats, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food ~~as specified under 12VAC5-421-330 A 1,~~ and game animals under a voluntary inspection program as specified under 12VAC5-421-330 A ~~2~~ 1; and raw eggs that are not prepared as specified under subdivision 1 a of this subsection:[P]

Minimum	
Temperature °F (°C)	Time
145 (63)	3 minutes
150 (66)	1 minute
158 (70)	<1 second (instantaneous)

3. 165°F (74°C) or above for 15 seconds for poultry, [baluts,] wild game animals as specified under 12VAC5-421-330 A ~~3~~ 2, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, ~~or~~ poultry, or ratites.[P]

B. Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

1. In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature;[Pf] and

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg) or more
Still Dry	350°F (177°C) or more	250°F (121°C) or more
Convection	325°F (163°C) or more	250°F (121°C) or more
High Humidity[1]	250°F (121°C) or less	250°F (121°C) or less
[1]Relative humidity greater than 90% for at least ~~1~~ one hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

2. As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature.[P]

Temperature °F (°C)	Time[1] in Minutes	Temperature °F (°C)	Time[1] in Seconds
130 (54.4)	112	147 (63.9)	134
131 (55.0)	89	149 (65.0)	85
133 (56.1)	56	151 (66.1)	54
135 (57.2)	36	153 (67.2)	34
136 (57.8)	28	155 (68.3)	22
138 (58.9)	18	157 (69.4)	14
140 (60.0)	12	158 (70.0)	0
142 (61.1)	8		
144 (62.2)	5		
145 (62.8)	4		
[1]Holding time may include postoven heat rise.			

C. A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

1. The food establishment serves a population that is not a highly susceptible population;

2. The steak is labeled, as specified under 12VAC5-421-270 E, to indicate that it meets the definition of "whole-muscle, intact beef"; and

3. The steak is cooked on both the top and bottom to a surface temperature of 145°F (63°C) or above and a cooked color change is achieved on all external surfaces.

D. A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare, or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in subsection C of this section, may be served or

offered for sale [upon request or consumer selection] in a ready-to-eat form if:

1. ~~(i)~~ As specified under subdivisions 3 a and b of 12VAC5-421-950 the food establishment serves a population that is not a highly susceptible population ~~and (ii) the~~;

2. The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat;[Pf] and

3. The consumer is informed as specified under 12VAC5-421-930 that to ensure its safety, the food should be cooked as specified under ~~subsections~~ subsection A or B of this section; or

~~2.~~ 4. The regulatory authority grants a variance from subsection A or B of this section as specified in 12VAC5-421-3570 based on a HACCP plan that:

a. Is submitted by the permit holder and approved as specified under 12VAC5-421-3570;

b. Documents scientific data or other information that shows that a lesser time and temperature regimen results in a safe food; and

c. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions [of the variance].

12VAC5-421-710. Microwave cooking.

Raw animal foods cooked in a microwave oven shall be:

1. Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

2. Covered to retain surface moisture;

3. Heated to a temperature of at least 165°F (74°C) in all parts of the food;[P] and

4. Allowed to stand covered for two minutes after cooking to obtain temperature equilibrium.

12VAC5-421-720. Plant food cooking for hot holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 135°F (57°C).[Pf]

12VAC5-421-725. Noncontinuous cooking.

Raw animal foods that are cooked using a noncontinuous cooking process shall be:

1. Subject to an initial heating process that is no longer than 60 minutes in duration;[P]

2. Immediately after initial heating, cooled according to the time and temperature requirements specified for cooked time/temperature control for safety food under 12VAC5-421-800 A;[P]

3. After cooling, held frozen or cold, as specified for time/temperature control for safety food under 12VAC5-421-820 A 2;[P]

4. Prior to sale or service, cooked using a process that heats all parts of the food to a temperature [and for a time] as designated in 12VAC5-421-700 A, B, and C;[P]

5. Cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under 12VAC5-421-800 A if not [either] hot held as specified under 12VAC5-421-820 A 1, served immediately, or held using time as a public health control as specified under 12VAC5-421-850 after complete [~~cooking~~ cooling];[P] and

6. Prepared and stored according to written procedures that:

a. Have obtained prior approval from the regulatory authority;[Pf]

b. Are maintained in the food establishment and are made available to the regulatory authority upon request;[Pf]

c. Describe how the requirements specified under subdivisions 1 through 5 of this section are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met;[Pf]

d. Describe how the foods, after initial heating, but prior to complete [~~cooling~~ cooking], are to be marked or otherwise identified as foods that must be cooked as specified under subdivision 4 of this section prior to being offered for sale or service;[Pf] and

e. Describe how the foods, after initial heating but prior to cooking as specified in subdivision 4 of this section, are to be separated from ready-to-eat foods as specified under 12VAC5-421-470 A.[Pf]

12VAC5-421-730. Parasite destruction.

A. Except as specified in subsection B of this section, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked or marinated-partially cooked fish shall be:

1. Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168 hours (seven days) in a freezer;[P]

2. Frozen at -31°F (-35°C) or below until solid and stored at -31°F (-35°C) or below for a minimum of 15 hours;[P] or

3. Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a minimum of 24 hours.[P]

B. Subsection A of this section does not apply to:

1. Molluscan shellfish, including the shucked adductor muscle of scallops;

2. Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin, Northern); ~~or~~

3. Aquacultured fish, such as salmon, that:

a. If raised in open water, are raised in net-pens; or

b. Are raised in land-based operations such as ponds or tanks; and

c. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish~~.~~, or

4. Fish eggs that have been removed from the skein and rinsed.

12VAC5-421-740. Records, creation and retention.

A. Except as specified in 12VAC5-421-730 B and subsection B of this section, if raw, marinated, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food establishment for 90 calendar days beyond the time of service or sale of the fish.Pf

B. If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 12VAC5-421-730 may substitute for the records specified under subsection A of this section.

C. If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in 12VAC5-421-730 B 3, a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 12VAC5-421-730 B 3 shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish.Pf

[12VAC5-421-755. Preparation for immediate service.

Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.]

12VAC5-421-760. Reheating for hot holding.

A. Except as specified under subsections B, C, and E of this section, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach at least 165°F (74°C) for 15 seconds.P

B. Except as specified under subsection C of this section, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165°F (74°C) and the food is rotated or stirred, covered, and allowed to stand covered two minutes after reheating.P

C. Ready-to-eat [time/temperature control for safety] food [~~taken from a~~ that has been] commercially processed [~~, hermetically sealed container, or from an intact package from~~ and packaged in] a food processing plant that is inspected by the [~~food~~] regulatory authority that has jurisdiction over the plant [~~,~~] shall be heated to a temperature of at least 135°F (57°C) [when being reheated] for hot holding.P

D. Reheating for hot holding as specified under subsections A ~~through~~, B, and C of this section shall be done rapidly and the time the food is between 41°F (5°C) and the temperatures specified under subsections A ~~through~~, B, and C of this section may not exceed two hours.P

E. Remaining unsliced portions of meat roasts that are cooked as specified under 12VAC5-421-700 B may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 12VAC5-421-700 B.

Article 5

Limitation of Growth of Organisms of Public Health Concern

12VAC5-421-765. Treating juice.

Juice packaged in a food establishment shall be:

1. Treated under a HACCP plan as specified in ~~subdivisions 2 through 5 of~~ 12VAC5-421-3630 to attain a five-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance;P or

2. Labeled, if not treated to yield a five-log reduction of the most resistant microorganism of public health significance:Pf

a. As specified under 12VAC5-421-900;Pf and

b. As specified in 21 CFR 101.17(g) with the [~~phrase~~ following], "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."Pf

12VAC5-421-780. ~~Potentially hazardous~~ Time/temperature control for safety food, slacking.

Frozen ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food that is slacked to moderate the temperature shall be held:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or

2. At any temperature if the food remains frozen.

12VAC5-421-790. Thawing.

A. Except as specified in subdivision 4 of this ~~section~~ subsection, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food shall be thawed:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or

2. Completely submerged under running water:

a. At a water temperature of 70°F (21°C) or below;

b. With sufficient water velocity to agitate and float off loose particles in an overflow; and

c. For a period of time that does not allow thawed portions of ready-to-eat food to rise above 41°F (5°C); or

d. For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under 12VAC5-421-700 A or B to be above 41°F (5°C) for more than four hours including:

(1) The time the food is exposed to the running water and the time needed for preparation for cooking; or

(2) The time it takes under refrigeration to lower the food temperature to 41°F (5°C);

3. As part of a cooking process if the food that is frozen is:

a. Cooked as specified under 12VAC5-421-700 A or B or 12VAC5-421-710; or

b. Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

4. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

B. Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

1. Prior to its thawing under refrigeration as specified [~~under~~ in] subdivision A 1 of this section.

2. Prior to, or immediately upon completion of, its thawing using procedures specified in subdivision A 2 of this section.

12VAC5-421-800. Cooling.

A. Cooked ~~potentially hazardous food (time/temperature controlled for safety food)~~ time/temperature control for safety food shall be cooled:

1. Within two hours, from 135°F (57°C) to 70°F (21°C);[P] and

2. Within a total of six hours from 135°F (57°C) to 41°F (5°C) or less.[P]

B. ~~Potentially hazardous food (time/temperature control for safety food)~~ Time/temperature control for safety food shall be cooled within four hours to 41°F (5°C) or less if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.[P]

C. Except as specified in subsection D of this section, a ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food received in compliance with laws allowing a temperature above 41°F (5°C) during shipment from the supplier as specified in 12VAC5-421-340 B, shall be cooled within four hours to 41°F (5°C) or less.[P]

D. Raw ~~shell~~ eggs shall be received as specified under 12VAC5-421-340 C and immediately placed in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.[P]

12VAC5-421-810. Cooling methods.

A. Cooling shall be accomplished in accordance with the time and temperature criteria specified under 12VAC5-421-800 by using one or more of the following methods based on the type of food being cooled:

1. Placing the food in shallow pans;[Pf]

2. Separating the food into smaller or thinner portions;[Pf]

3. Using rapid cooling equipment;[Pf]

4. Stirring the food in a container placed in an ice water bath;[Pf]

5. Using containers that facilitate heat transfer;[Pf]

6. Adding ice as an ingredient;[Pf] or

7. Other effective methods.[Pf]

B. When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

1. Arranged in the equipment to provide maximum heat transfer through the container walls; and

2. Loosely covered, or uncovered if protected from overhead contamination as specified under 12VAC5-421-610 A 2, during the cooling period to facilitate heat transfer from the surface of the food.

12VAC5-421-820. ~~Potentially hazardous~~ Time/temperature control for safety food; hot and cold holding.

A. Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 12VAC5-421-850 [and except as specified in subsections B and C of this section], ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food shall be maintained:

1. At 135°F (57°C) or above, except that roasts cooked to a temperature and for a time specified under 12VAC5-421-700 B or reheated as specified in 12VAC5-421-760 E may be held at a temperature of 130°F (54°C) or above;[P] or

2. At 41°F (5°C) or less.[P]

B. ~~Shell eggs~~ Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.[P]

C. ~~Potentially hazardous food (time/temperature control for safety food)~~ Time/temperature control for safety food in a homogenous liquid form may be maintained outside the temperature control requirements, as specified in subsection A of this section, while contained within specially designed equipment that complies with the design and construction requirements as specified under subdivision 5 of 12VAC5-421-1230.[P]

12VAC5-421-830. Ready-to-eat, ~~potentially hazardous food~~ time/temperature control for safety food; date marking.

A. Except when packaging food using a reduced oxygen packaging method as specified under 12VAC5-421-870, and except as specified in subsections D and E of this section, refrigerated ready-to-eat ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food prepared and held in a food establishment for more than 24 hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded when held at a temperature of 41°F (5°C) or less for a maximum of seven days. The day of preparation shall be counted as day 1. [Pf]

B. Except as specified in subsections D ~~through~~, E, and F of this section, refrigerated ready-to-eat, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food prepared and packaged by a food processing plant shall be clearly marked at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in subsection A of this section and:[Pf]

1. The day the original container is opened in the food establishment shall be counted as day 1;[Pf] and

2. The day or date marked by the food establishment shall not exceed a manufacturer's ~~use by~~ "use by" date if the manufacturer determined the ~~use by~~ "use by" date based on food safety.[Pf]

C. A refrigerated, ready-to-eat, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food ingredient or a portion of a refrigerated, ready-to-eat, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient.[Pf]

D. A date marking system that meets the criteria specified in subsections A and B of this section may include:

1. Using a method approved by the regulatory authority for refrigerated, ready-to-eat ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft-serve mix or milk in a dispensing machine;

2. Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified in subsection A of this section;

3. Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date ~~of~~ or day by which the food must be consumed on the premises, sold, or discarded as specified under subsection B of this section; or

4. Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority upon request.

E. Subsections A and B of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

F. Subsections A and B of this section do not apply to shellstock.

~~F.~~ G. Subsection B of this section does not apply to the following foods prepared and packaged by a food processing plant inspected by a regulatory authority:

1. Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110 ~~Current good manufacturing practice in manufacturing, packing or holding food~~;

2. Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133 ~~Cheeses and related cheese products~~, such as cheddar, gruyere, parmesan and reggiano, and romano;

3. Semi-soft cheese containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR Part 133 ~~Cheeses and cheese related products~~, such as blue, edam, gorgonzola, gouda, and monterey jack;

4. Cultured dairy products as defined in 21 CFR Part 131 ~~Milk and cream~~, such as yogurt, sour cream, and buttermilk;

5. Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products as defined in 21 CFR Part 114 ~~Acidified foods~~;

6. Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami ~~that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers, and that retain the original casing on the product~~; and

7. Shelf stable salt-cured products such as prosciutto and Parma (ham) ~~that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers~~.

12VAC5-421-840. Ready-to-eat, ~~potentially hazardous~~ time/temperature control for safety food; disposition.

A. A food specified under 12VAC5-421-830 A or B shall be discarded if it:

1. Exceeds either of the temperature and time [~~combinations~~ combination] specified in 12VAC5-421-830 A, except time that the product is frozen;[P]

2. Is in a container or package that does not bear a date or day;[P] or

3. Is [~~appropriately~~ inappropriately] marked with a date or day that exceeds a temperature and time combination as specified in 12VAC5-421-830 A.[P]

[B. Refrigerated, ready-to-eat, time/temperature control for safety food prepared in a food establishment and dispensed through a vending machine with an automatic shutoff control shall be disgarded if it exceeds a temperature and time combination as specified in 12VAC5-421-830 A.[P]]

12VAC5-421-850. Time as a public health control.

A. Except as specified under subsection D of this section, if time without temperature control is used as the public health control for a working supply of ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food before cooking or for ready-to-eat ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food that is displayed or held for sale or service, written procedures shall be prepared in advance, maintained in the food establishment, and made available to the regulatory authority upon request that specify:[Pf]

1. Methods of compliance with subdivisions B 1 ~~through~~, 2, and 3 or C 1 through 5 of this section;[Pf] and

2. Methods of compliance with 12VAC5-421-800 for food that is prepared, cooked, and refrigerated before time is used as a public health control.[Pf]

B. If time without temperature control is used as the public health control up to a maximum of four hours:

[1. The food shall have an initial temperature of 41°F (5°C) or less when removed from cold holding temperature control or 135°F (57°C) or greater when removed from hot holding temperature control;[P]

~~1.~~ 2.] The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;[P]

[~~2.~~ 3.] The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control;[P] and

[~~3.~~ 4.] The food in unmarked containers or packages, or marked to exceed a four-hour limit shall be discarded.[P]

C. If time without temperature control is used as the public health control up to a maximum of six hours:

1. The food shall have an initial temperature of 41ºF (5ºC) or less when removed from temperature control and the food temperature may not exceed 70ºF (21ºC) within a maximum time period of six hours;[P]

2. The food shall be monitored to ensure the warmest portion of the food does not exceed 70ºF (21ºC) during the six-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70ºF (21ºC) during the six-hour holding period;[P]

3. The food shall be marked or otherwise identified to indicate:[Pf]

a. The time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control,[Pf] and

b. The time that is six hours past the point in time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control;[Pf]

4. The food shall be:

a. Discarded if the temperature of the foods exceeds 70ºF (21ºC);[P] or

b. Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of six hours from the point in time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control;[P] and

5. The food in unmarked containers or packages, or marked with a time that exceeds the six-hour limit shall be discarded.[P]

D. A food establishment that serves a highly susceptible population may not use time as specified under ~~subsections~~ subsection A, B, or C of this section as the public health control for raw eggs.

12VAC5-421-860. Variance requirement.

A food establishment shall obtain a variance from the regulatory authority as specified in 12VAC5-421-3570 and 12VAC5-421-3580 before:[Pf]

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement;[Pf]

2. Curing food;[Pf]

3. Using food additives or adding components such as vinegar:[Pf]

a. As a method of food preservation rather than as a method of flavor enhancement;[Pf] or

b. To render a food so that it is not ~~potentially hazardous~~ a time/temperature control for safety food; [Pf]

4. Packaging time/temperature control for safety food using a reduced oxygen packaging method except ~~as specified under 12VAC5-421-870 where a barrier to Clostridium botulinum in addition to refrigeration exists~~ where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under 12VAC5-421-870;[Pf]

5. Operating a molluscan shellfish life-support system display tank used to store [~~and~~ or] display shellfish that are offered for human consumption;[Pf]

6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment;[Pf]

7. Sprouting seeds or beans;[Pf] or

8. Preparing food by another method that is determined by the regulatory authority to require a variance.[Pf]

12VAC5-421-870. Reduced oxygen packaging; without a variance, criteria.

A. Except for a food establishment that obtains a variance as specified under 12VAC5-421-860 [~~and except as specified under subsections C and E of this section~~], a food establishment that packages ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food using a reduced oxygen packaging method shall [~~ensure that there are at least two barriers in place to~~] control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes.[P]

B. ~~A~~ Except as specified under subsection F of this section, a food establishment that packages ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food using a reduced oxygen method shall have a HACCP plan that contains the following information specified under subdivisions 3 and 4 of 12VAC5-421-3630 ~~D~~:[Pf]

1. Identifies food to be packaged;[Pf]

2. Except as specified in subsections C and E and as specified in subsection D of this section, requires that the packaged food shall be maintained at 41°F (5°C) or less and meet at least one of the following criteria:[Pf]

a. Has an A_w of 0.91 or less,[Pf]

b. Has a pH of 4.6 or less,[Pf]

c. Is a meat or poultry product cured ~~as~~ at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21~~, Use of food ingredients and sources of radiation,~~ and is received in an intact package,[Pf] or

d. Is a food with a high level of competing organisms such as raw meat ~~or~~, raw poultry~~;~~, or raw vegetables [~~.~~][Pf]

3. Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:[Pf]

a. Maintain food at 41°F (5°C) or below,[Pf] and

b. Discard the food if within ~~14~~ 30 calendar days of its packaging [~~if~~] it [is] not served for on-premises consumption, or consumed if served or sold for off-premises consumption;[Pf]

4. Limits the refrigerated shelf life to no more than ~~14~~ 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;[P]

5. Includes operational procedures that:

a. Prohibit contacting [ready-to-eat] food with bare hands [as specified in 12VAC5-421-450 B],[Pf]

b. Identify a designated work area and the method by which:[Pf]

(1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination,[Pf] and

(2) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation,[Pf] and

c. Delineate cleaning and sanitization procedures for food contact surfaces; and[Pf]

6. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:[Pf]

a. Concepts required for safe operation,[Pf]

b. Equipment and facilities,[Pf] and

c. Procedures specified under subdivision B 5 of this section and subdivisions 3 and 4 of 12VAC5-421-3630 ~~D~~.; and[Pf]

7. Is provided to the regulatory authority prior to implementation as specified under 12VAC5-421-3620 [B].

C. Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.[P]

D. Except as specified in ~~subsection~~ subsections C and F of this section, a food establishment ~~may package~~ that packages [time/temperature control for safety] food using a cook-chill or sous-vide process ~~without obtaining a variance if~~ shall:

1. ~~The food establishment implements~~ Provide to the regulatory authority prior to implementation a HACCP plan that contains the information as specified under subdivisions 3 and 4 of 12VAC5-421-3630 ~~D~~.;[Pf]

2. ~~The~~ Ensure the food is:

a. Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the bagged product to another business entity or the consumer~~;~~;[Pf]

b. Cooked to heat all parts of the food to a temperature and for a time as specified under [subsections A, B, and C of] 12VAC5-421-700~~,~~ [~~subsections A, B, and C of this section~~];[P]

c. Protected from contamination [before and] after cooking as specified in 12VAC5-421-450 through [~~12VAC5-421-690~~ 12VAC5-421-765]~~;~~;[P]

d. Placed in a package [~~or bag~~] with an oxygen barrier and sealed before cooking, or placed in a package [~~or bag~~] and sealed immediately after cooking, and before reaching a temperature below 135°F (57°C)~~;~~;[P]

e. Cooled to 41°F (5°C) in the sealed package [~~or bag~~] as specified under 12VAC5-421-800, and ~~subsequently~~:[P]

(1) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that temperature until consumed or discarded within 30 days after the date of ~~preparation,~~ packaging;[P]

(2) ~~Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C), removed from refrigeration equipment that maintains a 34°F (1°C) food temperature and then held~~ Held at 41°F (5°C) or less for no more than ~~72 hours~~ seven days, at which time the food must be consumed or discarded;[P] or

~~(3) Cooled to 38°F (3°C) or less within 24 hours of reaching 41°F (5°C) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded;[P] or~~

~~(4)~~ (3) Held frozen with no shelf-life restriction while frozen until consumed or used [~~.~~;][P]

f. Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily~~.~~;[Pf]

g. If transported ~~off-site~~ off site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation~~.~~;[Pf] and

h. Labeled with the product name and the date packaged;[Pf] and

3. ~~The~~ Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan, are maintained and are:

a. Made available to the regulatory authority upon request,[Pf] and

b. Held for six months;[Pf] and

4. ~~Written~~ Implement written operational procedures as specified under subdivision B 5 of this section and a training program as specified under subdivision B 6 of this section [~~are implemented~~].[Pf]

E. ~~A~~ Except as specified under subsection F of this section, a food establishment ~~may package~~ that packages cheese using a reduced oxygen packaging method ~~without obtaining a variance if it~~ shall:

1. ~~Limits~~ Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 ~~Hard Cheeses~~, 21 CFR 133.169 ~~Pasteurized process cheese~~, or 21 CFR 133.187 ~~Semi-soft cheeses~~;[P]

2. ~~Has~~ Have a HACCP plan that contains the information specified in subdivisions 3 and 4 of 12VAC5-421-3630 ~~D~~ and as specified under subdivisions B 1, B 3 a, B 5, and B 6 of this section;[Pf]

3. ~~Except as specified under subdivision B 2, B 3 b, and B 4, complies with subsection B of this section;~~

~~4. Labels~~ 3. Label the package on the principal display panel with a "use by" date that does not exceed 30 days [from its packaging] or the original manufacturer's "sell by" or "use by" date, whichever [~~comes~~ occurs] first;[Pf] and

~~5. Discards~~ 4. Discard the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.[Pf]

F. A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package [~~TCS~~ time/temperature control for safety] food that is always:

1. Labeled with the production time and date.

2. Held at 41°F [(5°C)] or less during refrigerated storage [~~.~~; and]

3. Removed from its [~~package~~ packaging] in the food establishment within 48 hours after packaging.

Article 6

Food Identity, Presentation, and On-Premises Labeling

12VAC5-421-880. Standards of identity.

Packaged food shall comply with standard of identity requirements in 21 CFR Parts 131-169 and 9 CFR Part 319 ~~– Definitions and Standards of Identity or Composition~~, and the general requirements in 21 CFR Part 130 ~~– Food Standards: General~~ and 9 CFR Part 319, Subpart A ~~– General~~.

12VAC5-421-900. Food labels.

A. Food packaged in a food establishment, shall be labeled as specified in accordance with all applicable laws and regulations, including 21 CFR Part 101 ~~– Food Labeling,~~ and 9 CFR Part 317 ~~– Labeling, Marking Devices, and Containers~~.

B. Label information shall include:

1. The common name of the food, or absent a common name, an adequately descriptive identity statement;

2. If made from two or more ingredients, a list of ingredients [and sub-ingredients] in descending order of predominance by weight, including a declaration of artificial [~~color or flavor~~ colors, artificial flavors,] and chemical preservatives, if contained in the food;

3. An accurate declaration of the [net] quantity of contents;

4. The name and place of business of the manufacturer, packer, or distributor;

5. The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient;[Pf]

6. Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) – through (5), nutrition labeling

as specified in 21 CFR Part 101 ~~, Food Labeling,~~ and 9 CFR Part 317~~,~~ Subpart B ~~, Nutrition Labeling~~; and

7. For any salmonid fish containing canthaxanthin [or astaxanthin] as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin [or astaxanthin].

C. Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:

1. The manufacturer's or processor's label that was provided with the food; or

2. A card, sign, or other method of notification that includes the information specified under subdivisions B 1, 2 and 5 of this section.

D. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:

1. A health, nutrient content, or other claim is not made;

2. There are no state or local laws requiring labeling; and

3. The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

12VAC5-421-930. [~~Consumption~~ Consumer advisory: consumption] of animal [~~products~~ foods] that are raw, undercooked, or not otherwise processed to eliminate pathogens.

A. Except as specified in 12VAC5-421-700 C and D 4 and under 12VAC5-421-950 ~~C~~, if an animal food such as beef, eggs, fish, lamb, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food, the permit holder shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in subsections B and C of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.Pf

B. Disclosure shall include:

1. A description of the animal-derived foods, such as "oysters on the half shell (raw oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)";Pf or

2. Identification of the animal-derived foods by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.Pf

C. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:

1. "Regarding the safety of these items, written information is available upon request";Pf

2. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness";Pf or

3. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."Pf

Article 7
Contaminated Food

12VAC5-421-940. Discarding unsafe, adulterated, or contaminated food.

A. A food that is unsafe, adulterated, or not from an approved source as specified under 12VAC5-421-270 through 12VAC5-421-330 shall be rendered unusable and discarded.P

B. Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 12VAC5-421-90 shall be rendered unusable and discarded.P

C. Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be rendered unusable and discarded.P

Article 8
Special Requirements for Highly Susceptible Populations

12VAC5-421-950. Pasteurized foods, prohibited reservice, and prohibited food.

In a food establishment that serves a highly susceptible population:

1. The following criteria apply to juice:

a. For the purposes of this paragraph only, children who are age nine or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;

b. Prepackaged juice or a prepackaged beverage containing juice~~,~~ that bears a warning label as specified in 21 CFR 101.17(g) ~~Food Labeling,~~ (Juices that have not been specifically processed to prevent, reduce or eliminate the presence of pathogens) or a packaged juice or beverage containing juice~~,~~ that bears a warning label as specified under subdivision 2 of 12VAC5-421-765 ~~shall~~ may not be served or offered for sale;P and

c. Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified in subdivisions 2 through 5 of 12VAC5-421-3630 and as specified ~~under~~ [in] 21 CFR 120.24~~, Process controls~~.P

2. Pasteurized ~~shell~~ eggs or egg products shall be substituted for raw ~~shell~~ eggs in the preparation of:[P]

a. Foods such as Caesar salad, hollandaise or ~~biarnaise~~ Bearnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages;[P] and

b. Except as specified in subdivision 6 of this section, recipes in which more than one egg is broken and the eggs are combined.[P]

3. The following foods shall not be served or offered for sale in a ready-to-eat form:

a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare;[P]

b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw ~~shell~~ eggs, and meringue;[P] and

c. Raw seed sprouts.[P]

4. Food employees shall not contact ready-to-eat food as specified in 12VAC5-421-450 B and E.[P]

5. Time only, as the public health control as specified under 12VAC5-421-850 D, may not be used for raw eggs.[P]

6. Subdivision 2 b of this section does not apply if:

a. The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under 12VAC5-421-700 A 1, and served immediately, such as an omelet, soufflé, or scrambled eggs;

b. The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or

c. The preparation of the food is conducted under a HACCP plan that:

(1) Identifies the food to be prepared;

(2) Prohibits contacting ready-to-eat food with bare hands;

(3) Includes specifications and practices that ensure:

(a) Salmonella Enteritidis growth is controlled before and after cooking; and

(b) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 12VAC5-421-700 A 2;

d. Contains the information specified under subdivision 4 of 12VAC5-421-3630 including procedures that:

(1) Control cross contamination of ready-to-eat food with raw eggs; and

(2) Delineate cleaning and sanitization procedures for food-contact surfaces; and

e. Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

7. Except as specified in subdivision 8 of this section, food may be re-served as specified under 12VAC5-421-680 B 1 and 2.

8. Foods may not be re-served under the following conditions:

[~~1.~~ a.] Any food served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.

[~~2.~~ b.] Packages of food from any patients, clients, or other consumers should not be re-served to persons in protective environment isolation

Part IV
Equipment, Utensils, and Linens

Article 1
Materials for Construction and Repair

12VAC5-421-960. Multiuse, characteristics.

Materials that are used in the construction of utensils and food-contact surfaces of equipment shall not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be:[P]

1. Safe;[P]

2. Durable, corrosion-resistant, and nonabsorbent;

3. Sufficient in weight and thickness to withstand repeated warewashing;

4. Finished to have a smooth, easily cleanable surface; and

5. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

12VAC5-421-980. Lead, use limitation.

A. Ceramic, china, crystal utensils, and decorative utensils such as hand-painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:[P]

Utensil Category	Ceramic Article Description	Maximum Lead mg/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls > 1.1 Liter (1.16 Quart)	1.0
Small Hollowware (excluding cups and mugs	Bowls <1.1 Liter (1.16 Quart)	2.0
Flat tableware	Plates, Saucers	3.0

B. Pewter alloys containing lead in excess of 0.05% may not be used as a food contact surface.[P]

C. Solder and flux containing lead in excess of 0.2% may not be used as a food contact surface.

12VAC5-421-990. Copper, use limitation.

A. Except as specified in subsections B and C of this section, copper and copper alloys such as brass shall not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.[P]

B. Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

C. Copper and copper alloys may be used in contact with apple butter and molasses [~~ingredients~~] that have a pH below 6 [~~in the preparation of these items provided the contact time is less than 24 hours.~~ during the typical processing times (i.e., mixing, cooking, and cooling) for these products, as long as laboratory analysis does not reveal excessive levels of copper or other heavy metals in the finished product. Apple butter and molasses may not be held or stored in copper or copper alloys for time periods any longer than the typical processing times for these products].

12VAC5-421-1000. Galvanized metal, use limitation.

Galvanized metal shall not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.[P]

12VAC5-421-1070. Single-service and single-use, characteristics.

A. Materials that are used to make single-service and single-use articles shall not:

1. Allow the migration of deleterious substances;[P] or

2. Impart colors, odors, or tastes to food.

B. Materials that are used to make single-service and single-use articles shall be ~~safe and clean.~~:

1. Safe,[P] and

2. Clean.

12VAC5-421-1090. Food temperature measuring devices.

Food temperature measuring devices shall not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.[P]

12VAC5-421-1100. Food-contact surfaces; cleanability.

[A.] Multiuse food-contact surfaces shall be:

1. Smooth;[Pf]

2. Free of breaks, open seams, cracks, chips, [inclusions,] pits, and similar imperfections;[Pf]

3. Free of sharp internal angles, corners, and crevices;[Pf]

4. Finished to have smooth welds and joints;[Pf] and

5. [~~Accessible~~ Except as specified in subsection B of this section, accessible] for cleaning and inspection by one of the following methods:

a. Without being disassembled~~,~~;[Pf]

b. By disassembling without the use of tools~~,~~;[Pf] or

c. By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.[Pf]

[B. Subdivision A 5 of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.]

12VAC5-421-1110. CIP equipment.

A. CIP equipment shall meet the characteristics specified under 12VAC5-421-1100 and shall be designed and constructed so that:

1. Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces,[Pf] and

2. The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.

B. CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

12VAC5-421-1180. Temperature measuring devices; food.

A. Food temperature measuring devices that are scaled only in Fahrenheit or dually scaled in Fahrenheit and Celsius shall be scaled in 2°F increments and accurate to ±2°F in the intended range of use.[Pf]

B. Food temperature measuring devices that are scaled only in Celsius shall be scaled in 1°C increments accurate to ±1°C in the intended range of use.[Pf]

12VAC5-421-1190. Temperature measuring devices; ambient air and water.

A. Ambient air and water temperature measuring devices that are scaled in Fahrenheit or dually scaled in Fahrenheit and Celsius ~~and~~ shall be designed to be easily readable and scaled in 3°F increments and accurate to ±3°F in the intended range of use.[Pf]

B. Ambient air and water temperature measuring devices that are scaled only in Celsius shall be scaled in 1.5°C increments and accurate to ±1.5°C in the intended range of use.[Pf]

12VAC5-421-1230. Dispensing equipment, protection of equipment and food.

In equipment that dispenses or vends liquid food or ice in unpackaged form:

1. The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip

aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;

2. The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

3. The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

a. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or

b. Available for self-service during hours when it is not under the full-time supervision of a food employee; and

4. The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

5. Dispensing equipment in which ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food in homogenous liquid form is maintained outside of the temperature control requirements as specified in 12VAC5-421-820 C shall:

a. Be specifically designed and equipped to maintain the commercial sterility of aseptically packaged food in a homogenous liquid form for a specified duration from the time of opening the packaging within the equipment;[P] and

b. Conform to the requirements for this equipment as specified in NSF/ANSI 18-2006 Manual Food and Beverage Dispensing Equipment, 2012, (NSF International).[P]

12VAC5-421-1240. Vending machine, vending stage closure.

The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not ~~potentially hazardous~~ time/temperature control for safety food such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

1. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

2. Available for self-service during hours when it is not under the full-time supervision of a food employee.

12VAC5-421-1300. Molluscan shellfish tanks.

A. Except as specified under subsection B of this section, molluscan shellfish life support system display tanks shall not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to consumers that the shellfish are for display only.[P]

B. Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in 12VAC5-421-3570 and a HACCP plan that:[Pf]

1. Is submitted by the permit holder and approved as specified under 12VAC5-421-3580;[Pf] and

2. Ensures that:

a. Water used with fish other than molluscan shellfish does not flow into the molluscan tank;[Pf]

b. The safety and quality of the shellfish as they were received are not compromised by the use of the tank;[Pf] and

c. The identity of the source of the shellstock is retained as specified under 12VAC5-421-440.[Pf]

12VAC5-421-1310. Vending machines, automatic shutoff.

A. A machine vending ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food shall have an automatic control that prevents the machine from vending food:

1. If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that ~~can not~~ cannot maintain food temperatures as specified under Part III (12VAC5-421-260 et seq.) of this chapter;[P] and

2. If a condition specified under subdivision 1 of this subsection occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under Part III.[P]

B. When the automatic shutoff within a machine vending ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food is activated:

1. In a refrigerated vending machine, the ambient temperature shall not exceed 41°F (5°C) for more than 30 minutes immediately after the machine is filled, serviced, or restocked;[P] or

2. In a hot holding vending machine, the ambient temperature shall not be less than 135°F (57°C) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.[P]

12VAC5-421-1320. Temperature measuring devices.

A. In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located

to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

B. Except as specified in subsection C of this section, cold or hot holding equipment used for ~~potentially hazardous food~~ time/temperature control for safety food shall be designed to include and shall be equipped with at least one integral or affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

C. Subsection B of this section does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, ~~bainmaries~~ bains-marie, steam tables, insulated food transport containers, and salad bars.

D. Temperature measuring devices shall be designed to be easily readable.

E. Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than 2°F or 1°C in the intended range of use.Pf

12VAC5-421-1350. Warewashing machines, temperature measuring devices.

A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

1. In each wash and rinse tank;Pf and

2. As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.Pf

12VAC5-421-1360. Manual warewashing equipment, heaters and baskets.

If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

1. Designed with an integral heating device that is capable of maintaining water at a temperature not less than 171°F (77°C);Pf and

2. Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.Pf

12VAC5-421-1370. Warewashing machines, sanitizer level indicator automatic dispensing of detergents and sanitizers.

A. A warewashing machine installed after March 1, 2002, shall be equipped to:

1. Automatically dispense detergents and sanitizers;Pf and

2. Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles.Pf

B. Existing warewashing equipment shall be upgraded or replaced to meet the requirements of subsection A of this section.Pf

12VAC5-421-1435. Food equipment, certification and classification.

Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with the requirements of Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et seq.) of this part.

Article 3
Numbers and Capacities

12VAC5-421-1450. Cooling, heating, and holding capacities.

Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity ~~and capable of providing~~ to provide food temperatures as specified under Part III (12VAC5-421-260 et seq.) of this chapter.Pf

12VAC5-421-1460. Manual warewashing, sink compartment requirements.

A. Except as specified in subsection C of this section, a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.Pf

B. Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in subsection C of this section shall be used.Pf

C. Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:

1. High-pressure detergent sprayers;

2. Low-pressure or line-pressure spray detergent foamers;

3. Other task-specific cleaning equipment;

4. Brushes or other implements;

5. [~~2-compartment~~ Two-compartment] sinks as specified under subsections D and E of this section; or

6. Receptacles that substitute for the compartments of a multicompartment sink.

D. Before a [~~2-compartment~~ two-compartment] sink is used:

1. The permit holder shall have its use approved; and

2. The permit holder shall limit the number of kitchenware items cleaned and sanitized in the two-compartment sink and shall limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of

raw meat and another or cleanup at the end of a shift, and shall:

a. (i) Make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use, and (ii) use a detergent-sanitizer to sanitize and apply the detergent-sanitizer in accordance with the manufacturer's label instructions and as specified under 12VAC5-421-1710; or

b. A hot water sanitization immersion step shall be used as specified under subdivision 3 of 12VAC5-421-1860.

E. A [~~2 compartment~~ two-compartment] sink shall not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

12VAC5-421-1500. Utensils, consumer self-service.

A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar.[Pf]

12VAC5-421-1510. Food temperature measuring devices.

A. Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under Part III (12VAC5-421-260 et seq.) of this chapter.[Pf]

B. A temperature measuring device with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish fillets.[Pf]

12VAC5-421-1520. Temperature measuring devices, manual and mechanical warewashing.

A. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

B. In hot water mechanical warewashing operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the utensil surface temperature.

12VAC5-421-1530. Sanitizing solutions, testing devices.

A test kit or other device that accurately measures the concentration in mg/L (ppm) of sanitizing solutions shall be provided and readily accessible for use.[Pf]

12VAC5-421-1535. Cleaning agents and sanitizers, availability.

A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of operation.

B. Except for chemical sanitizers that are generated on site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under Article 6 shall be provided and available for use during all hours of operation.

12VAC5-421-1630. Warewashing equipment, cleaning agents.

When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 12VAC5-421-1460 C, shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.[Pf]

12VAC5-421-1650. Manual warewashing equipment, wash solution temperature.

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 110°F (43°C) or the temperature specified on the cleaning agent manufacturer's label instructions.[Pf]

12VAC5-421-1660. Mechanical warewashing equipment, wash solution temperature.

A. The temperature of the wash solution in spray type warewashers that use hot water to sanitize shall not be less than:

1. For a stationary rack, single temperature machine, 165°F (74°C);[Pf]

2. For a stationary rack, dual temperature machine, 150°F (66°C);[Pf]

3. For a single tank, conveyor, dual temperature machine, 160°F (71°C);[Pf] or

4. For a multitank, conveyor, multitemperature machine, 150°F (66°C).[Pf]

B. The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize shall not be less than 120°F (49°C).[Pf]

12VAC5-421-1670. Manual warewashing equipment, hot water sanitization temperatures.

If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 171°F (77°C) or above.[P]

12VAC5-421-1680. Mechanical warewashing equipment, hot water sanitization temperatures.

A. Except as specified in subsection B of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold shall not be more than 194°F (90°C), or less than:[Pf]

1. For a stationary rack, single temperature machine, 165°F (74°C);[Pf] or

2. For all other machines, 180°F (82°C).[Pf]

B. The maximum temperature specified under subsection A of this section does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying

devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

12VAC5-421-1700. Manual and mechanical warewashing equipment, chemical sanitization - temperature, pH, concentration, and hardness.

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at ~~exposure~~ contact times specified under subdivision 3 of 12VAC5-421-1900 ~~A 3~~ shall be listed in 40 CFR 180.940 [~~Sanitizing solutions~~], shall be used in accordance with the [~~EPA approved manufacturer's~~ EPA-registered] label use instructions,[P] and shall be used as follows:

1. A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;[P]

Minimum Concentration	Minimum Temperature	
mg/L (ppm)	pH 10 or less °F (°C)	pH 8 or less °F (°C)
25-49	120 (49)	120 (49)
50-99	100 (38)	75 (24)
100	55 (13)	55 (13)

2. An iodine solution shall have a:

a. Minimum temperature of ~~75°F (24°C)~~ 68°F (20°C);[P]

b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective;[P] and

c. Concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm);[P]

3. A quaternary ammonium compound solution shall:

a. Have a minimum temperature of 75°F (24°C);[P]

b. Have a concentration as specified under 40 CFR 180.940 and as indicated by the manufacturer's use directions included in the labeling;[P] and

c. Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;[P]

4. If another solution of a chemical specified under subdivisions 1, 2 and 3 of this section is used, the permit holder shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved;[P] ~~or~~

5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the ~~manufacturer's use directions included in the labeling~~ EPA-registered label use instructions;[P] and

6. If a chemical sanitizer is generated by a device located on site at the food establishment it shall be used as specified in subdivisions 1 through 4 of this section and shall be produced by a device that:

a. Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[P]

b. Complies with 40 CFR 152.500 and 40 CFR 156.10,[P]

c. Displays the EPA device manufacturing facility registration number on the device,[Pf] and

d. Is operated and maintained in accordance with manufacturer's instructions.[Pf]

12VAC5-421-1720. Warewashing equipment, determining chemical sanitizer concentration.

Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.[Pf]

12VAC5-421-1730. Good repair and calibration.

A. Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et seq.) of this part or shall be discarded.

B. Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.[Pf]

C. Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.

12VAC5-421-1740. Single-service and single-use articles, required use.

A food establishment without facilities specified under Articles 6 (12VAC5-421-1770 et seq.) and 7 ~~(12VAC5-421-1880~~ [~~(12VAC5-421-1890~~ (12VAC5-421-1885] et seq.) of this part for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.[P]

Article 6

Cleaning of Equipment and Utensils

12VAC5-421-1770. Equipment, food-contact surfaces, ~~nonfood-contact~~ non-food-contact surfaces, and utensils.

A. Equipment food-contact surfaces and utensils shall be clean to sight and touch.[Pf]

B. The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.

C. ~~Nonfood-contact~~ Non-food-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.

12VAC5-421-1780. Equipment food-contact surfaces and utensils.

A. Equipment food-contact surfaces and utensils shall be cleaned:

1. Except as specified in subsection B of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry;[P]

2. Each time there is a change from working with raw foods to working with ready-to-eat foods;[P]

3. Between uses with raw fruits and vegetables and with ~~potentially hazardous food~~ time/temperature control for safety food;[P]

4. Before using or storing a food temperature measuring device;[P] and

5. At any time during the operation when contamination may have occurred.[P]

B. Subdivision A 1 of this section does not apply if the food contact surface or utensil is in contact with a succession of different [~~raw animal foods~~ types of raw meat and poultry] each requiring a higher cooking temperature as specified under 12VAC5-421-700 than the previous [~~food, such as preparing raw fish followed by cutting raw poultry on the same cutting board~~ type].

C. Except as specified in subsection D of this section, if used with ~~potentially hazardous food~~ time/temperature control for safety food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every four hours.[P]

D. Surfaces of utensils and equipment contacting ~~potentially hazardous food~~ time/temperature control for safety food may be cleaned less frequently than every four hours if:

1. In storage, containers of ~~potentially hazardous food~~ time/temperature control for safety food and their contents are maintained at temperatures specified under Part III (12VAC5-421-260 et seq.) of this chapter and the containers are cleaned when they are empty;

2. Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and (i) the utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature; and (ii) the cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment:

Temperature	Cleaning Frequency
41°F (5.0°C) or less	24 hours
>41°F - 45°F (>5.0°C - 7.2°C)	20 hours
>45°F - 50°F (>7.2°C - 10.0°C)	16 hours
>50°F - 55°F (>10.0°C - 12.8°C)	10 hours

3. Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat ~~potentially hazardous food~~ time/temperature control for safety food that is maintained at the temperatures specified under Part III, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;

4. Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Part III;

5. Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;

6. The cleaning schedule is approved based on consideration of:

a. Characteristics of the equipment and its use;

b. The type of food involved;

c. The amount of food residue accumulation; and

d. The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or

7. In-use utensils are intermittently stored in a container of water in which the water is maintained at 135°F (57°C) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

E. Except when dry cleaning methods are used as specified under 12VAC5-421-1810, surfaces of utensils and equipment contacting food that is not ~~potentially hazardous~~ time/temperature control for safety food shall be cleaned:

1. At any time when contamination may have occurred;

2. At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;

3. Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers;

4. [~~Equipment~~ At a frequency specified by the manufacturer or absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold. To include equipment] such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, [cooking oil storage tanks and distribution lines,] beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment [~~:~~

~~a. At a frequency specified by the manufacturer; or~~

~~b. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold~~].

12VAC5-421-1810. Dry cleaning.

A. If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not ~~potentially hazardous~~ time/temperature control for safety food.

B. Cleaning equipment used in dry cleaning food-contact surfaces shall not be used for any other purpose.

12VAC5-421-1870. ~~Returnables, cleaning for refilling.~~ (Repealed.)

~~A. Except as specified in subsections B and C of this section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.~~

~~B. A food-specific container for beverages may be refilled at a food establishment if:~~

~~1. Only a beverage that is not a potentially hazardous food is used as specified under 12VAC5-421-600 A;~~

~~2. The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;~~

~~3. Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;~~

~~4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and~~

~~5. The container is refilled by: an employee of the food establishment, or the owner of the container if the beverage system includes a contamination-free transfer process that can not be bypassed by the container owner.~~

~~C. Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.~~

[Article 7
Sanitization of Equipment and Utensils

12VAC5-421-1885. Food-contact surfaces and utensils.

Equipment food-contact surfaces and utensils shall be sanitized.]

[~~Article 7~~
~~Sanitization of Equipment and Utensils~~]

12VAC5-421-1890. Before use after cleaning.

Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.[P]

12VAC5-421-1900. Hot water and chemical.

After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:

1. Hot water manual operations by immersion for at least 30 seconds as specified under 12VAC5-421-1670;[P]

2. Hot water mechanical operations by being cycled through equipment that is set up as specified under 12VAC5-421-1610, 12VAC5-421-1680, and 12VAC5-421-1690 and achieving a utensil surface temperature of 160°F (71°C) as measured by an irreversible registering temperature indicator;[P] or

3. Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 12VAC5-421-1700. Contact times shall be consistent with those on EPA-registered label use instructions by providing:

a. Except as specified under subdivision 3 b of this section, ~~an exposure~~ a contact time of at least 10 seconds for a chlorine solution specified under subdivision 1 of 12VAC5-421-1700 ~~A~~;[P]

b. ~~An exposure~~ A contact time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 100°F (38°C) or a pH of 8 or less and a temperature of at least 75°F (24°C);[P]

c. ~~An exposure~~ A contact time of at least 30 seconds for other chemical sanitizing solutions;[P] or

d. ~~An exposure~~ A contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in 12VAC5-421-10.[P]

12VAC5-421-1920. ~~Specifications~~ Laundering frequency for linens, cloth gloves, napkins, and wiping cloths.

A. Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.

B. Cloth gloves used as specified in 12VAC5-421-580 D shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork, and fish.

C. Linens and napkins that are used as specified under 12VAC5-421-560 and cloth napkins shall be laundered between each use.

D. Wet wiping cloths shall be laundered daily.

E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

12VAC5-421-2040. Preset tableware.

A. ~~Tableware~~ Except as specified in subsection B of this section, tableware that is preset shall be protected from contamination by being wrapped, covered, or inverted.

B. ~~When~~ Preset tableware ~~is preset,~~ may be exposed~~, unused settings shall be~~ if:

1. ~~Removed~~ Unused settings are removed when a consumer is seated; or

2. ~~Cleaned and sanitized before further use if the settings are~~ Settings not removed when a consumer is seated are cleaned and sanitized before further use.

12VAC5-421-2045. Rinsing equipment and utensils after cleaning and sanitizing.

After being cleaned and sanitized, equipment and utensils shall not be rinsed before air drying or used unless:

1. The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under Articles 2 (12VAC5-421-1080 et seq.) and 5 (12VAC5-421-1570) of this part; and

2. The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA-registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

Part V
Water, Plumbing, and Waste

Article 1
Water

12VAC5-421-2050. Approved system.

~~Drinking~~ Pure water shall be obtained from an approved ~~source that is~~ water system defined as:

1. A ~~public water system~~ waterworks constructed, maintained, and operated in compliance with 12VAC5-590;[P] or

2. A ~~nonpublic water system that is~~ private well constructed, maintained, and operated ~~according to law~~ in compliance with 12VAC5-630.[P]

12VAC5-421-2060. System flushing and disinfection.

~~A drinking~~ An approved water system shall be flushed and disinfected ~~before being placed in service~~ after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. A sample shall be collected from the water system and the results of the analysis shall be total coliform negative prior to placing the water system into service.[P]

12VAC5-421-2070. Bottled drinking water.

Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR Part 129 ~~Processing and Bottling of Bottled drinking water~~.[P]

12VAC5-421-2080. ~~Quality~~ Pure water standards.

Except as specified under 12VAC5-421-2090:

1. Water from a ~~public water system~~ waterworks shall meet ~~the applicable~~ water quality and quantity standards ~~found~~ in ~~the Virginia Waterworks Regulations (12VAC5-590)~~ accordance with 12VAC5-590;[P] and

2. Water from a ~~nonpublic water system~~ private well shall meet the ~~bacteriological~~ water quality standards ~~found~~ in ~~the Virginia Waterworks Regulations (12VAC5-590)~~ accordance with 12VAC5-630-370 [and not exceed 10 mg/L of nitrate (as N)].[P]

12VAC5-421-2090. ~~Nondrinking~~ Nonpotable water.

A. A ~~nondrinking~~ nonpotable water supply shall be used only if its use is approved by the regulatory authority.[P]

B. ~~Nondrinking~~ Nonpotable water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection, and irrigation.[P]

12VAC5-421-2100. Sampling.

~~Except when used as specified under 12VAC5-421-2090, water~~ Water from a ~~nonpublic water system~~ private well shall be sampled and tested at least annually ~~and as required by state water quality regulations~~ for nitrate and total coliform.

1. If nitrate [~~(as N)~~, which is reported as "N" on the test results,] exceeds 10 mg/L, the owner shall notify the regulatory authority.[Pf]

2. If a sample is total coliform positive, the positive culture medium shall be further analyzed to determine if E. coli is present. The owner shall notify the regulatory authority within two days from when the owner is notified of the coliform positive test result.[Pf]

3. If E. coli is present, the owner shall notify the regulatory authority.[Pf]

12VAC5-421-2110. Sample report.

~~The most recent~~ All sample ~~report~~ reports for the ~~nonpublic water system~~ private well shall be retained on file in the food establishment ~~or the report shall be maintained as specified by state water quality regulations~~ for a minimum of five years and be made available to the regulatory authority upon request.

12VAC5-421-2120. Capacity.

A. The approved water ~~source and~~ system capacity shall be of sufficient capacity to meet the maximum daily water demands and the peak hourly water demands of the food establishment.[Pf]

B. Hot water generation and distribution systems shall ~~be sufficient to~~ meet the peak hot water demands throughout the food establishment.[Pf]

12VAC5-421-2130. Pressure.

Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under subdivisions 1 and 2 of 12VAC5-421-2160 to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure.[Pf]

12VAC5-421-2150. ~~Distribution, delivery, and retention system.~~ (Repealed.)

~~Water shall be received from the source through the use of:~~

~~1. An approved public water main; or~~

~~2. One or more of the following that shall be constructed, maintained, and operated according to law:~~

~~a. Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,~~

~~b. Water transport vehicles, and~~

~~c. Water containers.~~

12VAC5-421-2160. Alternative water supply.

Water meeting the requirements specified under 12VAC5-421-2050 through 12VAC5-421-2130 shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

1. A supply of containers of commercially bottled drinking water;[Pf]

2. One or more closed portable water containers;[Pf]

3. An enclosed vehicular water tank;[Pf]

4. An on-premises water storage tank;[Pf] or

5. Piping, tubing, or hoses connected to an adjacent approved ~~source~~ system in a manner approved by the department.[Pf]

Article 2
Plumbing System

12VAC5-421-2170. Approved materials.

A. A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law.[P]

B. A water filter shall be made of safe materials.[P]

12VAC5-421-2180. Approved system and cleanable fixtures.

A. A plumbing system shall be designed, constructed, and installed according to law.[P]

B. A plumbing fixture such as a handwashing lavatory, toilet, or urinal shall be easily cleanable.

12VAC5-421-2190. Handwashing sink, water temperature, and flow.

A. A handwashing sink shall be equipped to provide water at a temperature of at least 100°F (38°C) through a mixing valve or combination faucet.[Pf]

B. A steam mixing valve shall not be used at a handwashing sink.

C. A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

D. An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

12VAC5-421-2200. Backflow prevention, air gap.

An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and shall not be less than ~~1~~ one inch (25 mm).[P]

12VAC5-421-2210. Backflow prevention device, design standard.

A backflow or backsiphonage prevention device installed on a water supply system shall comply with the Virginia Uniform Statewide Building Code (13VAC5-63) for construction, installation, maintenance, inspection, and testing for that specific application and type of device.[P]

12VAC5-421-2230. Handwashing sinks, numbers, and capacities.

A. Except as specified in subsection B [and C] of this section, at least one handwashing sink, or the number of handwashing sinks necessary for their convenient use by employees in areas specified under 12VAC5-421-2280, and not fewer than the number of handwashing sinks required by law shall be provided.[Pf]

B. If approved and capable of removing the [~~multiple~~] types of soils encountered in the food operations [involved], automatic handwashing facilities may be substituted for handwashing sinks in a food establishment [~~with~~ that has] at least one handwashing sink.

~~B.~~ C. If approved, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

12VAC5-421-2250. Service sink.

A. At least one service sink or one curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

B. Toilets and urinals shall not be used as a service sink for the disposal of mop water and similar liquid waste.

12VAC5-421-2260. Backflow prevention device, when required.

A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb (threaded faucet) if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law by:

1. Providing an air gap as specified under 12VAC5-421-2200;[P] or

2. Installing an approved backflow prevention device as specified under 12VAC5-421-2210.[P]

12VAC5-421-2270. Backflow prevention device, carbonator.

A. If not provided with an air gap as specified under 12VAC5-421-2200, a double check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 1 inch (100 mesh to 25.4mm) shall be installed

upstream from a carbonating device and downstream from any copper in the water supply line.[P]

B. A ~~single or double~~ dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise ~~provided~~ approved as specified under subsection A of this section.

12VAC5-421-2280. Handwashing sinks, location.

A handwashing sink shall be located:

1. To ~~be readily accessible for~~ allow convenient use by employees in food preparation, food dispensing, and warewashing areas;[Pf] and

2. In, or immediately adjacent to, toilet rooms.[Pf]

12VAC5-421-2310. Using a handwashing sink.

A. A handwashing sink shall be maintained so that it is accessible at all times for employee use.[Pf]

B. A handwashing sink shall not be used for purposes other than handwashing.[Pf]

C. An automatic handwashing facility shall be used in accordance with manufacturer's instructions.[Pf]

12VAC5-421-2320. Prohibiting a cross connection.

A. ~~Except as specified in 9 CFR 308.3(d) for firefighting, a~~ A person shall not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.[P]

B. The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.[Pf]

12VAC5-421-2330. Scheduling inspection and service for a water system device.

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.[Pf]

12VAC5-421-2340. Water reservoir of fogging devices, cleaning.

A. A reservoir that is used to supply water to a device such as a produce fogger shall be:

1. Maintained in accordance with manufacturer's specifications;[P] and

2. Cleaned in accordance with manufacturer's specifications or according to the procedures specified under subsection B of this section, whichever is more stringent.[P]

B. Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

1. Draining and complete disassembly of the water and aerosol contact parts;[P]

2. Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;[P]

3. Flushing the complete system with water to remove the detergent solution and particulate accumulation;[P] and

4. Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L (ppm) hypochlorite solution.[P]

12VAC5-421-2350. System maintained in good repair.

A plumbing system shall be (i) repaired according to law[P] and (ii) maintained in good repair.

Article 3
Mobile Water Tank and Mobile Food Establishment Water Tank

12VAC5-421-2360. ~~Approved~~ Mobile water tank [approved] materials.

Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

1. Safe;[P]

2. Durable, corrosion resistant, and nonabsorbent; and

3. Finished to have a smooth, easily cleanable surface.

12VAC5-421-2420. Hose, construction and identification.

A hose used for conveying ~~drinking~~ potable water from a water tank shall be:

1. Safe;[P]

2. Durable, corrosion resistant, and nonabsorbent;

3. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;

4. Finished with a smooth interior surface; and

5. Clearly and durably identified as to its use if not permanently attached.

12VAC5-421-2430. Filter, compressed air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and ~~drinking~~ potable water system when compressed air is used to pressurize the water tank system.[P]

12VAC5-421-2460. System flushing and disinfection.

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.[P]

12VAC5-421-2490. Tank, pump, and hoses, dedication.

A. Except as specified in subsection B of this section, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.[P]

B. Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

12VAC5-421-2520. Backflow prevention.

A. Except as specified in subsections B, C, and D of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.[P]

B. Subsection A of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

C. If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within five feet (1.5 meters) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

D. If allowed by law, a warewashing or culinary sink may have a direct connection.

12VAC5-421-2540. Conveying sewage.

Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.[P]

12VAC5-421-2550. Removing mobile food establishment wastes.

~~Sewage~~ No public health hazard or nuisance shall result when sewage and other liquid wastes ~~shall be~~ are removed from a mobile food establishment at an approved waste servicing area or by a permitted sewage transport vehicle ~~in such a way that a public health hazard or nuisance is not created~~.[Pf]

12VAC5-421-2570. Approved sewage disposal system.

Sewage shall be disposed through an approved facility that is:

1. A public sewage treatment plant;[P] or

2. An individual sewage disposal system that is sized, constructed, maintained, and operated according to ~~law~~ the State Board of Health's regulations promulgated pursuant to Chapter 6 (§ 32.1-163 et seq.) of Title 32 of the Code of Virginia, including 12VAC5-610, 12VAC5-613, and 12VAC5-640.[P]

12VAC5-421-2990. Private homes and living or sleeping quarters, use prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters shall not be used for conducting food establishment operations.[P]

Article 3
Numbers and Capacities

12VAC5-421-3020. Handwashing cleanser, availability.

Each handwashing sink or group of two adjacent handwashing sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap.[Pf]

12VAC5-421-3030. Hand drying provision.

Each handwashing sink or group of adjacent handwashing sinks shall be provided with:

1. Individual, disposable towels;[Pf]

2. A continuous towel system that supplies the user with a clean towel; ~~or~~[Pf]

3. A heated-air hand drying device~~.~~;[Pf] or

4. A hand drying device that employs an air-knife system that delivers high-velocity, pressurized air at ambient temperatures.[Pf]

12VAC5-421-3070. Toilet tissue, availability.

A supply of toilet tissue shall be available at each toilet.[Pf]

12VAC5-421-3150. Distressed merchandise, segregation and location.

Products that are held by the permit holder for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles.[Pf]

12VAC5-421-3210. Cleaning maintenance tools, preventing contamination.

Food preparation sinks, handwashing lavatories, and warewashing equipment shall not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.[Pf]

12VAC5-421-3270. Controlling pests.

The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:

1. Routinely inspecting incoming shipments of food and supplies;

2. Routinely inspecting the premises for evidence of pests;

3. Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 12VAC5-421-3360, 12VAC5-421-3440, and 12VAC5-421-3450;[Pf] and

4. Eliminating harborage conditions.

12VAC5-421-3310. Prohibiting animals.

A. Except as specified in subsections B and C of this section, live animals shall not be allowed on the premises of a food establishment.[Pf]

B. Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:

1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

2. Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

3. In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person~~,~~ if a health or safety hazard will not result from the presence or activities of the service animal;

4. Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, ~~or~~ residential care facilities, and food establishment bed and breakfast facilities at times other than during meals if:

a. Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas;

b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present; and

c. Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; [~~and~~]

5. In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals [~~.~~; and]

6. Dogs in outdoor dining areas if:

a. The outdoor dining area is not fully enclosed with floor to ceiling walls and is not considered a part of the interior physical facility.

b. The outdoor dining area is equipped with an entrance that is separate from the main entrance to the food establishment and the separate entrance serves as the sole means of entry for patrons accompanied by dogs.

c. A sign stating that dogs are allowed in the outdoor dining area is posted at each entrance to the outdoor dining area in such a manner as to be clearly observable by the public.

[d. A sign within the outdoor dining area stating the requirements as specified in subdivisions 6 e, 6 f, and 6 g of this subsection is provided in such a manner as to be clearly observable by the public.

~~d.~~ e.] Food and water provided to dogs is served using equipment that is not used for service of food to persons or is served in single-use articles.

[~~e.~~ f.] Dogs are not allowed on chairs, seats, benches, or tables.

[~~f.~~ g.] Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.

[~~g.~~ h.] Establishment provides effective means for cleaning up dog vomitus and fecal matter.

[~~h. A sign within the outdoor dining area stating the requirements as specified in subdivisions 6 d, e, and f of this subsection is provided in such a manner as to be clearly observable by the public.~~]

C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles ~~can not~~ cannot result.

D. In bed and breakfast facilities serving 18 or fewer customers, live animals shall be allowed in the facility but shall not be fed using the same equipment or utensils that are used to feed humans.

Part VII
Poisonous or Toxic Materials

Article 1
Labeling and Identification

12VAC5-421-3320. Original containers - identifying information, prominence.

Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label.[Pf]

12VAC5-421-3330. Working containers - common name.

Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material.[Pf]

Article 2
Operational Supplies and Applications

12VAC5-421-3340. Storage, separation.

Poisonous or toxic materials shall be stored so they ~~can not~~ cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

1. Separating the poisonous or toxic materials by spacing or partitioning; [~~and~~[P P] and]

2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This subsection does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles~~; and,~~.[P]

~~3. Detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes and other chemicals shall be stored separately from insecticides and rodenticides.~~

12VAC5-421-3350. Presence and use restriction.

A. Only those poisonous or toxic materials that are required for the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food establishment.[Pf]

B. Subsection A of this section does not apply to packaged poisonous or toxic materials that are for retail sale.

12VAC5-421-3360. Conditions of use.

Poisonous or toxic materials shall be:

1. Used according to:

a. Law and this chapter~~,~~;

b. Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment~~,~~;[P]

c. The conditions of certification, if certification is required, for use of the pest control materials~~,~~;[P] and

d. Additional conditions that may be established by the regulatory authority~~; and~~.[P]

2. Applied so that:

a. A hazard to employees or other persons is not constituted~~,~~;[P] and

b. Contamination including toxic residues due to drip, drain, fog, splash, or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:[P]

(1) Removing the items, covering the items with impermeable covers, or taking other appropriate preventive actions~~,~~;[P] and

(2) Cleaning and sanitizing equipment and utensils after the application.[P]

3. A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC § 136(e) (Federal Insecticide, Fungicide and Rodenticide Act), or a person under the direct supervision of a certified applicator.[Pf]

12VAC5-421-3370. Poisonous or toxic material containers.

A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food.[P]

12VAC5-421-3380. Sanitizers, criteria.

Chemical sanitizers, including chemical sanitizing solutions generated on site, and other chemical antimicrobials applied to food-contact surfaces shall ~~meet~~:

1. Meet the requirements specified in 40 CFR 180.940,[P] or

2. Meet the requirements as specified in 40 CFR 180.2020.[P]

12VAC5-421-3390. Chemicals for washing fruits and vegetables, criteria.

A. Chemicals, including those generated on site, used to wash or peel raw, whole fruits and vegetables shall ~~meet the requirements specified in 21 CFR 173.315~~:

1. Be an approved food additive listed for this intended use in 21 CFR 173,[P] or

2. Be generally recognized as safe (GRAS) for this intended use,[P] or

3. Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification),[P] and

4. Meet the requirements in the 40 CFR Part 156.[P]

B. Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368.[P]

12VAC5-421-3400. Boiler water additives, criteria.

Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310.[P]

12VAC5-421-3410. Drying agents, criteria.

Drying agents used in conjunction with sanitization shall:

1. Contain only components that are listed as one of the following:

a. Generally recognized as safe for use in food as specified in 21 CFR Part 182 ~~– Substances Generally Recognized as Safe,~~ or 21 CFR Part 184 ~~– Direct Food Substances Affirmed as Generally Recognized as Safe~~,[P]

b. Generally recognized as safe for the intended use as specified in 21 CFR Part 186 ~~– Indirect Food Substances Affirmed as Generally Recognized as Safe~~,[P]

c. Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to food as described in 21 CFR 170.30,[P]

d. Subject of an effective Food Contact Notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) § 409(h),[P]

~~c.~~ e. Approved for use as a drying agent under a prior sanction specified in 21 CFR Part 181 ~~– Prior Sanctioned Food Ingredients,~~ as specified in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4),[P]

~~d.~~ f. Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175~~–~~ through 178,[P] or

~~e.~~ g. Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 ~~– Threshold of Regulation for Substances Used in Food-contact Articles~~;[P] and

2. When sanitization is with chemicals, the approval required under ~~subdivisions~~ subdivision 1 ~~c~~ e or ~~e~~ g of this section or the regulation as an indirect food additive required under subdivision 1 ~~d~~ f of this section, shall be specifically for use with chemical sanitizing solutions.[P]

12VAC5-421-3420. Lubricants - incidental food contact, criteria.

Lubricants shall meet the requirements specified in 21 CFR 178.3570 if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces,

or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.[P]

12VAC5-421-3430. Restricted use pesticides, criteria.

Restricted use pesticides specified under subdivision 3 of 12VAC5-421-3360 ~~C~~ shall meet the requirements specified in 40 CFR [Part] 152, Subpart I ~~– Classification of Pesticides~~.[P]

12VAC5-421-3440. Rodent bait stations.

Rodent bait shall be contained in a covered, tamper-resistant bait station.[P]

12VAC5-421-3450. Tracking powders, pest control, and monitoring.

A. [~~A~~ Except as specified in subsection B of this section, a] tracking powder pesticide shall not be used in a food establishment.[P]

B. If used, a nontoxic tracking powder such as talcum or flour shall not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

12VAC5-421-3460. Medicines - restriction and storage.

A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment.[Pf]

B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.[P]

12VAC5-421-3470. Refrigerated medicines, storage.

Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

1. Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines;[P] and

2. Located so they are inaccessible to children.[P]

12VAC5-421-3480. First aid supplies, storage.

First aid supplies that are in a food establishment for the employees' use shall be:

1. Labeled as specified under 12VAC5-421-3320;[Pf] and

2. Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles.[P]

Article 3
Stock and Retail Sale

12VAC5-421-3500. Storage and display, separation.

Poisonous or toxic materials shall be stored and displayed for retail sale so they ~~can not~~ cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

1. Separating the poisonous or toxic materials by spacing or partitioning;[P] and

2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.[P]

12VAC5-421-3590. Disposition of a variance request.

A. ~~The commissioner may grant the variance request and if~~ If the commissioner proposes to deny the variance he shall provide the owner an opportunity to an informal ~~hearing~~ fact-finding conference as provided in § 2.2-4019 of the Code of Virginia. Following this opportunity for an informal ~~hearing~~ fact-finding conference the commissioner may reject any application for a variance by sending a rejection notice to the applicant. The rejection notice shall be in writing and shall state the reasons for the rejection. ~~A rejection notice constitutes a case decision.~~

B. If the commissioner proposes to grant a variance request submitted pursuant to this part, the applicant shall be notified in writing of this decision. Such notice shall identify the variance, the food establishment involved, and shall specify the period of time for which the variance will be effective. Such notice shall provide that the variance will be terminated when the food establishment comes into compliance with the applicable regulation and may be terminated upon a finding by the commissioner that the food establishment has failed to comply with any requirements or schedules issued in conjunction with the variance. The effective date of the variance shall be as noted in the variance letter.

C. All variances granted to any food establishment may not be transferable unless otherwise stated. Each variance shall be attached to the permit to ~~which it is granted. Each variance is revoked when the permit to which it is attached is revoked~~ operate and posted prominently in a conspicuous place for public view.

D. No owner or permit holder may challenge the terms or conditions of a variance after 30 calendar days have elapsed from the receipt of the variance.

E. ~~Each variance shall be posted prominently in a conspicuous place for public view and in close proximity to the permit to which it relates.~~ Each variance is revoked when the permit to ~~which it~~ operate is ~~attached is~~ revoked, suspended, or ~~if the permit is not revalidated or renewed~~ expired.

Article 2
Plan Submission and Approval

12VAC5-421-3600. Facility and operating plans ~~– when plans are required~~.

A permit applicant or permit holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

1. The construction of a food establishment;[Pf]

2. The conversion of an existing structure for use as a food establishment;[Pf] or

3. The remodeling of a food establishment or a change of type of food establishment or food operation as specified under [~~12VAC5-421-3710~~] ~~C~~ [subdivision 3 of 12VAC-421-3700] if the regulatory authority determines that plans and specifications are necessary to ensure compliance with ~~this regulation~~ this chapter.[Pf]

[12VAC5-421-3620. When a HACCP plan is required.

A. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under 12VAC5-421-3630 and the relevant provisions of this chapter if:

1. Submission of a HACCP plan is required according to law;

2. A variance is required as specified under 12VAC5-421-860, 12VAC5-421-1300 B, or 12VAC5-421-700 D ~~2~~ 4; or

3. The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under 12VAC5-421-3610, an inspectional finding, or a variance request.

B. ~~A permit applicant or permit holder shall have a properly prepared HACCP plan~~ Before engaging in reduced oxygen packaging without a variance as specified under 12VAC5-421-870, a permit applicant or permit holder shall submit a properly prepared HACCP plan to the regulatory authority.]

12VAC5-421-3630. Contents of a HACCP plan.

For a food establishment that is required under 12VAC5-421-3620 to have a HACCP plan, ~~the plan and specifications shall indicate~~ the permit applicant or permit holder shall submit to the regulatory authority a properly prepared HACCP plan that includes:

1. General information such as the name of the permit applicant or permit holder, the food establishment address, and contact information;[Pf]

~~1.~~ 2. A categorization of the types of ~~potentially hazardous foods~~ time/temperature control for safety food that ~~are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority~~ is to be controlled under the HACCP plan;[Pf]

~~2.~~ 3. A flow diagram ~~by specific food or category type identifying critical control points and providing information on the following~~ or chart for each specific food or category type that identifies:[Pf]

a. Each step in the process,[Pf]

b. The hazards and controls for each step in the flow diagram or chart,[Pf]

c. The steps that are critical control points,[Pf]

~~a. Ingredients~~ d. The ingredients, materials, and equipment used in the preparation of that food,[Pf] and

~~b.~~ e. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;[Pf]

~~3. Food employee and supervisory training plan that addresses the food safety issues of concern.~~

4. ~~A statement of standard operating procedures for the plan under consideration including clearly identifying~~ A critical control point summary for each specific food or category type that clearly identifies:

a. Each critical control point~~,~~;[Pf]

b. The critical limits for each critical control point~~,~~;[Pf]

c. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge~~,~~;[Pf]

d. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points~~,~~;[Pf]

e. Action to be taken by the person in charge if the critical limits for each critical control point are not met~~,~~;[Pf] and

f. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;[Pf] and

5. Supporting documents such as;

a. Food employee and supervisory training plan addressing food safety issues;[Pf]

b. Copies of blank records forms that are necessary to implement a HACCP plan;[Pf]

c. Additional scientific data or other information, as required by the regulatory authority supporting the determination that food safety is not compromised by the proposal.[Pf]

~~5. Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.~~

6. Any other information required by the regulatory authority.

12VAC5-421-3670. Application procedure, submission ~~30 calendar days~~ before proposed opening.

An applicant seeking to operate a nontemporary food establishment shall submit an application for a permit at least 30 calendar days before the date planned for opening a food establishment or at least 30 calendar days before the expiration date of the current permit for an existing facility. An applicant seeking to operate a temporary food establishment shall submit an application for a permit at least

10 calendar days before the date planned for opening the temporary food establishment.

12VAC5-421-3700. Contents of the application.

The application shall include:

1. The name, mailing address, telephone number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;

2. Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;

3. A statement specifying whether the food establishment:

a. Is mobile or stationary and temporary or permanent; and

b. Is an operation that includes one or more of the following:

(1) Prepares, offers for sale, or serves ~~potentially hazardous food~~ time/temperature control for safety food:

(a) Only to order upon a consumer's request;

(b) In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency; or

(c) Using time as the public health control as specified under 12VAC5-421-850;

(2) Prepares ~~potentially hazardous food~~ time/temperature control for safety food in advance using a food preparation method that involves two or more steps which may include combining ~~potentially hazardous~~ time/temperature control for safety food ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing;

(3) Prepares food as specified under subdivision 3 b (2) of this section for delivery to and consumption at a location off the premises of the food establishment where it is prepared;

(4) Prepares food as specified under subdivision 3 b (2) of this section for service to a highly susceptible population;

(5) Prepares only food that is not [~~potentially hazardous~~ time/temperature control for safety food]; or

(6) Does not prepare, but offers for sale only prepackaged food that is not ~~potentially hazardous~~ time/temperature control for safety food;

4. The name, title, address, and telephone number of the person directly responsible for the food establishment;

5. The name, title, address, and telephone number of the person who functions as the immediate supervisor of the person specified under subdivision 4 of this section such as the zone, district, or regional supervisor;

6. The names, titles, and addresses of:

a. The persons comprising the legal ownership as specified under subdivision 2 of this section including the owners and officers; and

b. The local resident agent if one is required based on the type of legal ownership;

7. A statement signed by the applicant that:

a. Attests to the accuracy of the information provided in the application; and

b. Affirms that the applicant will:

(1) Comply with this chapter; and

(2) Allow the regulatory authority access to the establishment as specified under 12VAC5-421-3820 and to the records specified under 12VAC5-421-440 and 12VAC5-421-2330 and subdivision 4 of 12VAC5-421-3630; and

8. Other information required by the regulatory authority.

12VAC5-421-3770. ~~Suspension~~ Summary suspension of a permit.

The director may summarily suspend ~~without a hearing~~ a permit to operate a restaurant if the director finds the continued operation constitutes a substantial and imminent threat to the public health, except the director may summarily suspend the permit of a temporary restaurant as addressed under 12VAC5-421-3870. Upon receipt of such notice that a permit is suspended, the permit holder shall cease food operations immediately and begin corrective action.

Whenever a permit is suspended, the holder of the permit or the person in charge shall be notified in writing by certified mail or by hand delivery. Upon service of notice that the permit is immediately suspended, the former permit holder shall be given an opportunity for ~~a hearing~~ an informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia. The request for ~~a hearing~~ an informal fact-finding conference shall be in writing. The written request shall be filed with the local department by the former holder of the permit. If written request for ~~a hearing~~ an informal fact-finding conference is not filed within 10 working days, the suspension is sustained. Each holder of a suspended permit shall be afforded an opportunity for an informal ~~hearing~~ fact-finding conference, within three working days of receipt of a request for the ~~hearing~~ informal fact-finding conference. The director may end the suspension at any time if the reasons for the suspension no longer exist.

12VAC5-421-3780. Revocation of a permit.

The director may, after providing an opportunity for ~~a hearing~~ an informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia, revoke a permit for flagrant or continuing violation of any of the requirements of this part.

~~Prior to revocation, the director shall notify in writing the holder of the permit, or the person in charge, of the specific reason for which the permit is to be revoked. The permit shall~~

~~be revoked at the end of the 15 days following service of such notice unless a written request for a hearing is filed before then with the director from which the permit was obtained. If no request for a hearing is filed within the 15 day period, the revocation of the permit shall be final.~~

Article 4
Inspection and Correction of Violations

12VAC5-421-3800. Periodic inspection.

Food establishments shall be inspected by the designee of the director. Inspections of the food establishments shall be performed as often as necessary for the enforcement of this part in accordance with the following:

1. Except as specified in subdivisions 2 and 3 of this section, the regulatory authority shall inspect a food establishment at least once every six months.

2. The regulatory authority may increase the interval between inspections beyond six months if:

a. The food establishment is fully operating under an approved and validated HACCP plan as specified under 12VAC5-421-3630;

b. The food establishment is assigned a less frequent inspection frequency based on ~~a written~~ an established risk-based inspection schedule ~~that is being~~ uniformly applied throughout the ~~jurisdiction~~ Commonwealth and ~~at least once every six months the establishment is contacted by telephone or other means by the regulatory authority to ensure that the establishment manager and the nature of the food operation are not changed~~ updated annually upon reissuance of the annual permit; or

c. The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not ~~potentially hazardous~~ time/temperature control for safety food, such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.

3. The regulatory authority shall ~~periodically~~ inspect ~~throughout its permit period~~ a temporary food establishment ~~that prepares, sells, or serves unpackaged potentially hazardous food and that~~ during its permit period, unless the Virginia Department of Health develops a written risk-based plan for adjusting the frequency of inspections of temporary food establishments that is uniformly applied throughout the Commonwealth.

~~a. Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or~~

~~b. Has inexperienced food employees.~~

12VAC5-421-3810. Performance-based and [~~priority-based~~ risk-based] inspections.

Within the parameters specified in 12VAC5-421-3800, the regulatory authority shall prioritize, and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this chapter and the establishment's potential as a vector of foodborne illness by evaluating:

1. Past performance for nonconformance with this chapter or HACCP plan requirements that are ~~critical~~ priority items or priority foundation items;

2. Past performance for numerous or repeat violations of this chapter or HACCP plan requirements that are ~~noncritical~~ core items;

3. Past performance for complaints investigated and found to be valid;

4. The hazards associated with the particular foods that are prepared, stored, or served;

5. The type of operation including the methods and extent of food storage, preparation, and service;

6. The number of people served; and

7. Whether the population served is a highly susceptible population.

12VAC5-421-3815. Competency of environmental health specialists.

A. An authorized representative of the commissioner who inspects a food establishment or conducts plan review for compliance with this chapter shall have the knowledge, skills, and ability to adequately perform the required duties. For the purposes of this section, competency shall be demonstrated when an environmental health specialist meets the training and standardization requirements specified in the Virginia Department of Health Procedures for Certification and Standardization of Retail Food Protection Staff, 2014, (VDH, Division of Food and Environmental Services).

B. The regulatory authority shall ensure that authorized representatives who inspect a food establishment or conduct plan review for compliance with this chapter have access to training and continuing education as needed to properly identify violations and apply this chapter.

12VAC5-421-3860. Documenting information and observations.

The regulatory authority shall document on an inspection report form:

1. Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under 12VAC5-421-3700, inspection date, and other information such as type of water supply and sewage disposal, status of the permit, and personnel certificates that may be required; and

2. Specific factual observations of violative conditions or other deviations from this chapter that require correction by the permit holder including:

a. Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this chapter specified under 12VAC5-421-60;

b. Failure of food employees, conditional employees, and the person in charge ~~to demonstrate their knowledge of their responsibility~~ to report a disease or medical condition as specified under 12VAC5-421-80 B and D;

c. Nonconformance with [~~critical~~ priority] items [or priority foundation items] of this chapter;

d. Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority as specified under 12VAC5-421-60;

e. Failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified under subdivision 4 f of 12VAC5-421-3630; and

f. Nonconformance with critical limits of a HACCP plan.

12VAC5-421-3910. Imminent health hazard, ceasing operations and reporting.

A. Except as specified in subsection B of this section, a permit holder shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.[P]

B. A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

12VAC5-421-3930. ~~Critical violation, timely~~ Timely correction.

A. Except as specified in subsection B of this section, a permit holder shall at the time of inspection correct a ~~critical violation of~~ priority item or priority foundation item in this chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.[Pf]

B. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer ~~time frame~~ timeframe, not to exceed ~~10 calendar days~~:

1. 72 hours after the inspection~~,~~ for the permit holder to correct ~~critical violations~~ priority items; or

2. 10 calendar days after the inspection for the permit holder to correct priority foundation items or HACCP plan deviations.

12VAC5-421-3940. Verification and documentation of correction.

A. After observing at the time of inspection a correction of a ~~critical violation or deviation~~ priority item or priority foundation item, the regulatory authority shall enter the ~~violation~~ observation and information about the corrective action on the inspection report.

B. As specified under 12VAC5-421-3930 B, after receiving notification that the permit holder has corrected a ~~critical violation~~ priority item or priority foundation item or a HACCP plan deviation, or at the end of the specified period of time, the regulatory authority shall verify correction ~~of the violation~~, document the information on an inspection report, and enter the report in the regulatory authority's records.

12VAC5-421-3950. ~~Noncritical violation~~ Core item, ~~time frame~~ timeframe for correction.

A. Except as specified in subsection B of this section, the permit holder shall correct ~~noncritical violations~~ core items by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

B. The regulatory authority may approve a compliance schedule that extends beyond the time limits specified under subsection A of this section if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

12VAC5-421-3960. Examination for condemnation of food.

Food may be examined or sampled by the department as often as necessary for enforcement of this chapter. Also, the department may, upon written notice to the owner or permit holder or person in charge impound any food which it believes is in violation of Part III (12VAC5-421-260 et seq.) or any other section of this chapter. The department shall tag, label, or otherwise identify any food subject to impoundment. No food under conditions specified in the impoundment shall be used, served or moved from the establishment. The department shall permit storage of the food under conditions specified in the impoundment unless storage is not possible without risk to the public health in which case immediate destruction shall be ~~ordered and~~ accomplished by the owner or permit holder or person in charge. The impoundment shall state that a request for ~~a hearing~~ an informal fact-finding conference may be filed within 10 days and that if no ~~hearing~~ conference is requested, the food shall be destroyed by the owner or permit holder or person in charge. ~~A hearing shall be held~~ The department shall hold an informal fact-finding conference if so requested, and on the basis of evidence produced at the hearing, the impoundment may be vacated, or

the owner or permit holder or person in charge of the food may be directed ~~by written order~~ in writing by the director to denature or destroy such food or to bring it into compliance with the provisions of this chapter.

12VAC5-421-3970. Enforcement of regulation.

A. This chapter shall be enforced by the State Board of Health and the State Health Commissioner, as executive officer of the board.

B. The directors are appointed by the board and commissioner as duly designated officers and are responsible for the implementation and enforcement of this chapter.

C. All food establishments shall operate in compliance with the requirements set forth in this chapter and shall not operate without a valid permit.

D. The commissioner shall be vested with all the authority of the board when it is not in session, subject to such rules and regulations as may be prescribed by the board.

E. Pursuant to the authority granted in §§ 32.1-26 and 35.1-6 of the Code of Virginia, the commissioner may issue orders to require any owner or permit holder or other person to comply with the provisions of ~~these regulations~~ this chapter. The order may require the following:

1. The immediate cessation and correction of the violation;

2. Appropriate remedial action to ensure that the violation does not continue or recur;

3. The submission of a plan to prevent future violations;

4. The submission of an application for a variance; and

5. Any other corrective action deemed necessary for proper compliance with the regulations.

~~F. Before the issuance of an order, the commissioner must comply with the requirements of § 35.1-6 of the Code of Virginia.~~

~~G. All orders issued pursuant to 12VAC5-421-3970 C shall become effective not less than 15 days after mailing a copy thereof by certified mail to the last known address of the owner or permit holder or person violating these regulations. Violation of an order is a Class 3 misdemeanor. See § 35.1-7 of the Code of Virginia.~~

~~H.~~ F. The commissioner may act as the agent of the board to enforce all effective orders and ~~these regulations~~ this chapter. Should any owner or permit holder fail to comply with any effective order or ~~these regulations~~ this chapter, the commissioner may:

1. Institute a proceeding to revoke the owner's or permit holder's permit in accordance with 12VAC5-421-3780;

2. Request the attorney for the Commonwealth to bring a criminal action;

3. Request the Attorney General to bring an action for civil penalty, injunction, or other appropriate remedy; or

4. Do any combination of the above.

~~I.~~ G. Not exclusive means of enforcement. Nothing contained in ~~12VAC5-421-3970~~ this section shall be interpreted to require the commissioner to issue an order prior to seeking enforcement of any regulations or statute through an injunction, mandamus or criminal prosecution.

~~J.~~ H. ~~Hearings~~ Proceedings before the commissioner or his designee shall include any of the following forms depending on the nature of the controversy and the interests of the parties involved.

1. Informal ~~hearings~~ fact-finding conferences. An informal ~~hearing~~ fact-finding conference is a meeting with a district or local health department with the district or local health director presiding and held in conformance with § 2.2-4019 of the Code of Virginia.

2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory proceeding before ~~the commissioner, or his designated hearing officer~~ a hearing officer as defined by § 2.2-4001 of the Code of Virginia, and held in conformance with § 2.2-4020 of the Code of Virginia.

12VAC5-421-3980. Request for ~~hearing~~ informal fact-finding conference.

A request for an informal ~~hearing~~ fact-finding conference shall be made by sending the request in writing to the district or local health department in the locality where the food establishment is located. Requests for ~~hearings~~ an informal fact-finding conference shall cite the ~~reason(s)~~ reason or reasons for the ~~hearing~~ request and shall cite the ~~section(s)~~ section or sections of ~~these regulations~~ this chapter involved and must be received within 30 days of the decision by the department that lead to the ~~hearing~~ request.

12VAC5-421-3990. ~~Hearing as a matter of right. (Repealed.)~~

~~Any owner or permit holder or named party whose rights, duties, or privileges have been, or may be affected by any case decision of the board or its subordinates in the administration of these regulations shall have a right to both informal and adjudicatory hearings. The commissioner may require participation in an informal hearing before granting the request for a full adjudicatory hearing. Exception: No person other than an owner shall have the right to an adjudicatory hearing to challenge the issuance of a permit to operate unless the person can demonstrate at an informal hearing that the minimum standards contained in these regulations have not been applied and that he will be injured in some manner by the issuance of the permit.~~

12VAC5-421-4000. Appeals.

A. Any appeal from a denial of a permit to operate a food establishment must be made in writing and received by the department within 30 days after service of the ~~final order in the case decision~~ denial. ~~In the event that service of a case decision upon a party is accomplished by mail, three days~~

~~shall be added to the 30-day period. Notice shall be consistent with Part 2A of the Rules of the Supreme Court of Virginia.~~

~~1. Any request for hearing on the denial of an application for a variance pursuant to 12VAC5-421-3590-A must be made in writing and received within sixty days of receipt of the denial notice.~~

~~2. Any request for a variance must be made in writing and received by the department prior to the denial of the food establishment permit, or within 60 days after such denial.~~

~~3. In the event a person applies for a variance within the 60-day period provided by subdivision 2 of this section, the date for appealing the denial of the permit, pursuant to subdivision 1 of this section, shall commence from the date on which the department acts on the request for a variance.~~

~~4.~~ B. Pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) an aggrieved owner or permit holder may appeal a final case decision of the commissioner to an appropriate circuit court.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (12VAC5-421)

~~Foodservice Establishment Inspection Report, EHS-152 (rev. 9/95).~~

~~Foodservice Critical Procedures Report, EHS-153 (rev. 9/95).~~

Food Establishment Inspection Report Form - Cover Page (eff. 2016)

Food Establishment Inspection Report Form - Narrative Page with Temperatures (eff. 2016)

Food Establishment Inspection Report Form - Narrative Page (eff. 2016)

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-421)

~~National Shellfish Sanitation Program Manual of Operations, Part II, Sanitation of the Harvesting, Processing and Distribution of Shellfish, 1995 Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration~~

Approved Drug Products with Therapeutic Equivalence Evaluations, 34th Edition, 2014, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs at http://www.fda.gov/cder/ob/default.htm

Grade "A" Pasteurized Milk Ordinance, 2013 Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835

Interstate Certified Shellfish Shippers List (updated monthly), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood (HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, 2013 Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood (HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835

NSF/ANSI 18-2012 Manual Food and Beverage Dispensing Equipment, 2012, NSF International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, MI 48113-0140, www.nsf.org

Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, Conference for Food Protection, 30 Elliott Court, Martinsville, IN 46151-1331

United States Standards, Grades, and Weight Classes for Shell Eggs, AMS-56, effective July 20, 2000, U.S. Department of Agriculture, Agricultural Marketing Service, Poultry Programs, STOP 0259, Room 3944-South, 1400 Independence Avenue, SW, Washington, DC 20250-0259

VDH Procedures for Certification and Standardization of Retail Food Protection Staff Workbook, 2014, Virginia Department of Health, Division of Food and Environmental Services, 109 Governor Street, 5th Floor, Richmond, VA 23219

VA.R. Doc. No. R16-2701; Filed June 2, 2016, 5:27 p.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Proposed Regulation

Titles of Regulations: **12VAC30-30. Groups Covered and Agencies Responsible for Eligibility Determination (amending 12VAC30-30-20).**

12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-130).

12VAC30-135. Demonstration Waiver Services (repealing 12VAC30-135-10 through 12VAC30-135-90).

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

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: August 26, 2016.

Agency Contact: Victoria Simmons, Regulatory Coordinator, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-6043, FAX (804) 786-1680, or email victoria.simmons@dmas.virginia.gov.

Basis: Section 32.1-325 of the Code of Virginia grants to the Board of Medical Assistance Services the authority to administer the Plan for Medical Assistance. Section 32.1-324 of the Code of Virginia authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance when the board is not in session, subject to such rules and regulations as may be prescribed by the board. The Medicaid authority was established by § 1902(a) of the Social Security Act (42 USC § 1396a), which provides the governing authority for DMAS to administer the state's Medicaid system.

The Patient Protection and Affordable Care Act (Public Law 111-148) (PPACA), as amended by the Health Care and Education Recovery Act of 2010 (Public Law 111-152), contains § 2303 State Eligibility Option for Family Planning Services, which established a new Medicaid eligibility group and the option for states to begin providing family planning services and supplies to individuals (both men and women) found to be eligible under this new group. Coverage of both of these services was previously only available under a demonstration project waiver for men and women not eligible for full Medicaid benefits.

Item 301 UU of Chapter 665 of the 2015 Acts of Assembly provides the following: "The Department of Medical Assistance Services shall seek federal authority to move the family planning eligibility group from a demonstration waiver to the State Plan for Medical Assistance. The department shall seek approval of coverage under this new state plan option for individuals with income up to 200% of the federal poverty level (FPL). For the purposes of this section, family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage or make direct referrals for abortions. The department shall have authority to implement necessary changes upon federal approval and prior to the completion of any regulatory process undertaken in order to effect such change."

Purpose: The Plan First program was initially covered by the Centers for Medicare and Medicaid Services (CMS) as a demonstration waiver program and covered general family planning services for persons who could not qualify for full Medicaid eligibility. The covered services included (i) examinations for both men and women for sexually transmitted diseases, (ii) birth control, (iii) cancer screenings for men and women, and (iv) family planning education and counseling. Demonstration projects, regardless of their subject, create significant administrative costs and reporting requirements for Medicaid programs. In order to approve a demonstration grant for a state, CMS requires significant data reporting, formal evaluations, and periodic grant renewals. Converting this family planning service to the State Plan, as now permitted by PPACA, relieves DMAS of these administrative costs and duties.

The purpose of this action is to move the waiver regulations into the state plan regulations, which has no effect on the health, safety, or welfare of citizens. The increase of the income eligibility level will permit more individuals to receive services under this program. The advantage to the individuals who qualify for this service is the coverage of family planning services and examinations for sexually transmitted diseases.

There are no disadvantages to the public or the Commonwealth associated with the proposed regulatory action.

Substance: The planned regulatory action makes three types of changes: (i) substantive changes required by CMS as a condition of the state plan amendment approval, (ii) substantive changes to the income level approved by CMS, and (iii) nonsubstantive editorial changes. In addition to moving this program out of demonstration waiver regulations and into state plan regulations, this action also increases the income level for eligibility, authorizes use of the DMAS Central Processing Unit or other contractor for determining eligibility (should DMAS determine that this is the most practicable approach), and clarifies that those individuals eligible for full-benefit coverage under Medicaid or FAMIS are not eligible under this program. The proposed regulatory action also authorizes coverage for additional (beyond initial) testing for sexually transmitted infections (STI) and newer methods of cervical cancer screening. The changes are designed to facilitate administration and update the services provided. In addition, this regulatory action includes nonsubstantive changes to selected language.

Current regulations treat individuals eligible for coverage under the Medicaid family planning option as a demonstration waiver versus the state plan option as approved by CMS. Under the demonstration waiver, the Commonwealth was allowed to waive certain limits for eligibility, including disallowing eligibility based on age, gender, or having had a sterilization procedure or hysterectomy. The demonstration waiver also disallowed retroactive eligibility. These limitations were required by CMS as a condition of waiver approval. The current regulations also limit the income level for eligibility to 133% FPL.

Current regulations limit eligibility determination to local departments of social services and are unclear with regard to enrollment for persons eligible for Medicaid or FAMIS under a full-benefits category. Current regulations limit testing for sexually transmitted diseases (STDs) to the initial visit and restrict cervical cancer screening to the Pap test.

By meeting CMS requirements for continuation of the Family Planning program as a state plan service, the proposed regulatory action brings the regulations into compliance with the state plan amendment currently approved by CMS. This action assures that the eligibility rules for the state plan family planning option are consistent with those for full benefit Medicaid program. Raising the income level for eligibility makes the program consistent with the FAMIS MOMS program for pregnant women, and offers more men and women access to family planning services. Updating the clinical services available (STI testing and cervical cancer screening options) conforms to the present standard of care.

The family planning program is a benefit to qualified low-income families by providing them with the means for obtaining medical family planning services to avoid unintended pregnancies and increase the spacing between births to help promote healthier mothers and infants.

The primary advantage of the family planning program to the Commonwealth is a cost savings to Medicaid for prenatal care, delivery, and infant care by preventing unintended pregnancies. According to the Virginia Department of Health's Pregnancy Risk Assessment Monitoring System (2010), unintended pregnancy continues to occur at a high rate in Virginia, where 42% of all pregnancies are unintended across the Commonwealth. Of these unintended pregnancies, 31% were mistimed (women who reported they wanted to be pregnant later) and 11% were unwanted (women who reported they did not want the pregnancy then or in the future).

Family planning services do not cover abortion services or referrals for abortions. This regulatory action would not affect individuals younger than 19 years of age unless they are in the FAMIS income range but are not eligible for FAMIS because of having other creditable health insurance. The majority of individuals younger than 19 years of age would be eligible for full Medicaid or FAMIS benefits.

The intent of this action is to align Virginia policy with that afforded by federal law, and in doing so expand family planning options for individuals who would not otherwise qualify for Medicaid or FAMIS coverage.

Issues: The primary advantage to the public is that more low-income women and men will have access to family planning services. This increased access will support these individuals' efforts to better plan for pregnancy and will also allow greater access to testing for STI and screening for cervical cancer.

The primary disadvantage to these individuals is that, by definition, this is a limited benefit program. Some individuals may not understand those limits as they apply for full Medicaid benefits or seek services that are not encompassed by this family planning program, requiring remedial education and redirection to more appropriate resources. A disadvantage of this program for providers is that they also may not understand this program's limits and, after failing to determine that their patient has limited available benefits, provide a full range of services only to have their claims denied.

There are no identified disadvantages to the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed regulation makes permanent the provision of family planning services under the new eligibility group authorized by the Centers for Medicare and Medicaid Services (CMS).

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

Estimated Economic Impact. These regulations contain rules for Medicaid family planning services. Family planning services are services necessary to prevent or delay a pregnancy and do not include abortion services. The services include education and counseling, physician office visits, annual gynecological exams, sexually transmitted disease screens, Pap tests, contraceptives, and sterilizations for family planning purposes. Prior to 2011, coverage of these services had been provided in Virginia under a demonstration project waiver which required a new demonstration and federal approval every three years. In 2010, the federal Affordable Care Act established a new Medicaid eligibility group and the option for states to begin providing family planning services and supplies to individuals found to be eligible under this new group. Consequently, Chapter 890 of the 2011 Acts of Assembly, Item 297 DDDDD required the Department of Medical Assistance Services (DMAS) to seek federal approval to provide family planning services under the new eligibility group. As a result, DMAS obtained federal authority in 2011 and has been providing these services under that authority since then.[1] The proposed changes have been implemented for some time and no significant economic impact upon promulgation of the proposed changes is expected. However, a general discussion is provided below to highlight the effects that have already likely occurred and will likely continue to be realized in the future.

As a result of the new eligibility rules in 2011, the income limit has increased from 133 percent of the federal poverty limit to 200 percent. The increase in the income level permitted more low-income women and men to have access to family planning services. In support of the waiver renewal application, DMAS estimated the cost effectiveness of family planning services in 2011. The study shows that the primary advantage of this change is costs savings to Medicaid for prenatal care, delivery, and infant care by preventing unintended pregnancies.

The study estimated that an additional 1,246 recipients would receive family planning services in fiscal year (FY) 2013. The cost of family planning services was estimated to be $323.53 per recipient for FY2013 and $403,123 in total to cover 1,246 additional recipients.[2] On the other hand, the cost of pregnancy care, delivery, and first year of life care was estimated to be $19,629.88 per recipient for FY2013, making

family planning services very cost effective. For example, assuming family planning services reduce the Medicaid population's pregnancy rate by 7.15 percent, approximately 89 unintended pregnancies in FY2013 could be assumed to have been averted. As a result, assuming all unintended pregnancies would have ended in births, approximately $1.7 million in FY2013 could be estimated to have been averted in costs for prenatal care, delivery, and first year of life care.[3 4]

In reality, some of the unintended pregnancies would not end in births. Thus, there is likely to be some financial savings to women who unintentionally get pregnant and who would otherwise terminate their pregnancies. Family planning services do not pay for abortion services unless the life or health of the mother is endangered if the fetus is carried to term. Thus, any abortion costs must be paid privately. Since the proposed change likely reduced the number of terminated pregnancies among unintended pregnancies, these women and/or their families probably realized some financial savings in abortion costs that would have otherwise occurred.

In addition, the non-financial effects of family planning are significant. The family planning services are expected to benefit the health and welfare of these women in their childbearing years, to reduce maternal mortality and morbidity, and to improve the health of children, by allowing women to plan their pregnancies, by decreasing their risk of experiencing poor birth outcomes, and by averting the unintended births.[5, 6] Adolescent women, women with several children, and women with existing health problems are particularly susceptible to health risks because their bodies may not be mature enough to handle a pregnancy and experience obstetrical complications, may not have gained sufficient strength following a previous pregnancy, or may face complications due to other health conditions, respectively. Closely spaced births (usually within 2 years) are more likely to be premature and low birth-weight. By practicing family planning, women can avoid high-risk births and reduce their chances of having a baby who will die in infancy. Poor birth outcomes may also result in expensive long lasting health care services for developmentally delayed children.

Some other additional benefits of expanding family planning services may stem from the use of contraceptives. Condoms offer protection against infection with HIV and STDs. Spermicides and diaphragm may help prevent STDs. Hormonal contraceptive methods may provide protection against iron deficiency, anemia, menstrual problems, and provide other similar benefits. Screening and testing may help detect some potential life threatening conditions such as cervical or breast cancer early on and improve recipient women's health.

The proposed change is beneficial also in terms of lower administrative costs. In order to approve a demonstration grant for a state, CMS requires significant data reporting, formal evaluations, and periodic grant renewals. Provision of services under the state plan eliminates these administrative costs. However, likely savings in administrative costs were probably offset to some extent by the increase in the caseloads.

Businesses and Entities Affected. The increase in the eligibility income level was estimated to allow an additional 1,246 recipients to receive Medicaid funded family planning services in FY2013. It is not known how many physician practices provide services to individuals in the family planning program.

Localities Particularly Affected. The proposed changes apply statewide.

Projected Impact on Employment. The increase in population receiving family planning services likely increased the demand for such services and likely had a positive impact on employment.

Effects on the Use and Value of Private Property. Increased demand for family planning services likely increased provider revenues and had positive impact on their asset values.

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

Small Businesses:

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

Costs and Other Effects. The affected providers are generally assumed to be small businesses. The proposed regulation does not impose costs on them, but likely resulted in an increase in demand for their services.

Alternative Method that Minimizes Adverse Impact. No adverse impact on small businesses is expected.

Adverse Impacts:

Businesses. The proposed regulation does not adversely affect non-small businesses.

Localities. The proposed regulation does not adversely affect localities.

Other Entities. The proposed regulation does not adversely affect other entities.

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[1] However since the waiver regulation has not moved into the state plan regulations, similar language has been included in budget bills after 2011. For example, see Chapter 665 of the 2015 Acts of Assembly, Item 301 UU.

[2] This estimate is probably slightly lower than actual cost for two reasons. First, transportation was not a covered service prior to 2011 which would add approximately $1.12 per member per month to the overall cost. Second, testing for sexually transmitted diseases was limited to the initial visit, and cervical cancer screening was limited to the Pap test both of which would also add to the overall cost.

[3] The literature strongly supports that every dollar spent on family planning services produces $3.00 to $5.63 savings in Medicaid expenditures for pregnancy and infant care due to averted pregnancies. For example, see "Contraceptive Needs and Services, 2010," Guttmacher Institute, July 2013

and Forrest and Samara, 1996, "Impact of Publicly Funded Contraceptive Services on Unintended Pregnancies and Implications for Medicaid Expenditures," Family Planning Perspectives, 28(5).

[4] Exact amount of the Commonwealth's share of estimated total savings depends on the federal match rate which is 90% for family planning services and 50% for pregnancy and infant care services. For simplicity, only total savings are stated.

[5] Trussell, James, et al., 1995, "The Economic Value of Contraception: A comparison of 15 Methods," American Journal of Public Health, v. 85 No. 4, pp. 494-503.

[6] Trussell, James et al., 1997, "Medical Care Costs Savings from Adolescent Contraceptive Use," Family Planning Perspectives, v. 29, No. 6.

Agency's Response to Economic Impact Analysis: The agency has reviewed the economic impact analysis prepared by the Department of Planning and Budget regarding the regulations concerning Plan First Family Planning Services (Optional Group). The agency concurs with this analysis.

Summary:

Pursuant to Item 301 UU of Chapter 665 of the 2015 Acts of Assembly, the proposed amendments move the family planning program from demonstration waiver regulations to state plan regulations. The proposed amendments (i) increase the income level for eligibility for the program; (ii) authorize use of the Department of Medical Assistance Services Central Processing Unit or other contractor for determining eligibility, provided that DMAS determines that this is the most practicable approach; (iii) clarify that individuals eligible for full-benefit coverage under Medicaid or FAMIS are not eligible under this program; and (iv) authorize coverage for additional testing, beyond the initial testing, for sexually transmitted infections and newer methods of cervical cancer screening.

12VAC30-30-20. Optional groups other than the medically needy.

The Title IV A agency determines eligibility for Title XIX services.

1. Caretakers and pregnant women who meet the income and resource requirements of AFDC but who do not receive cash assistance.

2. Individuals who would be eligible for AFDC, SSI or an optional state supplement as specified in 42 CFR 435.230, if they were not in a medical institution.

3. A group or groups of individuals who would be eligible for Medicaid under the plan if they were in a NF or an ICF/MR, who but for the provision of home and community-based services under a waiver granted under 42 CFR Part 441, Subpart G would require institutionalization, and who will receive home and community-based services under the waiver. The group or groups covered are listed in the waiver request. This option is effective on the effective date of the state's § 1915(c) waiver under which this ~~group(s)~~ group is covered. In the event an existing § 1915(c) waiver is amended to cover this ~~group(s)~~ group, this option is effective on the effective date of the amendment.

4. Individuals who would be eligible for Medicaid under the plan if they were in a medical institution, who are terminally ill, and who receive hospice care in accordance with a voluntary election described in § 1905(o) of the Act.

5. The state does not cover all individuals who are not described in § 1902(a)(10)(A)(i) of the Act, who meet the income and resource requirements of the AFDC state plan and who are under the age of 21. The state does cover reasonable classifications of these individuals as follows:

a. Individuals for whom public agencies are assuming full or partial financial responsibility and who are:

(1) In foster homes (and are under the age of 21).

(2) In private institutions (and are under the age of 21).

(3) In addition to the group under subdivisions 5 a (1) and (2) of this section, individuals placed in foster homes or private institutions by private nonprofit agencies (and are under the age of 21).

b. Individuals in adoptions subsidized in full or part by a public agency (who are under the age of 21).

c. Individuals in NFs (who are under the age of 21). NF services are provided under this plan.

d. In addition to the group under subdivision 5 c of this section, individuals in ICFs/MR (who are under the age of 21).

6. A child for whom there is in effect a state adoption assistance agreement (other than under Title IV-E of the Act), who, as determined by the state adoption agency, cannot be placed for adoption without medical assistance because the child has special care needs for medical or rehabilitative care, and who before execution of the agreement:

a. Was eligible for Medicaid under the state's approved Medicaid plan; or

b. Would have been eligible for Medicaid if the standards and methodologies of the Title IV-E foster care program were applied rather than the AFDC standards and methodologies.

The state covers individuals under the age of 21.

7. Section 1902(f) states and SSI criteria states without agreements under §§ 1616 and 1634 of the Act.

The following groups of individuals who receive a state supplementary payment under an approved optional state supplementary payment program that meets the following conditions. The supplement is:

a. Based on need and paid in cash on a regular basis.

b. Equal to the difference between the individual's countable income and the income standard used to determine eligibility for the supplement.

c. Available to all individuals in each classification and available on a statewide basis.

d. Paid to one or more of the following classifications of individuals:

(1) Aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(2) Blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(3) Disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(4) Individuals receiving a state administered optional state supplement that meets the conditions specified in 42 CFR 435.230.

The supplement varies in income standard by political subdivisions according to cost-of-living differences.

The standards for optional state supplementary payments are listed in 12VAC30-40-250.

8. Individuals who are in institutions for at least 30 consecutive days and who are eligible under a special income level. Eligibility begins on the first day of the 30-day period. These individuals meet the income standards specified in 12VAC30-40-220.

The state covers all individuals as described above.

9. Individuals who are 65 years of age or older or who are disabled as determined under § 1614(a)(3) of the Act, whose income does not exceed the income level specified in 12VAC30-40-220 for a family of the same size, and whose resources do not exceed the maximum amount allowed under SSI.

10. Individuals required to enroll in cost-effective employer-based group health plans remain eligible for a minimum enrollment period of one month.

11. Women who have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act in accordance with § 1504 of the Act and need treatment for breast or cervical cancer, including a pre-cancerous condition of the breast or cervix. These women are not otherwise covered under creditable coverage, as defined in § 2701(c) of the Public Health Services Act, are not eligible for Medicaid under any mandatory categorically needy eligibility group, and have not attained age 65.

12. Individuals who may qualify for the Medicaid Buy-In program under § 1902(a)(10)(A)(ii)(XV) of the Social Security Act (Ticket to Work Act) if they meet the requirements for the 80% eligibility group described in 12VAC30-40-220, as well as the requirements described in 12VAC30-40-105 and 12VAC30-110-1500.

13. Individuals under the State Eligibility Option of P.L. 111-148 § 2303 who are not pregnant and whose income does not exceed the state established income standard for pregnant women in the Virginia Medicaid and CHIP State Plan and related waivers, which is 200% of the federal poverty level, shall be eligible for the family planning program. Services are limited to family planning services as described in 12VAC30-50-130 D.

12VAC30-50-130. Skilled nursing facility services, EPSDT, school health services and family planning.

A. Skilled nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older.

Service must be ordered or prescribed and directed or performed within the scope of a license of the practitioner of the healing arts.

B. Early and periodic screening and diagnosis of individuals under 21 years of age, and treatment of conditions found.

1. Payment of medical assistance services shall be made on behalf of individuals under 21 years of age, who are Medicaid eligible, for medically necessary stays in acute care facilities, and the accompanying attendant physician care, in excess of 21 days per admission when such services are rendered for the purpose of diagnosis and treatment of health conditions identified through a physical examination.

2. Routine physicals and immunizations (except as provided through EPSDT) are not covered except that well-child examinations in a private physician's office are covered for foster children of the local social services departments on specific referral from those departments.

3. Orthoptics services shall only be reimbursed if medically necessary to correct a visual defect identified by an EPSDT examination or evaluation. The department shall place appropriate utilization controls upon this service.

4. Consistent with the Omnibus Budget Reconciliation Act of 1989 § 6403, early and periodic screening, diagnostic, and treatment services means the following services: screening services, vision services, dental services, hearing services, and such other necessary health care, diagnostic services, treatment, and other measures described in Social Security Act § 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services and which are medically necessary, whether or not such services are covered under the State Plan and notwithstanding the limitations, applicable to recipients ages 21 and over, provided for by the Act § 1905(a).

5. Community mental health services. These services in order to be covered (i) shall meet medical necessity criteria based upon diagnoses made by LMHPs who are practicing within the scope of their licenses and (ii) are reflected in provider records and on providers' claims for services by recognized diagnosis codes that support and are consistent with the requested professional services.

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

"Activities of daily living" means personal care activities and includes bathing, dressing, transferring, toileting, feeding, and eating.

"Adolescent or child" means the individual receiving the services described in this section. For the purpose of the use of these terms, adolescent means an individual 12-20 years of age; a child means an individual from birth up to 12 years of age.

"Behavioral health services administrator" or "BHSA" means an entity that manages or directs a behavioral health benefits program under contract with DMAS.

"Care coordination" means collaboration and sharing of information among health care providers, who are involved with an individual's health care, to improve the care.

"Certified prescreener" means an employee of the local community services board or behavioral health authority, or its designee, who is skilled in the assessment and treatment of mental illness and has completed a certification program approved by the Department of Behavioral Health and Developmental Services.

"Clinical experience" means providing direct behavioral health services on a full-time basis or equivalent hours of part-time work to children and adolescents who have diagnoses of mental illness and includes supervised internships, supervised practicums, and supervised field experience for the purpose of Medicaid reimbursement of (i) intensive in-home services, (ii) day treatment for children and adolescents, (iii) community-based residential services for children and adolescents who are younger than 21 years of age (Level A), or (iv) therapeutic behavioral services (Level B). Experience shall not include unsupervised internships, unsupervised practicums, and unsupervised field experience. The equivalency of part-time hours to full-time hours for the purpose of this requirement shall be as established by DBHDS in the document entitled Human Services and Related Fields Approved Degrees/Experience, issued March 12, 2013, revised May 3, 2013.

"DBHDS" means the Department of Behavioral Health and Developmental Services.

"DMAS" means the Department of Medical Assistance Services and its contractor or contractors.

"Human services field" means the same as the term is defined by DBHDS in the document entitled Human Services and Related Fields Approved Degrees/Experience, issued March 12, 2013, revised May 3, 2013.

"Individual service plan" or "ISP" means the same as the term is defined in 12VAC30-50-226.

"Licensed mental health professional" or "LMHP" means a licensed physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, licensed substance abuse treatment practitioner, licensed marriage and family therapist, or certified psychiatric clinical nurse specialist.

"LMHP-resident" or "LMHP-R" means the same as "resident" as defined in (i) 18VAC115-20-10 for licensed professional counselors; (ii) 18VAC115-50-10 for licensed marriage and family therapists; or (iii) 18VAC115-60-10 for licensed substance abuse treatment practitioners. An LMHP-resident shall be in continuous compliance with the regulatory requirements of the applicable counseling profession for supervised practice and shall not perform the functions of the LMHP-R or be considered a "resident" until the supervision for specific clinical duties at a specific site has been preapproved in writing by the Virginia Board of Counseling. For purposes of Medicaid reimbursement to their supervisors for services provided by such residents, they shall use the title "Resident" in connection with the applicable profession after their signatures to indicate such status.

"LMHP-resident in psychology" or "LMHP-RP" means the same as an individual in a residency, as that term is defined in 18VAC125-20-10, program for clinical psychologists. An LMHP-resident in psychology shall be in continuous compliance with the regulatory requirements for supervised experience as found in 18VAC125-20-65 and shall not perform the functions of the LMHP-RP or be considered a "resident" until the supervision for specific clinical duties at a specific site has been preapproved in writing by the Virginia Board of Psychology. For purposes of Medicaid reimbursement by supervisors for services provided by such residents, they shall use the title "Resident in Psychology" after their signatures to indicate such status.

"LMHP-supervisee in social work," "LMHP-supervisee," or "LMHP-S" means the same as "supervisee" as defined in 18VAC140-20-10 for licensed clinical social workers. An LMHP-supervisee in social work shall be in continuous compliance with the regulatory requirements for supervised practice as found in 18VAC140-20-50 and shall not perform the functions of the LMHP-S or be considered a "supervisee" until the supervision for specific clinical duties at a specific site is preapproved in writing by the Virginia Board of Social Work. For purposes of Medicaid reimbursement to their supervisors for services provided by supervisees, these persons shall use the title "Supervisee in Social Work" after their signatures to indicate such status.

"Progress notes" means individual-specific documentation that contains the unique differences particular to the individual's circumstances, treatment, and progress that is also signed and contemporaneously

dated by the provider's professional staff who have prepared the notes. Individualized and member-specific progress notes are part of the minimum documentation requirements and shall convey the individual's status, staff interventions, and, as appropriate, the individual's progress, or lack of progress, toward goals and objectives in the ISP. The progress notes shall also include, at a minimum, the name of the service rendered, the date of the service rendered, the signature and credentials of the person who rendered the service, the setting in which the service was rendered, and the amount of time or units/hours required to deliver the service. The content of each progress note shall corroborate the time/units billed. Progress notes shall be documented for each service that is billed.

"Psychoeducation" means (i) a specific form of education aimed at helping individuals who have mental illness and their family members or caregivers to access clear and concise information about mental illness and (ii) a way of accessing and learning strategies to deal with mental illness and its effects in order to design effective treatment plans and strategies.

"Psychoeducational activities" means systematic interventions based on supportive and cognitive behavior therapy that emphasizes an individual's and his family's needs and focuses on increasing the individual's and family's knowledge about mental disorders, adjusting to mental illness, communicating and facilitating problem solving and increasing coping skills.

"Qualified mental health professional-child" or "QMHP-C" means the same as the term is defined in 12VAC35-105-20.

"Qualified mental health professional-eligible" or "QMHP-E" means the same as the term is defined in 12VAC35-105-20 and consistent with the requirements of 12VAC35-105-590.

"Qualified paraprofessional in mental health" or "QPPMH" means the same as the term is defined in 12VAC35-105-20 and consistent with the requirements of 12VAC35-105-1370.

"Service-specific provider intake" means the face-to-face interaction in which the provider obtains information from the child or adolescent, and parent or other family member or members, as appropriate, about the child's or adolescent's mental health status. It includes documented history of the severity, intensity, and duration of mental health care problems and issues and shall contain all of the following elements: (i) the presenting issue/reason for referral, (ii) mental health history/hospitalizations, (iii) previous interventions by providers and timeframes and response to treatment, (iv) medical profile, (v) developmental history including history of abuse, if appropriate, (vi) educational/vocational status, (vii) current living situation and family history and relationships, (viii) legal status, (ix) drug and alcohol profile, (x) resources and strengths, (xi) mental status exam and profile, (xii) diagnosis, (xiii) professional summary and clinical formulation, (xiv) recommended care and treatment goals, and (xv) the dated signature of the LMHP, LMHP-supervisee, LMHP-resident, or LMHP-RP.

b. Intensive in-home services (IIH) to children and adolescents under age 21 shall be time-limited interventions provided in the individual's residence and when clinically necessary in community settings. All interventions and the settings of the intervention shall be defined in the Individual Service Plan. All IIH services shall be designed to specifically improve family dynamics, provide modeling, and the clinically necessary interventions that increase functional and therapeutic interpersonal relations between family members in the home. IIH services are designed to promote psychoeducational benefits in the home setting of an individual who is at risk of being moved into an out-of-home placement or who is being transitioned to home from an out-of-home placement due to a documented medical need of the individual. These services provide crisis treatment; individual and family counseling; communication skills (e.g., counseling to assist the individual and his parents or guardians, as appropriate, to understand and practice appropriate problem solving, anger management, and interpersonal interaction, etc.); care coordination with other required services; and 24-hour emergency response.

(1) These services shall be limited annually to 26 weeks. Service authorization shall be required for Medicaid reimbursement prior to the onset of services. Services rendered before the date of authorization shall not be reimbursed.

(2) Service authorization shall be required for services to continue beyond the initial 26 weeks.

(3) Service-specific provider intakes shall be required at the onset of services and ISPs shall be required during the entire duration of services. Services based upon incomplete, missing, or outdated service-specific provider intakes or ISPs shall be denied reimbursement. Requirements for service-specific provider intakes and ISPs are set out in this section.

(4) These services may only be rendered by an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, a QMHP-C, or a QMHP-E.

c. Therapeutic day treatment (TDT) shall be provided two or more hours per day in order to provide therapeutic interventions. Day treatment programs, limited annually to 780 units, provide evaluation; medication education and management; opportunities to learn and use daily living skills and to enhance social and interpersonal skills (e.g., problem solving, anger management, community

responsibility, increased impulse control, and appropriate peer relations, etc.); and individual, group and family counseling.

(1) Service authorization shall be required for Medicaid reimbursement.

(2) Service-specific provider intakes shall be required at the onset of services and ISPs shall be required during the entire duration of services. Services based upon incomplete, missing, or outdated service-specific provider intakes or ISPs shall be denied reimbursement. Requirements for service-specific provider intakes and ISPs are set out in this section.

(3) These services may be rendered only by an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, a QMHP-C, or a QMHP-E.

d. Community-based services for children and adolescents under 21 years of age (Level A).

(1) Such services shall be a combination of therapeutic services rendered in a residential setting. The residential services will provide structure for daily activities, psychoeducation, therapeutic supervision, care coordination, and psychiatric treatment to ensure the attainment of therapeutic mental health goals as identified in the individual service plan (plan of care). Individuals qualifying for this service must demonstrate medical necessity for the service arising from a condition due to mental, behavioral or emotional illness that results in significant functional impairments in major life activities in the home, school, at work, or in the community. The service must reasonably be expected to improve the child's condition or prevent regression so that the services will no longer be needed. The application of a national standardized set of medical necessity criteria in use in the industry, such as McKesson InterQual® Criteria or an equivalent standard authorized in advance by DMAS, shall be required for this service.

(2) In addition to the residential services, the child must receive, at least weekly, individual psychotherapy that is provided by an LMHP, LMHP-supervisee, LMHP-resident, or LMHP-RP.

(3) Individuals shall be discharged from this service when other less intensive services may achieve stabilization.

(4) Authorization shall be required for Medicaid reimbursement. Services that were rendered before the date of service authorization shall not be reimbursed.

(5) Room and board costs shall not be reimbursed. DMAS shall reimburse only for services provided in facilities or programs with no more than 16 beds.

(6) These residential providers must be licensed by the Department of Social Services, Department of Juvenile Justice, or Department of Behavioral Health and Developmental Services under the Standards for Licensed Children's Residential Facilities (22VAC40-151), Standards for Interim Regulation of Children's Residential Facilities (6VAC35-51), or Regulations for Children's Residential Facilities (12VAC35-46).

(7) Daily progress notes shall document a minimum of seven psychoeducational activities per week. Psychoeducational programming must include, but is not limited to, development or maintenance of daily living skills, anger management, social skills, family living skills, communication skills, stress management, and any care coordination activities.

(8) The facility/group home must coordinate services with other providers. Such care coordination shall be documented in the individual's medical record. The documentation shall include who was contacted, when the contact occurred, and what information was transmitted.

(9) Service-specific provider intakes shall be required at the onset of services and ISPs shall be required during the entire duration of services. Services based upon incomplete, missing, or outdated service-specific provider intakes or ISPs shall be denied reimbursement. Requirements for intakes and ISPs are set out in 12VAC30-60-61.

(10) These services may only be rendered by an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, a QMHP-C, a QMHP-E, or a QPPMH.

e. Therapeutic behavioral services (Level B).

(1) Such services must be therapeutic services rendered in a residential setting that provides structure for daily activities, psychoeducation, therapeutic supervision, care coordination, and psychiatric treatment to ensure the attainment of therapeutic mental health goals as identified in the individual service plan (plan of care). Individuals qualifying for this service must demonstrate medical necessity for the service arising from a condition due to mental, behavioral or emotional illness that results in significant functional impairments in major life activities in the home, school, at work, or in the community. The service must reasonably be expected to improve the child's condition or prevent regression so that the services will no longer be needed. The application of a national standardized set of medical necessity criteria in use in the industry, such as McKesson InterQual® Criteria, or an equivalent standard authorized in advance by DMAS shall be required for this service.

(2) Authorization is required for Medicaid reimbursement. Services that are rendered before the date of service authorization shall not be reimbursed.

(3) Room and board costs shall not be reimbursed. Facilities that only provide independent living services

are not reimbursed. DMAS shall reimburse only for services provided in facilities or programs with no more than 16 beds.

(4) These residential providers must be licensed by the Department of Behavioral Health and Developmental Services (DBHDS) under the Regulations for Children's Residential Facilities (12VAC35-46).

(5) Daily progress notes shall document that a minimum of seven psychoeducational activities per week occurs. Psychoeducational programming must include, but is not limited to, development or maintenance of daily living skills, anger management, social skills, family living skills, communication skills, and stress management. This service may be provided in a program setting or a community-based group home.

(6) The individual must receive, at least weekly, individual psychotherapy and, at least weekly, group psychotherapy that is provided as part of the program.

(7) Individuals shall be discharged from this service when other less intensive services may achieve stabilization.

(8) Service-specific provider intakes shall be required at the onset of services and ISPs shall be required during the entire duration of services. Services that are based upon incomplete, missing, or outdated service-specific provider intakes or ISPs shall be denied reimbursement. Requirements for intakes and ISPs are set out in 12VAC30-60-61.

(9) These services may only be rendered by an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, a QMHP-C, a QMHP-E, or a QPPMH.

(10) The facility/group home shall coordinate necessary services with other providers. Documentation of this care coordination shall be maintained by the facility/group home in the individual's record. The documentation shall include who was contacted, when the contact occurred, and what information was transmitted.

6. Inpatient psychiatric services shall be covered for individuals younger than age 21 for medically necessary stays for the purpose of diagnosis and treatment of mental health and behavioral disorders identified under EPSDT when such services are rendered by:

a. A psychiatric hospital or an inpatient psychiatric program in a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations; or a psychiatric facility that is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children or the Council on Quality and Leadership.

b. Inpatient psychiatric hospital admissions at general acute care hospitals and freestanding psychiatric hospitals shall also be subject to the requirements of 12VAC30-50-100, 12VAC30-50-105, and 12VAC30-60-25. Inpatient psychiatric admissions to residential treatment facilities shall also be subject to the requirements of Part XIV (12VAC30-130-850 et seq.) of Amount, Duration and Scope of Selected Services.

c. Inpatient psychiatric services are reimbursable only when the treatment program is fully in compliance with 42 CFR Part 441 Subpart D, as contained in 42 CFR 441.151 (a) and (b) and 441.152 through 441.156. Each admission must be preauthorized and the treatment must meet DMAS requirements for clinical necessity.

7. Hearing aids shall be reimbursed for individuals younger than 21 years of age according to medical necessity when provided by practitioners licensed to engage in the practice of fitting or dealing in hearing aids under the Code of Virginia.

C. School health services.

1. School health assistant services are repealed effective July 1, 2006.

2. School divisions may provide routine well-child screening services under the State Plan. Diagnostic and treatment services that are otherwise covered under early and periodic screening, diagnosis and treatment services, shall not be covered for school divisions. School divisions to receive reimbursement for the screenings shall be enrolled with DMAS as clinic providers.

a. Children enrolled in managed care organizations shall receive screenings from those organizations. School divisions shall not receive reimbursement for screenings from DMAS for these children.

b. School-based services are listed in a recipient's individualized education program (IEP) and covered under one or more of the service categories described in § 1905(a) of the Social Security Act. These services are necessary to correct or ameliorate defects of physical or mental illnesses or conditions.

3. Service providers shall be licensed under the applicable state practice act or comparable licensing criteria by the Virginia Department of Education, and shall meet applicable qualifications under 42 CFR Part 440. Identification of defects, illnesses or conditions and services necessary to correct or ameliorate them shall be performed by practitioners qualified to make those determinations within their licensed scope of practice, either as a member of the IEP team or by a qualified practitioner outside the IEP team.

a. Service providers shall be employed by the school division or under contract to the school division.

b. Supervision of services by providers recognized in subdivision 4 of this subsection shall occur as allowed under federal regulations and consistent with Virginia law, regulations, and DMAS provider manuals.

c. The services described in subdivision 4 of this subsection shall be delivered by school providers, but may also be available in the community from other providers.

d. Services in this subsection are subject to utilization control as provided under 42 CFR Parts 455 and 456.

e. The IEP shall determine whether or not the services described in subdivision 4 of this subsection are medically necessary and that the treatment prescribed is in accordance with standards of medical practice. Medical necessity is defined as services ordered by IEP providers. The IEP providers are qualified Medicaid providers to make the medical necessity determination in accordance with their scope of practice. The services must be described as to the amount, duration and scope.

4. Covered services include:

a. Physical therapy, occupational therapy and services for individuals with speech, hearing, and language disorders, performed by, or under the direction of, providers who meet the qualifications set forth at 42 CFR 440.110. This coverage includes audiology services.

b. Skilled nursing services are covered under 42 CFR 440.60. These services are to be rendered in accordance to the licensing standards and criteria of the Virginia Board of Nursing. Nursing services are to be provided by licensed registered nurses or licensed practical nurses but may be delegated by licensed registered nurses in accordance with the regulations of the Virginia Board of Nursing, especially the section on delegation of nursing tasks and procedures. The licensed practical nurse is under the supervision of a registered nurse.

(1) The coverage of skilled nursing services shall be of a level of complexity and sophistication (based on assessment, planning, implementation and evaluation) that is consistent with skilled nursing services when performed by a licensed registered nurse or a licensed practical nurse. These skilled nursing services shall include, but not necessarily be limited to dressing changes, maintaining patent airways, medication administration/monitoring and urinary catheterizations.

(2) Skilled nursing services shall be directly and specifically related to an active, written plan of care developed by a registered nurse that is based on a written order from a physician, physician assistant or nurse practitioner for skilled nursing services. This order shall be recertified on an annual basis.

c. Psychiatric and psychological services performed by licensed practitioners within the scope of practice are defined under state law or regulations and covered as physicians' services under 42 CFR 440.50 or medical or other remedial care under 42 CFR 440.60. These outpatient services include individual medical psychotherapy, group medical psychotherapy coverage, and family medical psychotherapy. Psychological and neuropsychological testing are allowed when done for purposes other than educational diagnosis, school admission, evaluation of an individual with intellectual disability prior to admission to a nursing facility, or any placement issue. These services are covered in the nonschool settings also. School providers who may render these services when licensed by the state include psychiatrists, licensed clinical psychologists, school psychologists, licensed clinical social workers, professional counselors, psychiatric clinical nurse specialist, marriage and family therapists, and school social workers.

d. Personal care services are covered under 42 CFR 440.167 and performed by persons qualified under this subsection. The personal care assistant is supervised by a DMAS recognized school-based health professional who is acting within the scope of licensure. This practitioner develops a written plan for meeting the needs of the child, which is implemented by the assistant. The assistant must have qualifications comparable to those for other personal care aides recognized by the Virginia Department of Medical Assistance Services. The assistant performs services such as assisting with toileting, ambulation, and eating. The assistant may serve as an aide on a specially adapted school vehicle that enables transportation to or from the school or school contracted provider on days when the student is receiving a Medicaid-covered service under the IEP. Children requiring an aide during transportation on a specially adapted vehicle shall have this stated in the IEP.

e. Medical evaluation services are covered as physicians' services under 42 CFR 440.50 or as medical or other remedial care under 42 CFR 440.60. Persons performing these services shall be licensed physicians, physician assistants, or nurse practitioners. These practitioners shall identify the nature or extent of a child's medical or other health related condition.

f. Transportation is covered as allowed under 42 CFR 431.53 and described at State Plan Attachment 3.1-D. Transportation shall be rendered only by school division personnel or contractors. Transportation is covered for a child who requires transportation on a specially adapted school vehicle that enables transportation to or from the school or school contracted provider on days when the student is receiving a Medicaid-covered service under the IEP. Transportation shall be listed in the child's IEP. Children requiring an aide during transportation on a specially adapted vehicle shall have this stated in the IEP.

g. Assessments are covered as necessary to assess or reassess the need for medical services in a child's IEP and shall be performed by any of the above licensed practitioners within the scope of practice. Assessments

and reassessments not tied to medical needs of the child shall not be covered.

5. DMAS will ensure through quality management review that duplication of services will be monitored. School divisions have a responsibility to ensure that if a child is receiving additional therapy outside of the school, that there will be coordination of services to avoid duplication of service.

D. Family planning services and supplies for individuals of child-bearing age.

1. Service must be ordered or prescribed and directed or performed within the scope of the license of a practitioner of the healing arts.

2. Family planning services shall be defined as those services that delay or prevent pregnancy. Coverage of such services shall not include services to treat infertility ~~nor~~ or services to promote fertility. Family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage, or make direct referrals for abortions.

3. Family planning services as established by § 1905(a)(4)(C) of the Social Security Act include annual family planning exams; cervical cancer screening for women; sexually transmitted infection (STI) testing; lab services for family planning and STI testing; family planning education, counseling, and preconception health; sterilization procedures; nonemergency transportation to a family planning service; and U.S. Food and Drug Administration approved prescription and over-the-counter contraceptives, subject to limits in 12VAC30-50-210.

Part I

~~Family Planning Waiver~~ (Repealed)

12VAC30-135-10. ~~Definitions.~~ (Repealed.)

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

~~"Creditable health coverage" means "creditable coverage" as defined under § 2701(c) of the Public Health Service Act (42 USC § 300gg(c)) and includes coverage that meets the requirements of § 2103 provided to a targeted low income child under Title XXI of the Social Security Act or under a waiver approved under § 2105(c)(2)(B) (relating to a direct service waiver).~~

~~"Family planning" means those services necessary to prevent or delay a pregnancy. It shall not include services to promote pregnancy such as infertility treatments. Family planning does not include counseling about, recommendations for or performance of abortions, or hysterectomies or procedures performed for medical reasons such as removal of intrauterine devices due to infections.~~

~~"FAMIS" means the Family Access to Medical Insurance Security Plan described in 12VAC30-141.~~

~~"Over-the-counter" means drugs and contraceptives that are available for purchase without requiring a physician's prescription.~~

~~"Third party" means any individual entity or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under the State Plan for Medical Assistance.~~

12VAC30-135-20. ~~Administration and eligibility determination.~~ (Repealed.)

~~A. The Department of Medical Assistance Services shall administer the family planning demonstration waiver services program under the authority of § 1115(a) of the Social Security Act and 42 USC § 1315.~~

~~B. Local departments of social services or a department contractor shall be responsible for determining eligibility of and for enrolling eligible individuals in the family planning waiver. Local departments of social services or a department contractor shall conduct periodic reviews and redeterminations of eligibility at least every 12 months while recipients are enrolled in the family planning waiver.~~

12VAC30-135-30. ~~Eligibility.~~ (Repealed.)

~~A. To be eligible under the family planning waiver, an individual must meet the eligibility conditions and requirements found in 12VAC30-40-10, have family income less than or equal to 133% of the federal poverty level, not have creditable health coverage, and not be eligible for enrollment in a Medicaid full benefit coverage group or FAMIS.~~

~~B. Individuals who have received a sterilization procedure or hysterectomy are ineligible under the waiver.~~

~~C. Individuals enrolled in the family planning waiver will not be retroactively eligible.~~

~~D. A recipient's enrollment in the family planning waiver shall be terminated if the individual receives a sterilization procedure or hysterectomy or is found to be ineligible as the result of a reported change or annual redetermination. The recipient's enrollment in the family planning waiver also shall be terminated if a reported change or annual redetermination results in eligibility for Virginia Medicaid in a full benefit coverage group or eligibility for FAMIS. A 10-day advance notice must be provided prior to cancellation of coverage under the family planning waiver unless the individual becomes eligible for a full benefit Medicaid covered group or FAMIS.~~

12VAC30-135-40. ~~Covered services.~~ (Repealed.)

~~A. Services provided under the family planning waiver are limited to:~~

~~1. Family planning office visits including annual gynecological or physical exams (one per 12 months), sexually transmitted diseases (STD) testing, cervical cancer screening tests (limited to one every six months);~~

~~2. Laboratory services for family planning and STD testing;~~

~~3. Family planning education and counseling;~~

~~4. Contraceptives approved by the Food and Drug Administration, including diaphragms, contraceptive injectables, and contraceptive implants;~~

~~5. Over the counter contraceptives; and~~

~~6. Sterilizations, not to include hysterectomies.~~

~~B. Services not covered under the family planning waiver include, but are not limited to:~~

~~1. Performance of, counseling for, or recommendations of abortions;~~

~~2. Infertility treatments;~~

~~3. Procedures performed for medical reasons;~~

~~4. Performance of a hysterectomy; and~~

~~5. Transportation to a family planning service.~~

12VAC30-135-50. ~~Provider qualifications.~~ (Repealed.)

~~Services provided under this waiver must be ordered or prescribed and directed or performed within the scope of the licensed practitioner. Any appropriately licensed Medicaid enrolled physician, nurse practitioner, or medical clinic may provide services under this waiver.~~

12VAC30-135-60. ~~Quality assurance.~~ (Repealed.)

~~The Department of Medical Assistance Services shall provide for continuing review and evaluation of the care and services paid by Medicaid under this waiver. To ensure a thorough review, trained professionals shall review cases either through desk audit or through on-site reviews of medical records. Providers shall be required to refund payments made by Medicaid if they are found to have billed Medicaid for services not covered under this waiver, if records or documentation supporting claims are not maintained, or if bills are submitted for medically unnecessary services.~~

12VAC30-135-70. ~~Reimbursement.~~ (Repealed.)

~~A. Providers will be reimbursed on a fee-for-service basis.~~

~~B. All reasonable measures including those measures specified under 42 USC § 1396 (a) (25) will be taken to ascertain the legal liability of third parties to pay for authorized care and services provided to eligible recipients.~~

~~C. A completed sterilization consent form, in accordance with the requirements of 42 CFR Part 441, Subpart F, must be submitted with all claims for payment for sterilization procedures.~~

12VAC30-135-80. ~~Recipients' rights and right to appeal.~~ (Repealed.)

~~Individuals found eligible for and enrolled in the family planning waiver shall have freedom of choice of providers. Individuals will be free from coercion or mental pressure and shall be free to choose their preferred methods of family planning. The client appeals process at 12VAC30-110 shall be applicable to applicants for and recipients of family planning services under this waiver.~~

12VAC30-135-90. ~~Sunset provision.~~ (Repealed.)

~~Consistent with federal requirements applicable to this § 1115 demonstration waiver, these regulations shall expire effective with the termination of the federally approved waiver.~~

VA.R. Doc. No. R15-2866; Filed June 3, 2016, 2:55 p.m.

Final Regulation

Titles of Regulations: **12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-226).**

12VAC30-60. Standards Established and Methods Used to Assure High Quality Care (amending 12VAC30-60-143).

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

Effective Date: July 27, 2016.

Agency Contact: Emily McClellan, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Richmond, VA 23219, telephone (803) 371-4300, or email emily.mcclellan@dmas.virginia.gov.

Summary:

The amendments (i) change the service's name from "mental health support services" to "mental health skill-building services"; (ii) increase the annual limits; (iii) prohibit overlap with similar services; (iv) reduce the number of hours of services that may be provided in an assisted living facility and Level A or Level B group home; and (v) require that providers communicate important information to other health care professionals who are providing care to the same individuals; and (vii) require service authorization for crisis intervention and crisis stabilization services.

Changes made to the final regulation after publication of the proposed include (i) removing the reference to service authorization for crisis services; (ii) clarifying the timeliness requirements in the crisis intervention and crisis stabilization registration process; (ii) changing the provider requirements for developing the individualized service plan; (iii) adjusting the mental health skill-building services (MHSS) annual maximum number of units allowed to match the new daily and weekly service limits and to conform to the unit values defined in 12VAC30-60-143; (iv) replacing the 15-minute unit values and respective maximum allowances with maximum limitations that match the MHSS unit values defined in 12VAC30-50-226.

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

12VAC30-50-226. Community mental health services.

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

"Activities of daily living" or "ADLs" means personal care tasks such as bathing, dressing, toileting, transferring, and eating or feeding. An individual's degree of independence in performing these activities is a part of determining appropriate level of care and service needs.

"Affiliated" means any entity or property in which a provider or facility has a direct or indirect ownership interest of 5.0% or more, or any management, partnership, or control of an entity.

"Behavioral health services administrator" or "BHSA" means an entity that manages or directs a behavioral health benefits program under contract with DMAS. DMAS' designated BHSA shall be authorized to constitute, oversee, enroll, and train a provider network; perform service authorization; adjudicate claims; process claims; gather and maintain data; reimburse providers; perform quality assessment and improvement; conduct member outreach and education; resolve member and provider issues; and perform utilization management including care coordination for the provision of Medicaid-covered behavioral health services. Such authority shall include entering into or terminating contracts with providers in accordance with DMAS authority pursuant to 42 CFR Part 1002 and § 32.1-325 D and E of the Code of Virginia. DMAS shall retain authority for and oversight of the BHSA entity or entities.

"Certified prescreener" means an employee of either the local community services board/behavioral health authority or its designee who is skilled in the assessment and treatment of mental illness and who has completed a certification program approved by DBHDS.

"Clinical experience" means ~~practical experience in providing direct services on a full-time basis (or the equivalent part-time experience as determined by DBHDS in the document entitled Human Services and Related Fields Approved Degrees/Experience, issued March 12,2013, revised May 3, 2013) to individuals with medically documented diagnoses of mental illness or intellectual/developmental disability or the provision of direct geriatric services or full-time (or the equivalent part-time experience) special education services~~, for the purpose of rendering (i) mental health day treatment/partial hospitalization, (ii) intensive community treatment, (iii) psychosocial rehabilitation, (iv) mental health ~~support~~ skill building, (v) crisis stabilization, or (vi) crisis intervention services, practical experience in providing direct services to individuals with diagnoses of mental illness or intellectual disability or the provision of direct geriatric services or special education services. Experience shall include supervised internships, supervised practicums, or supervised field experience. Experience shall not include unsupervised internships, unsupervised practicums, and unsupervised field experience. ~~This required clinical experience shall be calculated as set forth in DBHDS document entitled Human Services and Related Fields Approved Degrees/Experience, issued March 12, 2013, revised May 3, 2013.~~ The equivalency of part-time hours to full-time hours for the purpose of this requirement shall be established by DBHDS in the document titled Human Services and Related Fields Approved Degrees/Experience, issued March 12, 2013, revised May 3, 2013.

"Code" means the Code of Virginia.

"DBHDS" means the Department of Behavioral Health and Developmental Services consistent with Chapter 3 (§ 37.2-300 et seq.) of Title 37.2 of the Code of Virginia.

"DMAS" means the Department of Medical Assistance Services and its contractor or contractors consistent with Chapter 10 (§ 32.1-323 et seq.) of Title 32.1 of the Code of Virginia.

[~~"DSM-IV-TR" means the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision, copyright 2000, American Psychiatric Association.~~]

"DSM-5" means the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, copyright 2013, American Psychiatric Association.

"Human services field" means the same as the term is defined by DBHDS in the guidance document entitled Human Services and Related Fields Approved Degrees/Experience, issued March 12, 2013, revised May 3, 2013.

[~~"Instrumental activities of daily living skills" or "IADLS" means tasks such as meal preparation, shopping, housekeeping, and laundry. An individual's degree of independence in performing these activities is a part of determining appropriate level of care and service needs.~~]

"Individual" means the patient, client, or recipient of services described in this section.

"Individual service plan" or "ISP" means a comprehensive and regularly updated treatment plan specific to the individual's unique treatment needs as identified in the ~~clinical assessment~~ service-specific provider intake. The ISP contains ~~his~~, but is not limited to, the individual's treatment or training needs, ~~his~~ the individual's goals and measurable objectives to meet the identified needs, services to be provided with the recommended frequency to accomplish the measurable goals and objectives, the estimated timetable for achieving the goals and objectives, and an individualized discharge plan that describes transition to other appropriate services. The individual shall be included in the development of the ISP and the ISP shall be signed by the individual. If the individual is a minor child, the ISP shall also be signed by the individual's parent/legal guardian. Documentation shall be provided if the individual, who is a minor child or an adult who lacks legal capacity, is unable or unwilling to sign the ISP.

"Individualized training" means [~~training~~ instruction and practice] in functional skills and appropriate behavior related to the individual's health and safety, instrumental activities of daily living skills, and use of community resources; assistance with medical management; and monitoring health, nutrition, and physical condition. The training shall be [rehabilitative and] based on a variety of [incremental (or cumulative)] approaches or tools to organize and guide the individual's life planning and shall [~~be rooted in~~ reflect] what is important to the individual [~~while taking into account~~ in addition to] all other factors that affect his [~~life~~ functioning], including effects of the disability and issues of health and safety.

"Licensed mental health professional" or "LMHP" means ~~a licensed physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, licensed substance abuse treatment practitioner, licensed marriage and family therapist, or certified psychiatric clinical nurse specialist~~ the same as defined in 12VAC35-105-20.

"LMHP-resident" or "LMHP-R" means the same as "resident" as defined in (i) 18VAC115-20-10 for licensed professional counselors; (ii) 18VAC115-50-10 for licensed marriage and family therapists; or (iii) 18VAC115-60-10 for licensed substance abuse treatment practitioners. An LMHP-resident shall be in continuous compliance with the regulatory requirements of the applicable counseling profession for supervised practice and shall not perform the functions of the LMHP-R or be considered a "resident" until the supervision for specific clinical duties at a specific site has been preapproved in writing by the Virginia Board of Counseling. For purposes of Medicaid reimbursement to their supervisors for services provided by such residents, they shall use the title "Resident" in connection with the applicable profession after their signatures to indicate such status.

"LMHP-resident in psychology" or "LMHP-RP" means the same as an individual in a residency, as that term is defined in 18VAC125-20-10, program for clinical psychologists. An LMHP-resident in psychology shall be in continuous compliance with the regulatory requirements for supervised experience as found in 18VAC125-20-65 and shall not perform the functions of the LMHP-RP or be considered a "resident" until the supervision for specific clinical duties at a specific site has been preapproved in writing by the Virginia Board of Psychology. For purposes of Medicaid reimbursement by supervisors for services provided by such residents, they shall use the title "Resident in Psychology" after their signatures to indicate such status.

"LMHP-supervisee in social work," "LMHP-supervisee," or "LMHP-S" means the same as "supervisee" is defined in 18VAC140-20-10 for licensed clinical social workers. An LMHP-supervisee in social work shall be in continuous compliance with the regulatory requirements for supervised practice as found in 18VAC140-20-50 and shall not perform the functions of the LMHP-S or be considered a "supervisee" until the supervision for specific clinical duties at a specific site is preapproved in writing by the Virginia Board of Social Work. For purposes of Medicaid reimbursement to their supervisors for services provided by supervisees, these persons shall use the title "Supervisee in Social Work" after their signatures to indicate such status.

"Qualified mental health professional-adult" or "QMHP-A" means the same as defined in 12VAC35-105-20.

"Qualified mental health professional-child" or "QMHP-C" means the same as defined in 12VAC35-105-20.

"Qualified mental health professional-eligible" or "QMHP-E" means the same as defined in 12VAC35-105-20.

"Qualified paraprofessional in mental health" or "QPPMH" means the same as defined in 12VAC35-105-20.

"Register" or "registration" means notifying DMAS or its contractor that an individual will be receiving services that do not require service authorization.

"Review of ISP" means that the provider evaluates and updates the individual's progress toward meeting the individualized service plan objectives and documents the outcome of this review. For DMAS to determine that these reviews are satisfactory and complete, the reviews shall (i) update the goals, objectives, and strategies of the ISP to reflect any change in the individual's progress and treatment needs as well as any newly identified problems; (ii) be conducted in a manner that enables the individual to participate in the process; and (iii) be documented in the individual's medical record no later than 15 calendar days from the date of the review.

"Service authorization" means the process to approve specific services for an enrolled Medicaid, FAMIS Plus, or FAMIS individual by a DMAS service authorization contractor prior to service delivery and reimbursement in order to validate that the service requested is medically necessary and meets DMAS and DMAS contractor criteria for reimbursement. Service authorization does not guarantee payment for the service.

"Service-specific provider intake" means the same as defined in 12VAC30-50-130 and also includes individuals who are older than 21 years of age.

B. Mental health services. The following services, with their definitions, shall be covered: day treatment/partial hospitalization, psychosocial rehabilitation, crisis services, intensive community treatment (ICT), and mental health ~~supports~~ skill building. Staff travel time shall not be included in billable time for reimbursement. [~~1.~~] These services, in order to be covered, shall meet medical necessity criteria based upon diagnoses made by LMHPs who are practicing within the scope of their licenses and are reflected in provider records and on providers' claims for services by recognized diagnosis codes that support and are consistent with the requested professional services. [~~2.~~] These services are intended to be delivered in a person-centered manner. The

individuals who are receiving these services shall be included in all service planning activities. All services which do not require service authorization require registration. This registration shall transmit [service-specific information] to DMAS or its contractor [~~(i) the individual's name and Medicaid identification number; (ii) the specific service to be provided, the relevant procedure code and begin date of the service; and (iii) the provider's name and NPI, a provider contact name and phone number, and email address~~ in accordance with service authorization requirements].

[~~3.~~ 1.] Day treatment/partial hospitalization services shall be provided in sessions of two or more consecutive hours per day, which may be scheduled multiple times per week, to groups of individuals in a nonresidential setting. These services, limited annually to 780 units, include the major diagnostic, medical, psychiatric, psychosocial, and psychoeducational treatment modalities designed for individuals who require coordinated, intensive, comprehensive, and multidisciplinary treatment but who do not require inpatient treatment. One unit of service shall be defined as a minimum of two but less than four hours on a given day. Two units of service shall be defined as at least four but less than seven hours in a given day. Three units of service shall be defined as seven or more hours in a given day. Authorization is required for Medicaid reimbursement.

a. Day treatment/partial hospitalization services shall be time limited interventions that are more intensive than outpatient services and are required to stabilize an individual's psychiatric condition. The services are delivered when the individual is at risk of psychiatric hospitalization or is transitioning from a psychiatric hospitalization to the community. [The service-specific provider intake, as defined at 12VAC30-50-130, shall document the individual's behavior and describe how the individual is at risk of psychiatric hospitalization or is transitioning from a psychiatric hospitalization to the community.]

b. Individuals qualifying for this service must demonstrate a clinical necessity for the service arising from mental, behavioral, or emotional illness that results in significant functional impairments in major life activities. Individuals must meet at least two of the following criteria on a continuing or intermittent basis:

(1) Experience difficulty in establishing or maintaining normal interpersonal relationships to such a degree that they are at risk of hospitalization or homelessness or isolation from social supports;

(2) Experience difficulty in activities of daily living such as maintaining personal hygiene, preparing food and maintaining adequate nutrition, or managing finances to such a degree that health or safety is jeopardized;

(3) Exhibit such inappropriate behavior that the individual requires repeated interventions or monitoring by the mental health, social services, or judicial system that have been documented; or

(4) Exhibit difficulty in cognitive ability such that they are unable to recognize personal danger or recognize significantly inappropriate social behavior.

c. Individuals shall be discharged from this service when they are no longer in an acute psychiatric state and other less intensive services may achieve psychiatric stabilization.

d. Admission and services for time periods longer than 90 calendar days must be authorized based upon a face-to-face evaluation by a physician, psychiatrist, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, or psychiatric clinical nurse specialist.

e. These services may only be rendered by [~~either~~] an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, QMHP-A, QMHP-C, QMHP-E, or a QPPMH.

[~~4.~~ 2.] Psychosocial rehabilitation shall be provided at least two or more hours per day to groups of individuals in a nonresidential setting. These services, limited annually to 936 units, include assessment, education to teach the patient about the diagnosed mental illness and appropriate medications to avoid complication and relapse, opportunities to learn and use independent living skills and to enhance social and interpersonal skills within a supportive and normalizing program structure and environment. One unit of service is defined as a minimum of two but less than four hours on a given day. Two units are defined as at least four but less than seven hours in a given day. Three units of service shall be defined as seven or more hours in a given day. Authorization is required for Medicaid reimbursement. The service-specific provider intake, as defined at 12VAC30-50-130, shall document the individual's behavior and describe how the individual meets criteria for this service.

a. Individuals qualifying for this service must demonstrate a clinical necessity for the service arising from mental, behavioral, or emotional illness that results in significant functional impairments in major life activities. Services are provided to individuals: (i) who without these services would be unable to remain in the community or (ii) who meet at least two of the following criteria on a continuing or intermittent basis:

(1) Experience difficulty in establishing or maintaining normal interpersonal relationships to such a degree that they are at risk of psychiatric hospitalization, homelessness, or isolation from social supports;

(2) Experience difficulty in activities of daily living such as maintaining personal hygiene, preparing food and maintaining adequate nutrition, or managing finances to such a degree that health or safety is jeopardized;

(3) Exhibit such inappropriate behavior that repeated interventions documented by the mental health, social services, or judicial system are or have been necessary; or

(4) Exhibit difficulty in cognitive ability such that they are unable to recognize personal danger or significantly inappropriate social behavior.

b. These services may only be rendered by [~~either~~] an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, QMHP-A, QMHP-C, QMHP-E, or a QPPMH.

[~~5.~~ 3.] Crisis intervention shall provide immediate mental health care, available 24 hours a day, seven days per week, to assist individuals who are experiencing acute psychiatric dysfunction requiring immediate clinical attention. This service's objectives shall be to prevent exacerbation of a condition, to prevent injury to the client or others, and to provide treatment in the context of the least restrictive setting. Crisis intervention activities shall include assessing the crisis situation, providing short-term counseling designed to stabilize the individual, providing access to further immediate assessment and follow-up, and linking the individual and family with ongoing care to prevent future crises. Crisis intervention services may include office visits, home visits, preadmission screenings, telephone contacts, and other client-related activities for the prevention of institutionalization. The service-specific provider intake, as defined at 12VAC30-50-130, shall document the individual's behavior and describe how the individual meets criteria for this service. The provision of this service to an individual shall be registered with either DMAS [, DMAS contractors,] or the BHSA within one business day or the completion of the service-specific provider intake to avoid duplication of services and to ensure informed care coordination. [~~Authorization shall be required for Medicaid reimbursement.~~]

a. Individuals qualifying for this service must demonstrate a clinical necessity for the service arising from an acute crisis of a psychiatric nature that puts the individual at risk of psychiatric hospitalization. Individuals must meet at least two of the following criteria at the time of admission to the service:

(1) Experience difficulty in establishing or maintaining normal interpersonal relationships to such a degree that they are at risk of psychiatric hospitalization, homelessness, or isolation from social supports;

(2) Experience difficulty in activities of daily living such as maintaining personal hygiene, preparing food and maintaining adequate nutrition, or managing finances to such a degree that health or safety is jeopardized;

(3) Exhibit such inappropriate behavior that immediate interventions documented by mental health, social services, or the judicial system are or have been necessary; or

(4) Exhibit difficulty in cognitive ability such that they are unable to recognize personal danger or significantly inappropriate social behavior.

b. The annual limit for crisis intervention is 720 units per year. A unit shall equal 15 minutes.

c. These services may only be rendered by an LMHP, an LMHP-supervisee, LMHP-resident, LMHP-RP, or a certified prescreener.

[~~6.~~ 4.] Intensive community treatment (ICT), initially covered for a maximum of 26 weeks based on an initial service-specific provider intake and may be reauthorized for up to an additional 26 weeks annually based on written intake and certification of need by a licensed mental health provider (LMHP), shall be defined by 12VAC35-105-20 or LMHP-S, LMHP-R, and LMHP-RP and shall include medical psychotherapy, psychiatric assessment, medication management, and care coordination activities offered to outpatients outside the clinic, hospital, or office setting for individuals who are best served in the community. Authorization is required for Medicaid reimbursement.

a. To qualify for ICT, the individual must meet at least one of the following criteria:

(1) The individual must be at high risk for psychiatric hospitalization or becoming or remaining homeless due to mental illness or require intervention by the mental health or criminal justice system due to inappropriate social behavior.

(2) The individual has a history (three months or more) of a need for intensive mental health treatment or treatment for co-occurring serious mental illness and substance use disorder and demonstrates a resistance to seek out and utilize appropriate treatment options.

b. A written, service-specific provider intake, as defined at 12VAC30-50-130, that documents the individual's eligibility and the need for this service must be completed prior to the initiation of services. This intake must be maintained in the individual's records.

c. An individual service plan shall be initiated at the time of admission and must be fully developed, as defined in this section, within 30 days of the initiation of services.

d. The annual unit limit shall be 130 units with a unit equaling one hour.

e. These services may only be rendered by a team that meets the requirements of 12VAC35-105-1370.

[~~7.~~ 5.] Crisis stabilization services for nonhospitalized individuals shall provide direct mental health care to individuals experiencing an acute psychiatric crisis which may jeopardize their current community living situation. [~~Authorization shall be required for Medicaid reimbursement.~~] Services may be [~~authorized~~ provided] for up to a 15-day period per crisis episode following a face-to-face service-specific provider intake by an LMHP, LMHP-supervisee, LMHP-resident, or LMHP-RP. Only

one unit of service shall be reimbursed for this intake. The provision of this service to an individual shall be registered with either DMAS [, DMAS contractors,] or the BHSA within one [~~calendar~~ business] day of the completion of the service-specific provider intake to avoid duplication of services and to ensure informed care coordination. [~~See 12VAC30-50-226-B for registration requirements.~~]

a. The goals of crisis stabilization programs shall be to avert hospitalization or rehospitalization, provide normative environments with a high assurance of safety and security for crisis intervention, stabilize individuals in psychiatric crisis, and mobilize the resources of the community support system and family members and others for on-going maintenance and rehabilitation. The services must be documented in the individual's records as having been provided consistent with the ISP in order to receive Medicaid reimbursement.

b. The crisis stabilization program shall provide to individuals, as appropriate, psychiatric assessment including medication evaluation, treatment planning, symptom and behavior management, and individual and group counseling.

c. This service may be provided in any of the following settings, but shall not be limited to: (i) the home of an individual who lives with family or other primary caregiver; (ii) the home of an individual who lives independently; or (iii) community-based programs licensed by DBHDS to provide residential services but which are not institutions for mental disease (IMDs).

d. This service shall not be reimbursed for (i) individuals with medical conditions that require hospital care; (ii) individuals with primary diagnosis of substance abuse; or (iii) individuals with psychiatric conditions that cannot be managed in the community (i.e., individuals who are of imminent danger to themselves or others).

e. The maximum limit on this service is 60 days annually.

f. Services must be documented through daily progress notes and a daily log of times spent in the delivery of services. The service-specific provider intake, as defined at 12VAC30-50-130, shall document the individual's behavior and describe how the individual meets criteria for this service. Individuals qualifying for this service must demonstrate a clinical necessity for the service arising from an acute crisis of a psychiatric nature that puts the individual at risk of psychiatric hospitalization. Individuals must meet at least two of the following criteria at the time of admission to the service:

(1) Experience difficulty in establishing and maintaining normal interpersonal relationships to such a degree that the individual is at risk of psychiatric hospitalization, homelessness, or isolation from social supports;

(2) Experience difficulty in activities of daily living such as maintaining personal hygiene, preparing food and maintaining adequate nutrition, or managing finances to such a degree that health or safety is jeopardized;

(3) Exhibit such inappropriate behavior that immediate interventions documented by the mental health, social services, or judicial system are or have been necessary; or

(4) Exhibit difficulty in cognitive ability such that the individual is unable to recognize personal danger or significantly inappropriate social behavior.

g. These services may only be rendered by an LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, QMHP-A, QMHP-C, QMHP-E or a certified prescreener.

[~~8.~~ 6.] Mental health ~~support~~ skill-building services (MHSS) shall be defined as goal-directed training ~~and supports~~ to enable individuals to achieve and maintain community stability and independence in the most appropriate, least restrictive environment. Authorization is required for Medicaid reimbursement. Services that are rendered before the date of service authorization shall not be reimbursed. These services may be authorized up to six consecutive months as long as the individual meets the coverage criteria for this service. The service-specific provider intake, as defined at 12VAC30-50-130, shall document the individual's behavior and describe how the individual meets criteria for this service. ~~This program~~ These services shall provide goal-directed training in the following ~~services~~ areas in order to be reimbursed by Medicaid or the BHSA: ~~training in or reinforcement of~~ (i) functional skills and appropriate behavior related to the individual's health and safety, instrumental activities of daily living, and use of community resources; (ii) assistance with medication management; and (iii) monitoring of health, nutrition, and physical condition with goals towards self-monitoring and self-regulation of all of these activities. Providers shall be reimbursed only for training activities defined in the ISP and only where services meet the service definition, eligibility, and service provision criteria and this section. [~~Service-specific provider intakes~~ A review of MHSS services by an LMHP, LMHP-R, LMHP-RP, or LMHP-S] shall be repeated for all individuals who have received at least six months of MHSS to determine the continued need for this service.

a. Individuals qualifying for this service ~~must~~ shall demonstrate a clinical necessity for the service arising from a condition due to mental, behavioral, or emotional illness that results in significant functional impairments in major life activities. ~~Services are provided to individuals who without these services would be unable to remain in the community. The individual must meet at least two of the following criteria on a continuing or intermittent basis:~~ Services are provided to individuals who require individualized goal-directed training in order

to achieve or maintain stability and independence in the community.

~~(1) Have difficulty in establishing or maintaining normal interpersonal relationships to such a degree that the individual is at risk of psychiatric hospitalization or homelessness or isolation from social supports;~~

~~(2) Require help in basic living skills such as maintaining personal hygiene, preparing food and maintaining adequate nutrition or managing finances to such a degree that health or safety is jeopardized~~;

~~(3) Exhibit such inappropriate behavior that repeated interventions documented by the mental health, social services, or judicial system are or have been necessary; or~~

~~(4) Exhibit difficulty in cognitive ability such that they are unable to recognize personal danger or recognize significantly inappropriate social behavior.~~

b. ~~The individual must demonstrate functional impairments in major life activities. This may include individuals with a dual diagnosis of either mental illness and intellectual disability, or mental illness and substance abuse disorder.~~ Individuals ages 21 and older shall meet all of the following criteria in order to be eligible to receive mental health skill-building services:

(1) The individual shall have one of the following as a primary mental health diagnosis:

(a) Schizophrenia or other psychotic disorder as set out in the [~~DSM-IV-TR or~~] DSM-5;

(b) Major depressive disorder;

(c) Recurrent Bipolar I or Bipolar II; or

(d) Any other serious mental health disorder that a physician has documented specific to the identified individual within the past year and that includes all of the following: (i) is a serious mental illness; (ii) results in severe and recurrent disability; (iii) produces functional limitations in the individual's major life activities that are documented in the individual's medical record; and (iv) requires individualized training for the individual in order to achieve or maintain independent living in the community.

(2) The individual shall require individualized goal-directed training in order to acquire or maintain self-regulation of basic living skills, such as symptom management; adherence to psychiatric and physical health medication treatment plans; appropriate use of social skills and personal support systems; skills to manage personal hygiene, food preparation, and the maintenance of personal adequate nutrition; money management; and use of community resources.

(3) The individual shall have a prior history of any of the following: (i) psychiatric hospitalization; (ii) either residential or nonresidential crisis stabilization; (iii) intensive community treatment (ICT) or program of assertive community treatment (PACT) services; (iv) placement in a psychiatric residential treatment facility (RTC-Level C) as a result of decompensation related to the individual's serious mental illness; or (v) a temporary detention order (TDO) evaluation, pursuant to § 37.2-809 B of the Code of Virginia. This criterion shall be met in order to be initially admitted to services and not for subsequent authorizations of service. Discharge summaries from prior providers that clearly indicate (i) the type of treatment provided, (ii) the dates of the treatment previously provided, and (iii) the name of the treatment provider shall be sufficient to meet this requirement. Family member statements shall not suffice to meet this requirement.

(4) The individual shall have had a prescription for antipsychotic, mood stabilizing, or antidepressant medications within the 12 months prior to the service-specific provider intake date. If a physician or other practitioner who is authorized by his license to prescribe medications indicates that antipsychotic, mood stabilizing, or antidepressant medications are medically contraindicated for the individual, the provider shall obtain medical records signed by the physician or other licensed prescriber detailing the contraindication. This documentation shall be maintained in the individual's mental health skill-building services record, and the provider shall document and describe how the individual will be able to actively participate in and benefit from services without the assistance of medication. This criterion shall be met upon admission to services and shall not be required for subsequent authorizations of service. Discharge summaries from prior providers that clearly indicate (i) the type of treatment provided, (ii) the dates of the treatment previously provided, and (iii) the name of the treatment provider shall be sufficient to meet this requirement. Family member statements shall not suffice to meet this requirement.

c. Individuals [~~younger than~~ aged 18 to] 21 years [~~of age~~] shall meet all of the following criteria in order to be eligible to receive mental health skill-building services:

(1) The individual [~~, aged 16 years up to 21 years.~~] shall not be living in a supervised setting [~~(such as a foster home, group home, or other paid placement) and is providing for his own financial support or such an individual shall be actively transitioning into an independent living situation that is not a supervised setting (such as a foster home, group home, or other paid placement) and is providing for his own financial support~~ as described in § 63.2-905.1 of the Code of Virginia]. If the individual is transitioning into an independent living situation, MHSS shall only be authorized for up to six months prior to the date of transition;

(2) The individual shall have at least one of the following as a primary mental health diagnosis [~~:~~.]

(a) Schizophrenia or other psychotic disorder as set out in the [~~DSM–IV-TR or~~] DSM-5;

(b) Major depressive disorder;

(c) Recurrent Bipolar-I or Bipolar II; or

(d) Any other serious mental health disorder that a physician has documented specific to the identified individual within the past year and that includes all of the following: (i) is a serious mental illness or serious emotional disturbance; (ii) results in severe and recurrent disability; (iii) produces functional limitations in the individual's major life activities that are documented in the individual's medical record; and (iv) requires individualized training for the individual in order to achieve or maintain independent living in the community [~~:~~.]

(3) The individual shall require individualized goal-directed training in order to acquire or maintain self-regulation of basic living skills such as symptom management; adherence to psychiatric and physical health medication treatment plans; appropriate use of social skills and personal support systems; skills to manage personal hygiene, food preparation, and the maintenance of personal adequate nutrition; money management; and use of community resources.

(4) The individual shall have a prior history of any of the following: (i) psychiatric hospitalization; (ii) either residential or nonresidential crisis stabilization; (iii) intensive community treatment (ICT) or program of assertive community treatment (PACT) services; (iv) placement in a psychiatric residential treatment facility (RTC-Level C) as a result of decompensation related to the individual's serious mental illness; or (v) temporary detention order (TDO) evaluation pursuant to § 37.2-809 B of the Code of Virginia. This criterion shall be met in order to be initially admitted to services and not for subsequent authorizations of service. Discharge summaries from prior providers that clearly indicate (i) the type of treatment provided, (ii) the dates of the treatment previously provided, and (iii) the name of the treatment provider shall be sufficient to meet this requirement. Family member statements shall not suffice to meet this requirement.

(5) The individual shall have had a prescription for antipsychotic, mood stabilizing, or antidepressant medications, within the 12 months prior to the assessment date. If a physician or other practitioner who is authorized by his license to prescribe medications indicates that antipsychotic, mood stabilizing, or antidepressant medications are medically contraindicated for the individual, the provider shall obtain medical records signed by the physician or other licensed prescriber detailing the contraindication. This documentation of medication management shall be maintained in the individual's mental health skill-building services record. For individuals not prescribed antipsychotic, mood stabilizing, or antidepressant medications, the provider shall have documentation from the medication management physician describing how the individual will be able to actively participate in and benefit from services without the assistance of medication. This criterion shall be met in order to be initially admitted to services and not for subsequent authorizations of service. Discharge summaries from prior providers that clearly indicate (i) the type of treatment provided, (ii) the dates of the treatment previously provided, and (iii) the name of the treatment provider shall be sufficient to meet this requirement. Family member statements shall not suffice to meet this requirement.

(6) An independent clinical assessment, established in 12VAC30-130-3020, shall be completed for the individual.

~~c.~~ d. Service-specific provider intakes shall be required at the onset of services and individual service plans (ISPs) shall be required during the entire duration of services. Services based upon incomplete, missing, or outdated service-specific provider intakes or ISPs shall be denied reimbursement. Requirements for ~~provider-specific~~ service-specific provider intakes and ISPs are set out in 12VAC30-50-130.

~~d.~~ e. The yearly limit for mental health ~~support~~ skill-building services is [~~372~~ 520] units. Only direct face-to-face contacts and services to the individual shall be reimbursable. One unit is [~~at least one hour but less than three hours~~ 1 to 2.99 hours per day, two units is 3 to 4.99 hours per day].

~~e.~~ f. These services may only be rendered by an LMHP, [~~LMHP-supervisee, LMHP-resident,~~ LMHP-R, LMHP-RP, LMHP-S], QMHP-A, QMHP-C, QMHP-E, or QPPMH.

g. The provider shall clearly document details of the services provided during the entire amount of time billed.

h. The ISP shall not include activities that contradict or duplicate those in the treatment plan established by the group home or assisted living facility. The provider shall [~~attempt to~~] coordinate mental health skill-building services with the treatment plan established by the group home or assisted living facility and shall document all coordination activities in the medical record.

i. Limits and exclusions.

(1) Group home (Level A or B) and assisted living facility providers shall not serve as the mental health skill-building services provider for individuals residing in the provider's respective facility. Individuals residing in facilities may, however, receive MHSS from another

MHSS agency not affiliated with the owner of the facility in which they reside.

(2) Mental health skill-building services shall not be reimbursed for individuals who are receiving in-home residential services or congregate residential services through the Intellectual Disability Waiver or Individual and Family Developmental Disabilities Support Waiver.

(3) Mental health skill-building services shall not be reimbursed for individuals who are also receiving services under the Department of Social Services independent living program (22VAC40-151), independent living services (22VAC40-151 and 22VAC40-131), or independent living arrangement (22VAC40-131) or any Comprehensive Services Act-funded independent living skills programs.

(4) Mental health skill-building services shall not be available to individuals who are receiving treatment foster care (12VAC30-130-900 et seq.).

(5) Mental health skill-building services shall not be available to individuals who reside in intermediate care facilities for individuals with intellectual disabilities or hospitals.

(6) Mental health skill-building services shall not be available to individuals who reside in nursing facilities, except for up to 60 days prior to discharge. If the individual has not been discharged from the nursing facility during the 60-day period of services, mental health skill-building services shall be terminated and no further service authorizations shall be available to the individual unless a provider can demonstrate and document that mental health skill-building services are necessary. Such documentation shall include facts demonstrating a change in the individual's circumstances and a new plan for discharge requiring up to 60 days of mental health skill-building services.

(7) Mental health skill-building services shall not be available for residents of residential treatment centers (Level C facilities) except for the intake code H0032 (modifier U8) in the seven days immediately prior to discharge.

(8) Mental health skill-building services shall not be reimbursed if personal care services or attendant care services are being received simultaneously, unless justification is provided why this is necessary in the individual's mental health skill-building services record. Medical record documentation shall fully substantiate the need for services when personal care or attendant care services are being provided. This applies to individuals who are receiving additional services through the Intellectual Disability Waiver (12VAC30-120-1000 et seq.), Individual and Family Developmental Disabilities Support Waiver (12VAC30-120-700 et seq.), the Elderly or Disabled with Consumer Direction Waiver (12VAC30-120-900 et seq.), and EPSDT services (12VAC30-50-130).

(9) Mental health skill-building services shall not be duplicative of other services. Providers shall be required to ensure that if an individual is receiving additional therapeutic services that there will be coordination of services by either the LMHP, [~~LMHP supervisee, LMHP resident, LMHP resident in psychology~~ LMHP-R, LMHP-RP, LMHP-S], QMHP-A, QMHP-C, [~~or~~] QMHP-E [, or QPPMH] to avoid duplication of services.

(10) Individuals who have organic disorders, such as delirium, dementia, or other cognitive disorders not elsewhere classified, will be prohibited from receiving mental health skill-building services unless their physicians issue signed and dated statements indicating that the individuals can benefit from this service.

(11) Individuals who are not diagnosed with a serious mental health disorder but who have personality disorders or other mental health disorders, or both, that may lead to chronic disability shall not be excluded from the mental health skill-building services eligibility criteria provided that the individual has a primary mental health diagnosis from the list included in subdivision B [~~8~~ 6] b (1) or B [~~8~~ 6] c (2) of this section and that the provider can document and describe how the individual is expected to actively participate in and benefit from mental health skill-building services.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC30-50)

[~~Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition DSM-IV-TR, copyright 2000, American Psychiatric Association~~]

Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, DSM-5, 2013, American Psychiatric Association

Length of Stay by Diagnosis and Operation, Southern Region, 1996, HCIA, Inc.

Guidelines for Perinatal Care, 4th Edition, August 1997, American Academy of Pediatrics and the American College of Obstetricians and Gynecologists

Virginia Supplemental Drug Rebate Agreement Contract and Addenda

Office Reference Manual (Smiles for Children), prepared by DMAS' Dental Benefits Administrator, copyright 2005 (www.dmas.virginia.gov/downloads/pdfs/dental-office_reference_manual_06-09-05.pdf)

Patient Placement Criteria for the Treatment of Substance-Related Disorders ASAM PPC-2R, Second Edition, copyright 2001, American Society of Addiction Medicine

[~~Virginia Medicaid Durable Medical Equipment and Supplies Provider Manual, Appendix B (rev. 1/11), Department of Medical Assistance Services~~]

Human Services and Related Fields Approved Degrees/Experience, Department of Behavioral Health and Developmental Services (rev. 5/13)

12VAC30-60-143. Mental health services utilization criteria; definitions.

A. ~~This section sets out the utilization criteria and standards relative to the community mental health services set out in 12VAC30-50-226.~~ Definitions. The following words and terms when used in this section shall have the following meanings unless the context indicates otherwise:

["Child or adolescent" means the same as "adolescent or child" defined in 12VAC30-50-130.]

"Licensed mental health professional" or "LMHP" means the same as defined in 12VAC30-50-130.

"LMHP-resident" or "LMHP-R" means the same as defined in 12VAC30-50-130.

"LMHP-resident in psychology" or "LMHP-RP" means the same as defined in 12VAC30-50-130.

"LMHP-supervisee in social work," "LMHP-supervisee," or "LMHP-S" means the same as defined in 12VAC30-50-130.

"Qualified mental health professional-adult" or "QMHP-A" means the same as defined in 12VAC30-50-130.

"Qualified mental health professional-child" or "QMHP-C" means the same as defined in 12VAC30-50-130.

"Qualified mental health professional-eligible" or "QMHP-E" means the same as defined in [~~12VAC30-50-130~~ 12VAC35-105-20].

B. Utilization reviews shall include determinations that providers meet the following requirements:

1. The provider shall meet the federal and state requirements for administrative and financial management capacity. The provider shall obtain, prior to the delivery of services, and shall maintain and update periodically as the Department of Medical Assistance Services (DMAS) or its contractor requires, a current provider enrollment agreement for each Medicaid service that the provider offers. DMAS shall not reimburse providers who do not enter into a provider enrollment agreement for a service prior to offering that service.

2. The provider shall document and maintain individual case records in accordance with state and federal requirements.

3. The provider shall ensure eligible individuals have free choice of providers of mental health services and other medical care under the Individual Service Plan.

4. Providers shall comply with DMAS marketing requirements as set out in 12VAC30-130-2000. Providers that DMAS determines have violated these marketing requirements shall be terminated as a Medicaid provider pursuant to 12VAC30-130-2000 E. Providers whose contracts are terminated shall be afforded the right of appeal pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

5. If an individual receiving community mental health rehabilitative services is also receiving case management services pursuant to 12VAC30-50-420 or 12VAC30-50-430, the provider shall collaborate with the case manager by notifying the case manager of the provision of community mental health rehabilitative services and sending monthly updates on the individual's treatment status. A discharge summary shall be sent to the care coordinator/case manager within 30 calendar days of the discontinuation of services. Service providers and case managers who are using the same electronic health record for the individual shall meet requirements for delivery of the notification, monthly updates, and discharge summary upon entry of this documentation into the electronic health record.

6. The provider shall determine who the primary care provider is and inform him of the individual's receipt of community mental health rehabilitative services. The documentation shall include who was contacted, when the contact occurred, and what information was transmitted.

7. The provider shall include the individual and the family/caregiver, as may be appropriate, in the development of the ISP. To the extent that the individual's condition requires assistance for participation, assistance shall be provided. The ISP shall be updated annually or as the needs and progress of the individual changes. An ISP that is not updated either annually or as the treatment interventions based on the needs and progress of the individual change shall be considered outdated. An ISP that does not include all required elements specified in 12VAC30-50-226 shall be considered incomplete. All ISPs shall be completed, signed, and contemporaneously dated by the LMHP, ~~LMHP-supervisee, LMHP-resident~~, LMHP-R, LMHP-RP, [LMHP-S,] QMHP-A, QMHP-C, or QMHP-E preparing the ISP within a maximum of 30 days of the date of the completed intake unless otherwise specified. The child's or adolescent's ISP shall also be signed by the parent/legal guardian and the adult individual shall sign his own. If the individual, whether a child, adolescent, or an adult, is unwilling to sign the ISP, then the service provider shall document the clinical or other reasons why the individual was not able or willing to sign the ISP. Signatures shall be obtained unless there is a clinical reason that renders the individual unable to sign the ISP.

[(a) Every three months, the LMHP, LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-E shall review the ISP, modify the ISP as appropriate, and update the ISP, and all of these activities shall occur with the individual in a manner in which the individual may participate in the process. The ISP shall be rewritten at least annually.

(b) The goals, objectives, and strategies of the ISP shall be updated to reflect any change or changes in the individual's progress and treatment needs as well as any newly-identified problems.

(c) Documentation of ISP review shall be added to the individual's medical record no later than 15 days from the calendar date of the review as evidenced by the dated signatures of the LMHP, LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-E, and the individual.]

C. Day treatment/partial hospitalization services shall be provided following [a service-specific provider intake and be authorized by the LMHP,] ~~LMHP supervisee, LMHP resident, or~~ [LMHP-R, LMHP-RP, or LMHP-S. An ISP, as defined in 12VAC30-50-226, shall be fully completed, signed, and dated by either the LMHP,] ~~LMHP supervisee, LMHP resident,~~ [LMHP-R, LMHP-RP, LMHP-S, the QMHP-A, QMHP-E, or QMHP-C and reviewed/approved by the LMHP,] ~~LMHP supervisee, LMHP resident, or~~ [LMHP-R, LMHP-RP, or LMHP-S within 30 days of service initiation ~~a diagnostic assessment and be authorized by the physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, or licensed clinical nurse specialist psychiatric. An ISP shall be fully completed by either the LMHP or the QMHP-A or QMHP-C as defined in 12VAC35-105-20 within 30 days of service initiation~~].

1. The enrolled provider of day treatment/partial hospitalization shall be licensed by DBHDS as providers of day treatment services.

2. Services shall only be provided by an LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP, [LMHP-S,] QMHP-A, QMHP-C, QMHP-E, or a qualified paraprofessional under the supervision of a QMHP-A, QMHP-C, QMHP-E, or an LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP, [or LMHP-S] as defined at 12VAC35-105-20, except for [~~LMHP supervisee, LMSP resident, and~~ LMHP-R,] LMHP-RP, [and LMHP-S,] which are defined in 12VAC30-50-226.

3. The program shall operate a minimum of two continuous hours in a 24-hour period.

4. Individuals shall be discharged from this service when other less intensive services may achieve or maintain psychiatric stabilization.

D. Psychosocial rehabilitation services shall be provided to those individuals who have experienced long-term or repeated psychiatric hospitalization, or who experience difficulty in activities of daily living and interpersonal skills, or whose support system is limited or nonexistent, or who are unable to function in the community without intensive intervention or when long-term services are needed to maintain the individual in the community.

1. Psychosocial rehabilitation services shall be provided following a service-specific provider intake that clearly documents the need for services. This intake ~~that~~ shall be completed by either an LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP [, or LMHP-S]. An ISP shall be completed by either the LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP, [LMHP-S,] or the QMHP-A, QMHP-E, or QMHP-C and be reviewed/approved by either an LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP [, or LMHP-S] within 30 calendar days of service initiation. At least every three months, the LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] the QMHP-A, QMHP-C, or QMHP-E must review, modify as appropriate, and update the ISP.

2. Psychosocial rehabilitation services of any individual that continue more than six months shall be reviewed by an LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP [, or LMHP-S] who shall document the continued need for the service. The ISP shall be rewritten at least annually.

3. The enrolled provider of psychosocial rehabilitation services shall be licensed by DBHDS as a provider of psychosocial rehabilitation ~~or clubhouse~~ services.

4. Psychosocial rehabilitation services may be provided by an LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] QMHP-A, QMHP-C, QMHP-E, or a qualified paraprofessional under the supervision of a QMHP-A, a QMHP-C, a QMHP-E, or an LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP [, or LMHP-S].

5. The program shall operate a minimum of two continuous hours in a 24-hour period.

6. Time allocated for field trips may be used to calculate time and units if the goal is to provide training in an integrated setting, and to increase the individual's understanding or ability to access community resources.

E. ~~Crisis~~ [~~Admission to~~ Initiation of] crisis intervention services shall be indicated following a [service-specific provider intake that documents a] marked reduction in the individual's psychiatric, adaptive or behavioral functioning or an extreme increase in personal distress. [In order to receive reimbursement, providers shall register this service with DMAS, DMAS contractors, or the BHSA within one business day of the completion of the service-specific provider intake to avoid duplication of services and to ensure informed care coordination.]

1. The crisis intervention services provider shall be licensed as a provider of emergency services by DBHDS ~~pursuant to 12VAC35-105-30~~.

2. Client-related activities provided in association with a face-to-face contact are reimbursable.

3. An individual service plan (ISP) shall not be required for newly admitted individuals to receive this service. Inclusion of crisis intervention as a service on the ISP shall not be required for the service to be provided on an emergency basis.

4. For individuals receiving scheduled, short-term counseling as part of the crisis intervention service, an ISP shall be developed or revised ~~by the fourth face-to-face contact~~ to reflect the short-term counseling goals by the fourth face-to-face contact.

5. Reimbursement shall be provided for short-term crisis counseling contacts occurring within a 30-day period from the time of the first face-to-face crisis contact. Other than the annual service limits, there are no restrictions (regarding number of contacts or a given time period to be covered) for reimbursement for unscheduled crisis contacts.

6. Crisis intervention services may be provided to eligible individuals outside of the clinic and [~~billed~~ reimbursed], provided the provision of out-of-clinic services is clinically/programmatically appropriate. Travel by staff to provide out-of-clinic services shall not be reimbursable. Crisis intervention may involve contacts with the family or significant others. If other clinic services are billed at the same time as crisis intervention, documentation must clearly support the separation of the services with distinct treatment goals.

7. An LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] or a certified prescreener~~, as defined in 12VAC30-50-226,~~ shall conduct a face-to-face service-specific provider intake. The [~~assessment~~ intake] shall document the need for and the anticipated duration of the crisis service. [~~Crisis intervention will be provided by an LMHP or a certified prescreener.~~]

8. Crisis intervention shall be provided by either an LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] or a certified prescreener.

9. For an admission to a freestanding inpatient psychiatric facility for individuals younger than age 21, federal regulations (42 CFR 441.152) require certification of the admission by an independent team. The independent team must include mental health professionals, including a physician. These preadmission screenings cannot be billed unless the requirement for an independent team certification, with a physician's signature, is met.

10. Services shall be documented through daily notes and a daily log of time spent in the delivery of services.

F. Case management services pursuant to 12VAC30-50-420 (seriously mentally ill adults and emotionally disturbed children) or 12VAC30-50-430 (youth at risk of serious emotional disturbance).

1. Reimbursement shall be provided only for "active" case management clients, as defined. An active client for case management shall mean an individual for whom there is an ISP in effect that requires regular direct or client-related contacts or activity or communication with the individuals or families, significant others, service providers, and others including a minimum of one face-to-face individual contact within a 90-day period. Billing can be submitted only for months in which direct or client-related contacts, activity or communications occur.

2. The Medicaid eligible individual shall meet the DBHDS criteria of serious mental illness, serious emotional disturbance in children and adolescents, or youth at risk of serious emotional disturbance.

3. There shall be no maximum service limits for case management services. Case management shall not be billed for persons in institutions for mental disease.

4. The ISP shall document the need for case management and be fully completed within 30 calendar days of initiation of the service. The case manager shall review the ISP at least every three months. The review will be due by the last day of the third month following the month in which the last review was completed. A grace period will be granted up to the last day of the fourth month following the month of the last review. When the review was completed in a grace period, the next subsequent review shall be scheduled three months from the month the review was due and not the date of actual review.

5. The ISP shall also be updated at least annually.

6. The provider of case management services shall be licensed by DBHDS as a provider of case management services.

G. Intensive community treatment (ICT).

1. A service-specific provider intake that documents eligibility and the need for this service shall be completed by either the LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP [, or LMHP-S] prior to the initiation of services. This intake documentation shall be maintained in the individual's records. ~~Proper completion of the service specific provider intake shall comport with the requirements of 12VAC30-50-130.~~

2. An individual service plan, based on the needs as determined by the service-specific provider intake, must be initiated at the time of admission and must be fully developed by either the LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] QMHP-A, QMHP-C, or QMHP-E and approved by the LMHP, [~~LMHP supervisee, LMHP resident, or~~ LMHP-R,] LMHP-RP [, or LMHP-S] within 30 days of the initiation of services.

3. ICT may be billed if the individual is brought to the facility by ICT staff to see the psychiatrist. Documentation

must be present in the individual's record to support this intervention.

4. The enrolled ICT provider shall be licensed by the DBHDS as a provider of intensive community services or as a program of assertive community treatment, and must provide and make available emergency services 24-hours per day, seven days per week, 365 days per year, either directly or on call.

5. ICT services must be documented through a daily log of time spent in the delivery of services and a description of the activities/services provided. There must also be at least a weekly note documenting progress or lack of progress toward goals and objectives as outlined on the ISP.

H. Crisis stabilization services.

1. This service shall be [~~authorized~~ initiated] following a face-to-face service-specific provider intake by either an LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] or a certified prescreener, as defined in 12VAC30-50-226.

[2. In order to receive reimbursement, providers shall register this service with DMAS, DMAS contractors, or the BHSA within one business day of the completion of the service-specific provider intake to avoid duplication of services and to ensure informed care coordination.

~~2.~~ 3.] The service-specific provider intake must document the need for crisis stabilization services.

[~~3.~~ 4.] The Individual Service Plan (ISP) must be developed or revised within three calendar days of admission to this service. The LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] LMHP-RP, [LMHP-S,] certified prescreener, QMHP-A, QMHP-C, or QMHP-E shall develop the ISP.

[~~4.~~ 5.] Room and board, custodial care, and general supervision are not components of this service.

[~~5.~~ 6.] Clinic option services are not billable at the same time crisis stabilization services are provided with the exception of clinic visits for medication management. Medication management visits may be billed at the same time that crisis stabilization services are provided but documentation must clearly support the separation of the services with distinct treatment goals.

[~~6.~~ 7.] Individuals qualifying for this service must demonstrate a clinical necessity for the service arising from a condition due to an acute crisis of a psychiatric nature which puts the individual at risk of psychiatric hospitalization.

[~~7.~~ 8.] Providers of residential crisis stabilization shall be licensed by DBHDS as providers of ~~mental health~~ residential or nonresidential crisis stabilization services. Providers of community-based crisis stabilization shall be licensed by DBHDS as providers of mental health nonresidential crisis stabilization.

I. Mental health ~~support~~ skill-building services as defined in 12VAC30-50-226 B [~~8~~ 6]. ~~Refer to 12VAC30-50-226 for criteria, service authorization requirements, and service-specific provider intakes that shall apply for individuals in order to qualify for this service.~~

1. ~~Prior to~~ At admission, an appropriate face-to-face service-specific provider intake must be ~~completed,~~ conducted, documented, signed, and dated~~, and documented~~ by the LMHP, [~~LMHP supervisee, LMHP resident,~~ LMHP-R,] or LMHP-RP ~~indicating that service needs can best be met through mental health support services~~. Providers shall be reimbursed one unit for each intake utilizing the appropriate billing code. Service-specific provider intakes shall be repeated [~~when the individual receives six months of continual care and~~] upon any lapse in services of more than 30 calendar days. [Services of any individual that continue more than six months shall be reviewed by the LMHP, LMHP-R, LMHP-RP, or LMHP-S who shall document the continued need for the service in the individual's medical record.]

~~2. The ISP, as defined in 12VAC30-50-226, shall be completed, signed, and dated by either a LMHP, LMHP-supervisee, LMHP resident, LMHP-RP, QMHP-A, QMHP-C, or QMHP-E within 30 calendar days of service initiation, and shall indicate the specific supports and services to be provided and the goals and objectives to be accomplished. The LMHP, LMHP-supervisee, LMHP-resident, or LMHP-RP or QMHP-A, QMHP-C, or QMHP-E shall supervise the care if delivered by the qualified paraprofessional. If the care is supervised by the QMHP-A, QMHP-E, or QMHP-C, then the LMHP, LMHP-supervisee, LMHP resident, or LMHP-RP shall review and approve the supervision of the care delivered by the qualified paraprofessional.~~

~~3. Every three months, the LMHP, LMHP-supervisee, LMHP-resident, LMHP-RP, QMHP-A, QMHP-C, or QMHP-E shall review, modify as appropriate, and update the ISP showing a new signature and date of each revision. If the ISP review is conducted by the QMHP-A, QMHP-C, or QMHP-E, then it shall be reviewed/approved/signed/dated by the LMHP, LMHP-supervisee, LMHP-resident, or LMHP-RP. The ISP shall be rewritten, signed, and dated by either a QMHP-A, QMHP-C, QMHP-E, an LMHP, LMHP-supervisee, LMHP-resident, or LMHP-RP at least annually.~~

~~4. Only direct face-to-face contacts and services to individuals shall be reimbursable.~~

~~5. Any services provided to the individual that are strictly academic in nature shall not be billable. These include, but are not limited to, such basic educational programs as instruction in reading, science, mathematics, or the individual's work towards obtaining a GED.~~

~~6. Any services provided to individuals that are strictly vocational in nature shall not be billable. However, support~~

~~activities and activities directly related to assisting an individual to cope with a mental illness to the degree necessary to develop appropriate behaviors for operating in an overall work environment shall be billable.~~

~~7. Room and board, custodial care, and general supervision are not components of this service.~~

~~8. This service is not billable for individuals who reside in facilities where staff are expected to provide such services under facility licensure requirements.~~

~~9. Provider qualifications. The enrolled provider of mental health support services shall be licensed by DBHDS as a provider of supportive in-home services, intensive community treatment, or as a program of assertive community treatment. Individuals employed or contracted by the provider to provide mental health support services shall have training in the characteristics of mental illness and appropriate interventions, training strategies, and support methods for persons with mental illness and functional limitations.~~

~~10. Mental health support services, which continue for six consecutive months, shall be reviewed and renewed at the end of the six-month period of authorization by an LMHP, LMHP supervisee, LMHP resident, or LMHP RP who shall document the continued need for the services.~~

~~11. Mental health support services shall be documented through a daily log of time involved in the delivery of services and a minimum of a weekly summary note of services provided.~~

2. The primary psychiatric diagnosis shall be documented as part of the intake. The LMHP, [~~LMHP supervisee, or LMHP resident~~ LMHP-R, LMHP-RP, or LMHP-S] performing the intake shall document the primary mental health diagnosis on the intake form.

3. The LMHP, [~~LMHP supervisee, or LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-E] shall complete, sign, and date the ISP within 30 days of the admission to this service. The ISP shall include documentation of how many days per week and how many hours per week are required to carry out the goals in the ISP. The total time billed for the week shall not exceed the frequency established in the individual's ISP. The ISP shall indicate the dated signature of the LMHP, [~~LMHP supervisee, or LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S, QMHP-A, QMHP-C, or QMHP-E] and the individual. The ISP shall indicate the specific training and services to be provided, the goals and objectives to be accomplished, and criteria for discharge as part of a discharge plan that includes the projected length of service. If the individual refuses to sign the ISP, this shall be noted in the individual's medical record documentation.

4. Every three months, the LMHP, [~~LMHP supervisee, or LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, QMHP-C, or QMHP-E shall review with the individual in a manner in which he may participate with the process, modify as appropriate, and update the ISP. The ISP must be rewritten at least annually.

a. The goals, objectives, and strategies of the ISP shall be updated to reflect any change or changes in the individual's progress and treatment needs as well as any newly identified problem.

b. Documentation of this review shall be added to the individual's medical record no later than [~~the last day of the month in which this~~ 15 calendar days from the date of the] review [~~is conducted~~], as evidenced by the dated signatures of the LMHP, [~~LMHP supervisee, LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, QMHP-C, or QMHP-E and the individual.

5. The ISP shall include discharge goals that will enable the individual to achieve and maintain community stability and independence. The ISP shall fully support the need for interventions over the length of the period of service requested from the service authorization contractor.

6. Reauthorizations for service shall only be granted if the provider demonstrates to either DMAS or the service authorization contractor that the individual is benefitting from the service as evidenced by updates and modifications to the ISP that demonstrate progress toward ISP goals and objectives.

7. If the provider knows or has reason to know of the individual's nonadherence to a regimen of prescribed medication, medication adherence shall be a goal in the individual's ISP. If the care is delivered by the qualified paraprofessional, the supervising LMHP, [~~LMHP supervisee, LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, or QMHP-C shall be informed of any [nonadherence to the prescribed] medication regimen [~~nonadherence~~]. The LMHP, [~~LMHP supervisee, LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, or QMHP-C shall coordinate care with the prescribing physician regarding any [concerns about] medication [~~regimen~~] nonadherence [~~concerns~~ (provided that the individual has consented to such sharing of information)]. The provider shall document the following minimum elements of the contact between the LMHP, [~~LMHP supervisee, LMHP resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, or QMHP-C and the prescribing physician:

a. Name and title of caller;

b. Name and title of professional who was called;

c. Name of organization that the prescribing professional works for;

d. Date and time of call;

e. Reason for the care coordination call;

f. Description of medication regimen issue or issues to be discussed; and

g. Whether or not there was a resolution of medication regimen issue or issues.

8. Discharge summaries shall be prepared by providers for all of the individuals in their care. Documentation of prior psychiatric services history shall be maintained in the individual's mental health skill-building services medical record.

9. Documentation of prior psychiatric services history shall be maintained in the individual's mental health skill-building services medical record. The provider shall document evidence of the individual's prior psychiatric services history, as required by 12VAC30-50-226 B [~~8~~ 6] b (3) and 12VAC30-50-226 B [~~8~~ 6] c (4), by contacting the prior provider or providers of such health care services after obtaining written consent from the individual. Documentation of telephone contacts with the prior provider shall include the following minimum elements:

a. Name and title of caller;

b. Name and title of professional who was called;

c. Name of organization that the professional works for;

d. Date and time of call;

e. Specific placement provided;

f. Type of treatment previously provided;

g. Name of treatment provider; and

h. Dates of previous treatment.

[Discharge summaries from prior providers that clearly indicate (i) the type of treatment provided, (ii) the dates of the treatment previously provided, and (iii) the name of the treatment provider shall be sufficient to meet this requirement. Family member statements shall not suffice to meet this requirement.]

10. The provider shall document evidence of the psychiatric medication history, as required by 12VAC30-50-226 B [~~8~~ 6] b (4) and 12VAC30-50-226 B [~~8~~ 6] c (5), by maintaining a photocopy of prescription information from a prescription bottle or by contacting [~~a prior~~ the current or previous prescribing] provider of health care services or pharmacy after obtaining written consent from the individual. Prescription lists or medical records [, including discharge summaries,] obtained from the pharmacy or [current or previous prescribing] provider of health care services that contain (i) the name of the prescribing physician, (ii) the name of the medication with dosage and frequency, and (iii) the date of the prescription shall be sufficient to meet these criteria. [Family member statements shall not suffice to meet this requirement.]

11. In the absence of such documentation, the current provider shall document all contacts (i.e., telephone, [~~faxes)~~ faxes, electronic communication)] with the pharmacy or provider of health care services with the following minimum elements: (i) name and title of caller, (ii) name and title of prior professional who was called, (iii) name of organization that the professional works for, (iv) date and time of call, (v) specific prescription confirmed, (vi) name of prescribing physician, (vii) name of medication, and (viii) date of prescription.

12. Only direct face-to-face contacts and services to an individual shall be reimbursable.

13. Any services provided to the individual that are strictly academic in nature shall not be billable. These include, but are not limited to, such basic educational programs as instruction or tutoring in reading, science, mathematics, or GED.

14. Any services provided to individuals that are strictly vocational in nature shall not be billable. However, support activities and activities directly related to assisting an individual to cope with a mental illness to the degree necessary to develop appropriate behaviors for operating in an overall work environment shall be billable.

15. Room and board, custodial care, and general supervision are not components of this service.

16. Provider qualifications. The enrolled provider of mental health skill-building services must be licensed by DBHDS as a provider of mental health community support [(defined in 12VAC35-105-20)]. Individuals employed or contracted by the provider to provide mental health skill-building services must have training in the characteristics of mental illness and appropriate interventions, training strategies, and support methods for persons with mental illness and functional limitations. Mental health skill-building services shall be provided by either an LMHP, [~~LMHP-supervisee, LMHP-resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, QMHP-C, QMHP-E, or [~~QMHPP~~ QPPMH]. The LMHP, [~~LMHP-supervisee, LMHP-resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, or QMHP-C will supervise the care weekly if delivered by the QMHP-E or [~~QMHPP~~ QPPMH]. Documentation of supervision shall be maintained in the mental health skill-building services record.

[~~17. Mental health skill building services, which may continue for up to six consecutive months, must be reviewed and renewed at the end of the period of authorization by an LMHP, LMHP supervisee, LMHP resident who must document the continued need for the services.~~

~~18.~~ 17.] Mental health skill-building services [~~must~~ shall] be documented through a daily log of time involved in the delivery of services and a minimum of a weekly summary note of services provided. The provider shall clearly document services provided to detail what occurred during the entire amount of the time billed.

[~~19.~~ 18.] If mental health skill-building services are provided in a group home (Level A or B) or assisted living facility, effective July 1, 2014, there shall be a yearly limit of up to 4160 units per fiscal year and a weekly limit of up

to 80 units per week, with at least half of each week's services provided outside of the group home or assisted living facility. There shall be a daily limit of a maximum of 20 units. Prior to July 1, 2014, the previous limits shall apply. The ISP shall not include activities that contradict or duplicate those in the treatment plan established by the group home or assisted living facility. The provider shall attempt to coordinate mental health skill-building services with the treatment plan established by the group home or assisted living facility and shall document all coordination activities in the medical record.

[~~20.~~ 19.] Limits and exclusions.

a. Group home (Level A or B) and assisted living facility providers shall not serve as the mental health skill-building services provider for individuals residing in the provider's respective facility. Individuals residing in facilities may, however, receive MHSS from another MHSS agency not affiliated with the owner of the facility in which they reside.

b. Mental health skill-building services shall not be reimbursed for individuals who are receiving in-home residential services or congregate residential services through the Intellectual Disability Waiver or Individual and Family Developmental Disabilities Support Waiver.

c. Mental health skill-building services shall not be reimbursed for individuals who are also receiving independent living skills services, the Department of Social Services independent living program (22VAC40-151), independent living services (22VAC40-151 and 22VAC40-131), or independent living arrangement (22VAC40-131) or any Comprehensive Services Act-funded independent living skills programs.

d. Mental health skill-building services shall not be available to individuals who are receiving treatment foster care (12VAC30-130-900 et seq.).

e. Mental health skill-building services shall not be available to individuals who reside in intermediate care facilities for individuals with intellectual disabilities or hospitals.

f. Mental health skill-building services shall not be available to individuals who reside in nursing facilities, except for up to 60 days prior to discharge. If the individual has not been discharged from the nursing facility during the 60-day period of services, mental health skill-building services shall be terminated and no further service authorizations shall be available to the individual unless a provider can demonstrate and document that mental health skill-building services are necessary. Such documentation shall include facts demonstrating a change in the individual's circumstances and a new plan for discharge requiring up to 60 days of mental health skill-building services.

g. Mental health skill-building services shall not be available for residents of residential treatment centers (Level C facilities) except for the intake code H0032 (modifier U8) in the seven days immediately prior to discharge.

h. Mental health skill-building services shall not be reimbursed if personal care services or attendant care services are being received simultaneously, unless justification is provided why this is necessary in the individual's mental health skill-building services record. Medical record documentation shall fully substantiate the need for services when personal care or attendant care services are being provided. This applies to individuals who are receiving additional services through the Intellectual Disability Waiver (12VAC30-120-1000 et seq.), Individual and Family Developmental Disabilities Support Waiver (12VAC30-120-700 et seq.), the Elderly or Disabled with Consumer Direction Waiver (12VAC30-120-900 et seq.), and EPSDT services (12VAC30-50-130).

i. Mental health skill-building services shall not be duplicative of other services. Providers have a responsibility to ensure that if an individual is receiving additional therapeutic services that there will be coordination of services by either the LMHP, [~~LMHP-supervisee, LMHP-resident~~ LMHP-R, LMHP-RP, LMHP-S,] QMHP-A, QMHP-C, or QMHP-E to avoid duplication of services.

j. Individuals who have organic disorders, such as delirium, dementia, or other cognitive disorders not elsewhere classified, will be prohibited from receiving mental health skill-building services unless their physicians issue a signed and dated statement indicating that the individuals can benefit from this service.

k. Individuals who are not diagnosed with a serious mental health disorder but who have personality disorders or other mental health disorders, or both, that may lead to chronic disability, will not be excluded from the mental health skill-building services eligibility criteria provided that the individual has a primary mental health diagnosis from the list included in 12VAC30-50-226 B [~~8~~ 6] b (1) or 12VAC30-50-226 B [~~8~~ 6] c (2) and that the provider can document and describe how the individual is expected to actively participate in and benefit from mental health support services.

J. Except as noted in subdivision I [~~20~~ 18] of this section and in 12VAC30-50-226 B 6 [~~d~~ e], the limits described in this regulation and all others identified in 12VAC30-50-226 shall apply to all service authorization requests submitted to either DMAS or the BHSA as of [~~the effective date of this regulation~~ July 27, 2016]. As of [~~the effective date of this regulation~~ July 27, 2016], all annual limits, weekly limits, daily limits, and reimbursement for services shall apply to all

services described in 12VAC30-50-226 regardless of the date upon which service authorization was obtained.

VA.R. Doc. No. R14-3451; Filed June 3, 2016, 2:52 p.m.

Final Regulation

Titles of Regulations: **12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-190).**

12VAC30-141. Family Access to Medical Insurance Security Plan (amending 12VAC30-141-820).

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

Effective Date: July 27, 2016.

Agency Contact: Victoria Simmons, Regulatory Coordinator, Department of Medical Assistance Services, Policy Division, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-6043, FAX (804) 786-1680, TTY (800) 343-0634, or email victoria.simmons@dmas.virginia.gov.

Summary:

Pursuant to Item 301 LLLL 2 of Chapter 665 of the 2015 Acts of Assembly, the amendments add adult pregnant women to the individuals eligible to receive full dental services, excluding orthodontia, through Medicaid and FAMIS MOMS.

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

12VAC30-50-190. Dental services.

A. Dental services ~~are limited to recipients under~~ shall be covered for individuals younger than 21 years of age in fulfillment of the treatment requirements under the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program and defined as routine diagnostic, preventive, or restorative procedures necessary for oral health provided by or under the direct supervision of a dentist in accordance with the State Dental Practice Act.

1. The state agency will provide any medically necessary dental service to individuals younger than 21 years of age.

~~B.~~ 2. Certain dental services, as described in the agency's Office Reference Manual (Smiles for Children, ~~copyright 2005)~~ March 13, 2014), prepared by DMAS' dental benefits administrator, require preauthorization or prepayment review by the state agency or its designee.

3. Dental services for individuals younger than the age of 21 years that do not require preauthorization or prepayment review are initial, periodic, and emergency examinations; required radiography necessary to develop a treatment plan; patient education; dental prophylaxis; fluoride treatments; routine amalgam and composite restorations; stainless steel crowns, prefabricated steel post and temporary (polycarbonate crowns) and stainless steel bands; crown recementation; pulpotomies; emergency endodontics for temporary relief of pain; pulp capping; sedative fillings; therapeutic apical closure; topical palliative treatment for dental pain; removal of foreign body; simple extractions; root recovery; incision and drainage of abscess; surgical exposure of the tooth to aid eruption; sequestrectomy for osteomyelitis; and oral antral fistula closure.

~~C.~~ B. Dental services determined by the dental provider to be medically appropriate for an adult woman during the term of her pregnancy and through the end of the month following the 60th day postpartum shall be provided to a Medicaid-enrolled pregnant woman. The dental services that shall be covered are (i) diagnostic x-rays and exams; (ii) preventive cleanings; (iii) restorative fillings; (iv) endodontics (root canals); (v) periodontics (gum-related treatments); (vi) prosthodontics, both removable and fixed (crowns, bridges, partial plates, and dentures); (vii) oral surgery (tooth extractions and other oral surgeries); and (viii) adjunctive general services (all covered services that do not fall into specific professional categories). These services require prepayment review by the state agency or its designee.

C. ~~The~~ For the dental services covered for Medicaid-enrolled adult pregnant women, the state agency may place appropriate limits on a service based on medical necessity, for utilization control, or both. Examples of service limitations are: examinations, prophylaxis, fluoride treatment (once/six months); space maintenance appliances; bitewing x-ray—two films (once/12 months); routine amalgam and composite restorations (once/three years); dentures (once/five years); extractions, ~~orthodontics,~~ tooth guidance appliances, permanent crowns and bridges, endodontics, patient education and sealants (once).

D. Limited oral surgery procedures, as defined and covered under Title XVIII (Medicare), are covered for all recipients, and require preauthorization or prepayment review by the state agency or its designee as described in the agency's Office Reference Manual located on the DMAS website at: ~~(http://www.dmas.virginia.gov/downloads/pdfs/dental-office_reference_manual_06-09-05.pdf)~~ http://www.dmas.virginia.gov/Content_atchs/dnt/VA_SFC_ORM_140313.pdf.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC30-50)

Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition DSM-IV-TR, copyright 2000, American Psychiatric Association

Length of Stay by Diagnosis and Operation, Southern Region, 1996, HCIA, Inc.

Guidelines for Perinatal Care, 4th Edition, August 1997, American Academy of Pediatrics and the American College of Obstetricians and Gynecologists

Virginia Supplemental Drug Rebate Agreement Contract and Addenda

~~Office Reference Manual (Smiles for Children), prepared by DMAS' Dental Benefits Administrator, copyright 2005 (www.dmas.virginia.gov/downloads/pdfs/dental-office_reference_manual_06-09-05.pdf).~~

Office Reference Manual (Smiles for Children), prepared by DMAS' Dental Benefits Administrator, copyright 2010, dated March 13, 2014 (http://www.dmas.virginia.gov/Content_atchs/dnt/VA_SFC_ORM_140313.pdf)

Patient Placement Criteria for the Treatment of Substance-Related Disorders ASAM PPC-2R, Second Edition, copyright 2001, American Society of Addiction Medicine

Virginia Medicaid Durable Medical Equipment and Supplies Provider Manual, Appendix B (rev. 1/11), Department of Medical Assistance Services

Human Services and Related Fields Approved Degrees/Experience, Department of Behavioral Health and Developmental Services (rev. 5/13)

12VAC30-141-820. Benefit packages.

Pregnant women covered through FAMIS MOMS may receive the same medical and dental services and are subject to the same limitations on services as pregnant women (see 12VAC30-50-190) covered by the Medicaid program as defined in 12VAC30-10-140 and 12VAC30-50-10.

VA.R. Doc. No. R15-4215; Filed June 3, 2016, 3:01 p.m.

Notice of Extension of Emergency Regulation

Titles of Regulations: **12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (adding 12VAC30-50-600).**

12VAC30-121. Medicare-Medicaid Demonstration Waiver (adding 12VAC30-121-10 through 12VAC30-121-250).

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

Expiration Date Extended Through: December 8, 2016.

The Governor has approved the Department of Medical Assistance Services' request to extend the expiration date of the above-referenced emergency regulations for six months as provided for in § 2.2-4011 D of the Code of Virginia. Therefore, the emergency regulations will continue in effect through December 8, 2016. The emergency regulations relate to the implementation of (i) Item 307 RR of Chapter 806 of the 2013 Acts of Assembly, the 2013 Appropriation Act, which directed the Department of Medical Assistance Services (DMAS) to implement a care coordination program for a Medicare-Medicaid dual eligible enrollee; (ii) Item 307 AAAA of the Act, which directed DMAS to implement a process for administrative appeals of Medicaid/Medicare dual eligible recipients in accordance with the terms of the Memorandum of Understanding between DMAS and the Centers for Medicare and Medicaid Services for the Virginia Medicare-Medicaid Financial Alignment Demonstration Model; and (iii) Item 307 RRRR of the Act, which provides for achieving cost savings and standardization of administrative and other processes for providers. The emergency regulations were published in 31:9 VA.R. 613-633 December 29, 2014.

Agency Contact: Matthew Behrens, Project Manager, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 625-3673, FAX (804) 786-1680, or email matthew.behrens@dmas.virginia.gov.

VA.R. Doc. No. R15-3786; Filed June 3, 2016, 2:46 p.m.

Final Regulation

Title of Regulation: **12VAC30-120. Waivered Services (amending 12VAC30-120-360 through 12VAC30-120-420).**

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

Effective Date: July 27, 2016.

Agency Contact: Victoria Simmons, Regulatory Coordinator, Division of Policy and Research, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-6043, FAX (804) 786-1680, or email victoria.simmons@dmas.virginia.gov.

Summary:

The amendments (i) require individuals who are enrolled in the Elderly or Disabled with Consumer Direction Waiver and who are excluded from participating in mandatory managed care to be enrolled in Medicaid contracted managed care organizations and to receive all acute care services through the mandatory managed care delivery system and (ii) provide for expedited enrollment for Medicaid individuals into Medicaid contracted managed care organizations, especially for pregnant women.

Summary of Public Comments and Agency's Response: No public comments were received by the promulgating agency.

Part VI

~~Medallion II~~ Mandatory Managed Care

12VAC30-120-360. Definitions.

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

"Action" means the denial or limited authorization of a requested service, including the type or level of service; the reduction, suspension, or termination of a previously authorized service; the denial, in whole or in part, of payment for a service; the failure to provide services in a timely manner, as defined by the state; or the failure of an MCO to act within the timeframes provided in 42 CFR 438.408(b).

"Appeal" means a request for review of an action, as "action" is defined in this section.

"Area of residence" means the ~~individual's~~ member's address in the Medicaid eligibility file.

~~"Capitation payment" means a payment the department makes periodically to a contractor on behalf of each individual enrolled under a contract for the provision of medical services under the State Plan, regardless of whether the particular individual receives services during the period covered by the payment.~~

"Covered services" means Medicaid services as defined in the State Plan for Medical Assistance.

"Disenrollment" means the process of changing enrollment from one ~~Medallion II~~ Managed Care Organization (MCO) plan to another MCO, if applicable.

"DMAS" means the Department of Medical Assistance Services.

~~"Enrollee" or "enrollees" means people having current Medicaid eligibility who shall be in the process of being authorized by DMAS to be enrolled in Medallion II.~~

"Early Intervention" means EPSDT Early Intervention services provided pursuant to Part C of the Individuals with Disabilities Education Act (IDEA) of 2004 as set forth in 12VAC30-50-131.

"Eligible person" means any person eligible for Virginia Medicaid in accordance with the State Plan for Medical Assistance under Title XIX of the Social Security Act.

"Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

1. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

2. Serious impairment to bodily functions, or

3. Serious dysfunction of any bodily organ or part.

"Emergency services" means covered inpatient and outpatient services that are furnished by a provider that is qualified to furnish these services and that are needed to evaluate or stabilize an emergency medical condition.

"Enrollment broker" means an independent contractor that enrolls individuals in the contractor's plan and is responsible for the operation and documentation of a toll-free individual service helpline. The responsibilities of the enrollment broker include, but shall not be limited to, individual education and MCO enrollment, assistance with and tracking of individuals' complaints resolutions, and may include individual marketing and outreach.

~~"Exclusion from Medallion II"~~ "Exclude" means the removal of ~~an enrollee~~ a member from the ~~Medallion II~~ mandatory managed care program on a temporary or permanent basis.

"External quality review organization" or "EQRO" means an organization that meets the competence and independence requirements set forth in 42 CFR 438.354 and performs external quality reviews, other external quality review related activities as set forth in 42 CFR 438.358, or both.

"Grievance" means an expression of dissatisfaction about any matter other than an action, as "action" is defined in this section.

~~"Health care plan" means any arrangement in which any managed care organization undertakes to provide, arrange for, pay for, or reimburse any part of the cost of any health care services.~~

"Health care professional" means a provider as defined in 42 CFR 438.2.

"Individual" or "individuals" means ~~people~~ a person or persons who are eligible for Medicaid ~~but~~, who are not yet undergoing enrollment ~~nor~~ for mandatory managed care, and who are not enrolled in a mandatory managed care organization.

"Managed care organization" or "MCO" means an entity that meets the participation and solvency criteria defined in 42 CFR Part 438 and has an executed contractual agreement with DMAS to provide services covered under the ~~Medallion II~~ mandatory managed care program. Covered services for ~~Medallion II~~ mandatory managed care program individuals ~~must~~ shall be as accessible (in terms of timeliness, amount, duration, and scope) as compared to other Medicaid individuals served within the geographic area.

"Member" or "members" means people who have current Medicaid eligibility who are also enrolled in ~~Medallion II~~ mandatory managed care.

"Network" means doctors, hospitals or other health care providers who participate or contract with an MCO contractor and, as a result, agree to accept a ~~mutually agreed~~ mutually agreed upon sum or fee schedule as payment in full for covered services that are rendered to eligible participants.

"Newborn enrollment period" means the period from the child's date of birth plus the next two calendar months.

~~"Nonparticipating provider" means a health care entity or health care professional not in the contractor's participating provider network.~~

~~"Participant" or "participants" means an individual or individuals having current Medicaid eligibility who shall be authorized by DMAS to be a member or members of Medallion II.~~

"PCP of record" means a primary care physician of record with whom the recipient has an established history and such history is documented in the individual's records.

~~"Post-stabilization care services" means covered services related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the~~

~~stabilized condition or to improve or resolve the enrollee's condition.~~

~~"Potential enrollee" means a Medicaid individual who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO.~~

"Retractions" means the departure of an enrolled managed care organization from any one or more localities as provided for in 12VAC30-120-370.

"Rural exception" means a rural area designated in the § 1915(b) managed care waiver, pursuant to § 1932(a)(3)(B) of the Social Security Act and 42 CFR § 438.52(b) and recognized by the Centers for Medicare and Medicaid Services, wherein qualifying ~~Medallion II~~ mandatory managed care members are mandated to enroll in the one available contracted MCO.

~~"School health services" means those physical therapy, occupational therapy, speech therapy, nursing, psychiatric and psychological services rendered to children who qualify for these services under the federal Individuals with Disabilities Education Act (20 USC § 1471 et seq.) by (i) employees of the school divisions or (ii) providers that subcontract with school divisions, as described in 12VAC30-50-130.~~

"Spend-down" means the process of reducing countable income by deducting incurred medical expenses for medically needy individuals, as determined in the State Plan for Medical Assistance.

12VAC30-120-370. ~~Medallion II enrollees~~ Mandatory managed care members.

A. DMAS shall determine enrollment in ~~Medallion II~~ mandatory managed care. Medicaid eligible persons not meeting the exclusion criteria set out in this section ~~must~~ shall participate in the ~~Medallion II~~ mandatory managed care program. Enrollment in ~~Medallion II is~~ mandatory managed care shall not be a guarantee of continuing eligibility for services and benefits under the Virginia Medical Assistance Services Program.

1. DMAS reserves the right to exclude from participation in the ~~Medallion II~~ mandatory managed care program any member who has been consistently noncompliant with the policies and procedures of managed care or who is threatening to providers, MCOs, or DMAS. There must be sufficient documentation from various providers, the MCO, and DMAS of these noncompliance issues and any attempts at resolution. Members excluded from ~~Medallion II~~ mandatory managed care through this provision may appeal the decision to DMAS.

2. Qualifying individuals enrolled in the Elderly or Disabled with Consumer Direction (EDCD) Waiver pursuant to Part IX (12VAC30-120-900 et seq.) of this chapter who do not meet any exclusions in subsection B of this section shall be required to enroll in managed care and shall receive all acute care services through the mandatory managed care delivery system. For these individuals, services provided under 12VAC30-120-380 A 2 shall continue to be provided through the DMAS fee-for-service system.

B. The following individuals shall be excluded (as defined in 12VAC30-120-360) from participating in ~~Medallion II~~ mandatory managed care as defined in the § 1915(b) managed care waiver. Individuals excluded from ~~Medallion II~~ mandatory managed care shall include the following:

1. Individuals who are inpatients in state mental hospitals;

2. Individuals who are approved by DMAS as inpatients in long-stay hospitals, nursing facilities, or intermediate care facilities for individuals with intellectual disabilities;

3. Individuals who are placed on spend-down;

4. Individuals who are participating in the family planning waiver, or in federal waiver programs for home-based and community-based Medicaid coverage prior to managed care enrollment (except eligible EDCD members);

5. Individuals under age 21 who are approved for DMAS residential facility Level C programs as defined in 12VAC30-130-860;

6. Newly eligible individuals who are in the third trimester of pregnancy and who request exclusion within a department-specified timeframe of the effective date of their MCO enrollment. Exclusion may be granted only if the member's obstetrical provider ~~(e.g.~~ (i.e., physician, hospital, or midwife) does not participate with the ~~enrollee's~~ member's assigned MCO. Exclusion requests made during the third trimester may be made by the member, MCO, or provider. DMAS shall determine if the request meets the criteria for exclusion. Following the end of the pregnancy, these individuals shall be required to enroll to the extent they remain eligible for Medicaid;

7. Individuals, other than students, who permanently live outside their area of residence for greater than 60 consecutive days except those individuals placed there for medically necessary services funded by the MCO;

8. Individuals who receive hospice services in accordance with DMAS criteria;

9. Individuals with other comprehensive group or individual health insurance coverage, including Medicare, insurance provided to military dependents, and any other insurance purchased through the Health Insurance Premium Payment Program (HIPP);

10. Individuals requesting exclusion who are inpatients in hospitals, other than those listed in subdivisions 1 and 2 of this subsection, at the scheduled time of MCO enrollment or who are scheduled for inpatient hospital stay or surgery within 30 calendar days of the MCO enrollment effective date. The exclusion shall remain effective until the first day of the month following discharge. This exclusion reason shall not apply to members admitted to the hospital while already enrolled in a department-contracted MCO;

11. Individuals who request exclusion during ~~preassignment~~ assignment to an MCO or within a time set by DMAS from the effective date of their MCO enrollment, who have been diagnosed with a terminal condition and who have a life expectancy of six months or less. The ~~client's~~ individual's physician must certify the life expectancy;

12. Certain individuals between birth and age three certified by the Department of Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 USC § 1471 et seq.) who are granted an exception by DMAS to the mandatory ~~Medallion II~~ managed care enrollment;

13. Individuals who have an eligibility period that is less than three months;

14. Individuals who are enrolled in the Commonwealth's Title XXI SCHIP program;

15. Individuals who have an eligibility period that is only retroactive; and

16. Children enrolled in the Virginia Birth-Related Neurological Injury Compensation Program established pursuant to Chapter 50 (§ 38.2-5000 et seq.) of Title 38.2 of the Code of Virginia.

C. Members enrolled with a MCO who subsequently meet one or more of the criteria of ~~subsections A and~~ subsection B of this section during MCO enrollment shall be excluded from MCO participation as determined by DMAS, with the exception of those who subsequently become participants in the federal long-term care waiver programs, as otherwise defined elsewhere in this chapter, for home-based and community-based Medicaid coverage ~~(AIDS,~~ (IFDDS, ~~MR/ID~~ ID, EDCD, Day Support, or Alzheimer's, or as may be amended from time to time). These ~~individuals~~ members shall receive acute and primary medical services via the MCO and shall receive waiver services and related transportation to waiver services via the fee-for-service program.

Individuals excluded from mandatory managed care enrollment shall receive Medicaid services under the current fee-for-service system. When individuals no longer meet the criteria for exclusion, they shall be required to enroll in the appropriate managed care program.

D. Individuals who are enrolled in localities that qualify for the rural exception may meet exclusion criteria if their PCP of record, as defined in 12VAC30-120-360, cannot or will not participate with the one MCO in the locality. Individual requests to be excluded from MCO participation in localities meeting the qualification for the rural exception must be made to DMAS for consideration on a case-by-case basis. ~~Recipients~~ Members enrolled in MCO rural exception areas shall not have open enrollment periods and shall not be afforded the 90-day window after initial enrollment during which they may make a health plan or program change.

Individuals excluded from mandatory managed care enrollment shall receive Medicaid services under the current fee-for-service system. When individuals no longer meet the criteria for exclusion, they shall be required to enroll in the appropriate managed care program.

E. ~~Medallion II~~ Mandatory managed care plans shall be offered to individuals, and individuals shall be enrolled in those plans, exclusively through an independent enrollment broker under contract to DMAS.

F. ~~Clients~~ Members shall be enrolled as follows:

1. All eligible individuals, except those meeting one of the exclusions of subsection B of this section, shall be enrolled in ~~Medallion II~~ mandatory managed care.

2. Individuals shall receive a Medicaid card from DMAS~~,~~ and shall be provided authorized medical care in accordance with DMAS' procedures after Medicaid eligibility has been determined to exist.

3. Once individuals are enrolled in Medicaid, they will receive a letter indicating that they may select one of the contracted MCOs. These letters shall indicate ~~a preassigned~~ an assigned MCO, determined as provided in subsection F of this section, in which the ~~individual~~ member will be enrolled if he does not make a selection within a period specified by DMAS of not less than 30 days. Members who are enrolled in one mandatory MCO program who immediately become eligible for another mandatory MCO program are able to maintain consistent enrollment with their currently assigned MCO, if available. These members will receive a notification letter including information regarding their ability to change health plans under the new program.

4. Any newborn whose mother is enrolled with an MCO at the time of birth shall be considered a member of that same MCO for the newborn enrollment period.

a. This requirement does not preclude the member, once he is assigned a Medicaid identification number, from disenrolling from one MCO to enrolling with another in accordance with subdivision H 1 of this section.

b. The newborn's continued enrollment with the MCO is not contingent upon the mother's enrollment. Additionally, if the MCO's contract is terminated in whole or in part, the MCO shall continue newborn coverage if the child is born while the contract is active, until the newborn receives a Medicaid number or for the newborn enrollment period, whichever timeframe is earlier. ~~Children who do not receive a Medicaid identification number prior to the end of the newborn enrollment period will be disenrolled.~~ Newborns who remain eligible for participation in ~~Medallion II~~ mandatory managed care will be reenrolled in an MCO through the ~~preassignment~~ assignment process upon receiving a Medicaid identification number.

c. Any newborn whose mother is enrolled in an MCO at the time of birth shall receive a Medicaid identification number prior to the end of the newborn enrollment period in order to maintain the newborn's enrollment in an MCO.

5. Individuals who lose then regain eligibility for ~~Medallion II~~ mandatory managed care within 60 days will be reenrolled into their previous MCO without going through ~~preassignment~~ assignment and selection.

G. Individuals who do not select an MCO as described in subdivision F 3 of this section shall be assigned to an MCO as follows:

1. Individuals are assigned through a system algorithm based upon the ~~client's~~ member's history with a contracted MCO.

2. Individuals not assigned pursuant to subdivision 1 of this subsection shall be assigned to the MCO of another family member, if applicable.

3. Individuals who live in rural exception areas as defined in 12VAC30-120-360 ~~must~~ shall enroll with the one available MCO. These ~~persons~~ individuals shall receive ~~a preassignment~~ an assignment notification for enrollment into the MCO. Individuals in rural exception areas who are assigned to the one MCO may request exclusion from MCO participation if their PCP of record, as defined in 12VAC30-120-360, cannot or will not participate with the one MCO in the locality. Individual requests to be excluded from MCO participation in rural exception localities must be made to DMAS for consideration on a case-by-case basis.

4. All other individuals shall be assigned to an MCO on a basis of approximately equal number by MCO in each locality.

5. All eligible members are automatically assigned to a contracted MCO in their localities. Members are allowed 90 days after the effective date of new or initial enrollment to change to another MCO that participates in the geographic area where the member lives. ~~Recipients~~ Members residing in localities qualifying for a rural exception shall not be afforded the 90-day window after initial enrollment during which they may make a health plan or program change.

6. DMAS shall have the discretion to utilize an alternate strategy for enrollment or transition of enrollment from the method described in this section for expansions, retractions, or changes to ~~client~~ member populations, geographical areas, procurements, or any or all of these; such alternate strategy shall comply with federal waiver requirements.

H. Following their initial enrollment into an MCO, members shall be restricted to the MCO until the next open enrollment period, unless appropriately disenrolled or excluded by the department (as defined in 12VAC30-120-360).

1. During the first 90 calendar days of enrollment in a new or initial MCO, a member may disenroll from that MCO to enroll into another MCO for any reason. Such disenrollment shall be effective no later than the first day of the second month after the month in which the member requests disenrollment.

2. During the remainder of the enrollment period, the member may only disenroll from one MCO into another MCO upon determination by DMAS that good cause exists as determined under subsection ~~I~~ J of this section.

I. The department shall conduct an annual open enrollment for all ~~Medallion II~~ mandatory managed care members with the exception of those ~~clients~~ members who live in a designated rural exception area. The open enrollment period shall be the 60 calendar days before the end of the enrollment period. Prior to the open enrollment period, DMAS will inform the member of the opportunity to remain with the current MCO or change to another MCO, without cause, for the following year. Enrollment selections will be effective on the first day of the next month following the open enrollment period. Members who do not make a choice during the open enrollment period will remain with their current MCO selection.

J. Disenrollment for cause may be requested at any time.

1. After the first 90 days of enrollment in an MCO, members ~~must~~ may request disenrollment from DMAS based on cause. The request may be made orally or in writing to DMAS and ~~must~~ shall cite the reason or reasons why the member wishes to disenroll. Cause for disenrollment shall include the following:

a. A member's desire to seek services from a federally qualified health center that is not under contract with the member's current MCO, and the member requests a change to another MCO that subcontracts with the desired federally qualified health center;

b. Performance or nonperformance of service to the member by an MCO or one or more of its providers that is deemed by the department's external quality review organizations to be below the generally accepted community practice of health care. This may include poor quality care;

c. Lack of access to a PCP or necessary specialty services covered under the State Plan or lack of access to providers experienced in dealing with the member's health care needs;

d. A member has a combination of complex medical factors that, in the sole discretion of DMAS, would be better served under another contracted MCO;

e. The member moves out of the MCO's service area;

f. The MCO does not, because of moral or religious objections, cover the service the member seeks;

g. The member needs related services to be performed at the same time; not all related services are available

within the network, and the member's primary care provider or another provider determines that receiving the services separately would subject the member to unnecessary risk; or

h. Other reasons as determined by DMAS through written policy directives.

2. DMAS shall determine whether cause exists for disenrollment. Written responses shall be provided within a timeframe set by department policy; however, the effective date of an approved disenrollment shall be no later than the first day of the second month following the month in which the member files the request, in compliance with 42 CFR 438.56.

3. Cause for disenrollment shall be deemed to exist and the disenrollment shall be granted if DMAS fails to take final action on a valid request prior to the first day of the second month after the request.

4. The DMAS determination concerning cause for disenrollment may be appealed by the member in accordance with the department's client appeals process at 12VAC30-110-10 through ~~12VAC30-110-380~~ 12VAC30-110-370.

5. The current MCO shall provide, within two working days of a request from DMAS, information necessary to determine cause.

6. Members enrolled with a MCO who subsequently meet one or more of the exclusions in subsection B of this section during MCO enrollment shall be excluded as appropriate by DMAS, with the exception of those who subsequently become individuals participating in the IFDDS, ID, [EDCD], Day Support, or Alzheimer's federal waiver programs for home-based and community-based Medicaid coverage. These members shall receive acute and primary medical services via the MCO and shall receive waiver services and related transportation to waiver services via the fee-for-service program.

12VAC30-120-380. ~~Medallion II~~ MCO responsibilities.

A. The MCO shall provide, at a minimum, all medically necessary covered services provided under the State Plan for Medical Assistance and further defined by written DMAS regulations, policies and instructions, except as otherwise modified or excluded in this part.

1. Nonemergency services provided by hospital emergency departments shall be covered by MCOs in accordance with rates negotiated between the MCOs and the hospital emergency departments.

2. Services that shall be provided outside the MCO network shall include, but are not limited to, those services identified and defined by the contract between DMAS and the MCO. Services reimbursed by DMAS include, but shall not be limited to, dental and orthodontic services for children up to age 21; for all others, dental services ~~(~~as described in 12VAC30-50-190~~)~~, school health services ~~(as defined in 12VAC30-120-360)~~, community mental health services (rehabilitative, targeted case management and the following substance abuse treatment services: emergency services (crisis); intensive outpatient services; day treatment services; substance abuse case management services; and opioid treatment services)~~,~~ as defined in 12VAC30-50-228 and 12VAC30-50-491, ~~EPSDT~~ Early Intervention services provided pursuant to Part C of the Individuals with Disabilities Education Act (IDEA) of 2004 ~~(~~as defined in 12VAC30-50-131 and 12VAC30-50-415~~)~~, and long-term care services provided under the § 1915(c) home-based and community-based waivers including related transportation to such authorized waiver services.

3. The MCOs shall pay for emergency services and family planning services and supplies whether ~~they~~ such services are provided inside or outside the MCO network.

B. EPSDT services shall be covered by the MCO and defined by the contract between DMAS and the MCO. The MCO shall have the authority to determine the provider of service for EPSDT screenings.

C. The MCOs shall report data to DMAS under the contract requirements, which may include data reports, report cards for ~~clients~~ members, and ad hoc quality studies performed by the MCO or third parties.

D. Documentation requirements.

1. The MCO shall maintain records as required by federal and state law and regulation and by DMAS policy. The MCO shall furnish such required information to DMAS, the Attorney General of Virginia or his authorized representatives, or the State Medicaid Fraud Control Unit on request and in the form requested.

2. Each MCO shall have written policies regarding ~~enrollee~~ member rights and shall comply with any applicable federal and state laws that pertain to ~~enrollee~~ member rights and shall ensure that its staff and affiliated providers take those rights into account when furnishing services to ~~enrollees~~ members in accordance with 42 CFR 438.100.

E. The MCO shall ensure that the health care provided to its ~~clients~~ members meets all applicable federal and state mandates, community standards for quality, and standards developed pursuant to the DMAS managed care quality program.

F. The MCOs shall promptly provide or arrange for the provision of all required services as specified in the contract between the ~~state~~ Commonwealth and the ~~contractor~~ MCO. Medical evaluations shall be available within 48 hours for urgent care and within 30 calendar days for routine care. On-call clinicians shall be available 24 hours per day, seven days per week.

G. The MCOs ~~must~~ shall meet standards specified by DMAS for sufficiency of provider networks as specified in

the contract between the ~~state~~ Commonwealth and the ~~contractor~~ MCO.

H. Each MCO and its subcontractors shall have in place, and follow, written policies and procedures for processing requests for initial and continuing authorizations of service. Each MCO and its subcontractors shall ensure that any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the ~~enrollee's~~ member's condition or disease. Each MCO and its subcontractors shall have in effect mechanisms to ensure consistent application of review criteria for authorization decisions and shall consult with the requesting provider when appropriate.

I. In accordance with 42 CFR 447.50 through 42 CFR 447.60, MCOs shall not impose any cost sharing obligations on ~~enrollees~~ members except as set forth in 12VAC30-20-150 and 12VAC30-20-160.

J. An MCO may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of ~~an enrollee~~ a member who is his patient in accordance with 42 CFR 438.102.

K. An MCO that would otherwise be required to reimburse for or provide coverage of a counseling or referral service is not required to do so if the MCO objects to the service on moral or religious grounds and furnishes information about the service it does not cover in accordance with 42 CFR 438.102.

12VAC30-120-390. Payment rate for ~~Medallion II~~ MCOs.

The payment rate to MCOs that participate in the mandatory managed care program shall be set by negotiated contracts and in accordance with 42 CFR 438.6 and other pertinent federal regulations.

12VAC30-120-395. Payment rate for preauthorized or emergency care provided by out-of-network providers.

The MCOs shall pay for preauthorized or emergency services when provided outside the MCO network. Preauthorized or emergency services provided to a ~~Medallion II client~~ managed care member by a provider or facility not participating in the MCO's network will be reimbursed according to the current Medicaid fee schedule. This reimbursement shall be considered payment in full to the provider or facility of emergency services.

12VAC30-120-400. Quality control and utilization review.

A. DMAS shall rigorously monitor the quality of care provided by the MCOs. DMAS may contract with one or more external quality review organizations to perform focused studies on the quality of care provided by the MCOs. The external organizations may utilize data or other tools to ensure contract compliance and quality improvement activities. Specifically, DMAS shall monitor to determine if the MCO:

1. Fails substantially to provide the medically necessary items and services required under law or under the contract to be provided to an enrolled recipient and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual.

2. Engages in any practice that discriminates against individuals on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, or any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by § 1903(m) of the Social Security Act (42 USC § 1396b(m))) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

3. Misrepresents or falsifies information that it furnishes, under § 1903(m) of the Social Security Act (42 USC § 1396b(m)) to CMS, DMAS, an individual, or any other entity.

4. Fails to comply with the requirements of 42 CFR 417.479(d) through (g) relating to physician incentive plans, or fails to submit to DMAS its physician incentive plans as required or requested in 42 CFR 434.70.

5. Imposes on ~~enrollees~~ members premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

B. DMAS shall ensure that data on performance and patient results are collected.

C. DMAS shall ensure that quality outcomes information is provided to MCOs. DMAS shall ensure that changes which are determined to be needed as a result of quality control or utilization review are made.

12VAC30-120-410. Sanctions.

A. If DMAS determines that an MCO is not in compliance with applicable state or federal laws, regulations (including but not limited to the requirements of or pursuant to 12VAC30-120-380 E~~,~~ or 42 CFR 438, Subpart I), or ~~their Medallion II~~ the MCO contract, DMAS may impose sanctions on the MCO. The sanctions may include, but are not limited to:

1. Limiting enrollments in the MCO by freezing voluntary ~~recipient~~ member enrollments;

2. Freezing DMAS assignment of ~~recipients~~ members to the MCO;

3. Limiting MCO enrollment to specific areas;

4. Denying, withholding, or retracting payments to the MCO;

5. Terminating the MCO's ~~Medallion II~~ contract;

6. Intermediate sanctions including, but not limited to, the maximum civil money penalties specified in 42 CFR Part

438, Subpart I, for the violations set forth therein, or in accordance therewith; and

7. Civil monetary penalties as specified in 42 CFR 438.704.

B. In the case of an MCO that has repeatedly failed to meet the requirements of §§ 1903(m) and 1932 of the Social Security Act, DMAS shall, regardless of what other sanctions are imposed, impose the following sanctions:

1. Appoint a temporary manager to:

a. Oversee the operation of the Medicaid managed care organization upon a finding by DMAS that there is continued egregious behavior by the organization or there is a substantial risk to the health of ~~enrollees~~ members; or

b. Assure the health of the organization's ~~enrollees~~ members if there is a need for temporary management while (i) there is an orderly termination or reorganization of the organization or (ii) improvements are made to remedy the violations found under subsection A of this section. Temporary management under this subdivision may not be terminated until DMAS has determined that the MCO has the capability to ensure that the violations shall not recur.

2. Permit ~~individuals~~ members who are enrolled with the MCO to disenroll without cause. If this sanction is imposed, DMAS shall be responsible for notifying such ~~individuals~~ members of the right to disenroll.

C. Prior to terminating a contract as permitted under subdivision A 5 of this section, DMAS shall provide the MCO with a hearing. DMAS ~~may~~ shall not provide an MCO with a pretermination hearing before the appointment of a temporary manager under subdivision B 1 of this section.

D. Prior to imposing any sanction other than termination of the MCO's contract, DMAS shall provide the MCO with notice, develop procedures with which the MCO must comply to eliminate specific sanctions, and provide such other due process protections as the Commonwealth may provide.

E. In accordance with the terms of the contract, MCOs shall have the right to appeal any adverse action taken by DMAS. For appeal procedures not addressed by the contract, the MCO shall proceed in accordance with the appeals provisions of the Virginia Public Procurement Act (§ 2.2-4300 et seq. of the Code of Virginia). Pursuant to §§ 2.2-4364 and 2.2-4365 of the Code of Virginia, DMAS shall establish an administrative appeals procedure through which the MCO may elect to appeal decisions on disputes arising during the performance of its contract. Pursuant to § 2.2-4365 of the Code of Virginia, such appeal shall be heard by a hearing officer; however, in no event shall the hearing officer be an employee of DMAS. In conducting the administrative appeal, the hearing officer shall follow the hearing procedure used in § 2.2-4020 of the Code of Virginia.

F. When DMAS determines that an MCO committed one of the violations specified in 12VAC30-120-400 A, DMAS shall implement the provisions of 42 CFR 434.67.

1. Any sanction imposed pursuant to this subsection shall be binding upon the MCO.

2. The MCO shall have the appeals rights for any sanction imposed pursuant to this subsection as specified in 42 CFR 434.67.

12VAC30-120-420. ~~Client~~ Member grievances and appeals.

A. The MCOs shall, whenever ~~an enrolled client's~~ a member's request for covered services is reduced, denied or terminated, or payment for services is denied, provide a written notice in accordance with the notice provisions specified in 42 CFR 438.404 and 42 CFR 438.210(c), as defined by the contract between DMAS and the MCO, and any other statutory or regulatory requirements.

B. MCOs shall, at the initiation of either new ~~client~~ member enrollment or new provider/subcontractor contracts, or at the request of the ~~enrollee~~ member, provide to every ~~enrollee~~ member the information described in 42 CFR 438.10(g) concerning grievance/appeal rights and procedures.

C. Disputes between the MCO and the ~~client~~ member concerning any aspect of service delivery, including medical necessity and specialist referral, shall be resolved through a verbal or written grievance/appeals process operated by the MCO or through the DMAS appeals process. A provider who has the ~~enrollee's~~ member's written consent may act on behalf of ~~an enrollee~~ a member in the MCO grievance/appeals or the DMAS appeals process.

1. The ~~enrollee~~ member, provider, or representative acting on behalf of the ~~enrollee~~ member with the ~~enrollee's~~ member's written consent may file an oral or written grievance or appeal with the MCO. The MCO must accept grievances or appeals submitted within 30 days from the date of the notice of adverse action. Oral requests for appeals must be followed up in writing within 10 business days by the ~~enrollee~~ member, provider, or the representative acting on behalf of the ~~enrollee~~ member with the ~~enrollee's~~ member's consent, unless the request is for an expedited appeal. The ~~enrollee~~ member may also file a written request for a standard or expedited appeal with the DMAS Appeals Division within 30 days of the ~~client's~~ member's receipt of the notice of adverse action, in accordance with 42 CFR 431, Subpart E~~,~~; 42 CFR Part 438, Subpart F~~,~~; and ~~12VAC30-110~~ 12VAC30-110-10 through 12VAC30-110-370.

2. As specified in 12VAC30-110-100, pending the resolution of a grievance or appeal filed by a ~~client~~ member or his representative (including a provider acting on behalf of the ~~client)~~ member), coverage shall not be terminated or reduced for the ~~client~~ member for any reason which is the subject of the grievance or appeal.

3. The MCO shall ensure that the ~~individuals~~ employees or agents who make decisions on MCO grievances and appeals were not involved in any previous level of review or decision making, and where the reason for the grievance or appeal involves clinical issues, relates to a denial or a request for an expedited appeal, or where the appeal is based on a lack of medical necessity, shall ensure that the decision makers are health care professionals with the appropriate clinical expertise in treating the ~~enrollee's~~ member's condition or disease.

D. The MCO shall develop written materials describing the grievance/appeals system and its procedures and operation.

E. The MCO shall maintain a recordkeeping and tracking system for complaints, grievances, and appeals that includes a copy of the original complaint, grievance, or appeal; the decision; and the nature of the decision. This system shall distinguish Medicaid from commercial ~~enrollees~~ members, if the MCO does not have a separate system for Medicaid ~~enrollees~~ members.

F. At the time of enrollment and at the time of any adverse actions, the MCO shall notify the ~~client~~ member, in writing, that:

1. Medical necessity, specialist referral or other service delivery issues may be resolved through a system of grievances and appeals, within the MCO or through the DMAS client appeals process;

2. ~~Clients~~ Members have the right to appeal directly to DMAS; and

3. The MCO shall promptly provide grievance or appeal forms, reasonable assistance and written procedures to ~~clients~~ members who wish to register written grievances or appeals.

G. The MCO shall issue grievance/appeal decisions as defined by the contract between DMAS and the MCO. Oral grievance decisions are not required to be in writing.

H. The MCO shall issue standard appeal decisions within 30 days from the date of initial receipt of the appeal in accordance with 42 CFR 438.408 and as defined by the contract between DMAS and the MCO. The appeal decision shall be in writing and shall include, but shall not be limited to, the following:

1. The decision reached, the results and the date of the decision reached by the MCO;

2. The reasons for the decision;

3. The policies or procedures that provide the basis for the decision;

4. A clear explanation of further appeal rights and a timeframe for filing an appeal; and

5. For appeals that involve the termination, suspension, or reduction of a previously authorized course of treatment, the right to continue to receive benefits in accordance with 42 CFR 438.420 pending a hearing, and how to request continuation of benefits.

I. An expedited appeal decision shall be issued as expeditiously as the ~~enrollee's~~ member's condition requires and within three business days in cases of medical emergencies in which delay could result in death or serious injury to a ~~client~~ member. Extensions to these timeframes shall be allowed in accordance with 42 CFR 438.408 and as defined by the contract between DMAS and the MCO. Written confirmation of the decision shall promptly follow the verbal notice of the expedited decision.

J. Any appeal decision issued by the MCO may be appealed by the ~~client~~ member to DMAS in accordance with the department's Client Appeals regulations at 12VAC30-110-10 through ~~12VAC30-110-380~~ 12VAC30-110-370. DMAS shall conduct an evidentiary hearing in accordance with the Client Appeals regulations at 12VAC30-110-10 through ~~12VAC30-110-380~~ 12VAC30-110-370 and shall not base any appealed decision on the record established by any appeal decision of the MCO. The MCO shall comply with the DMAS appeal decision. The DMAS decision in these matters shall be final and shall not be subject to appeal by the MCO.

K. The MCO shall provide information necessary for any DMAS appeal within timeframes established by DMAS.

VA.R. Doc. No. R15-4135; Filed June 3, 2016, 2:58 p.m.

TITLE 14. INSURANCE

STATE CORPORATION COMMISSION

Final Regulation

REGISTRAR'S NOTICE: The State Corporation Commission is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts courts, any agency of the Supreme Court, and any agency that by the Constitution is expressly granted any of the powers of a court of record.

Title of Regulation: **14VAC5-395. Rules Governing Settlement Agents (amending 14VAC5-395-10, 14VAC5-395-20, 14VAC5-395-30 through 14VAC5-395-80; adding 14VAC5-395-75, 14VAC5-395-100; repealing 14VAC5-395-25).**

Statutory Authority: §§ 12.1-13 and 55-525.28 of the Code of Virginia.

Effective Date: July 1, 2016.

Agency Contact: Chuck F. Myers, Supervisor RESA Investigations Unit, Bureau of Insurance, State Corporation Commission, P.O. Box 1157, Richmond, VA 23218, telephone (804) 371-9619, FAX (804) 371-5661, or email chuck.myers@scc.virginia.gov.

Summary:

The amendments (i) define various terms, including "'agent' or 'insurance agent,'" "business entity," "designated licensed producer," "employee," "escrow, closing, or settlement services," and "settlement agent"; (ii) add reporting, registration, and escheatment requirements for settlement agents; (iii) address the use of title insurance agents who are independent contractors; and (iv) make various other technical and clarifying amendments. Changes in the regulations from the initial proposal include exempting title insurance companies from many registration, insurance and bonding, audit, and reporting requirements; narrowing the reporting requirements from allegations to final dispositions; and clarifying that settlement agents that utilize a title insurance agent who is an independent contractor will be held liable for any violations of Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or the Rules Governing Settlement Agents (14VAC5-395) committed by the independent contractor.

AT RICHMOND, JUNE 7, 2016

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. INS-2015-00170

Ex Parte: In re: Rules Governing Settlement Agents

ORDER ADOPTING REGULATIONS

On November 9, 2015, the State Corporation Commission ("Commission") entered an Order to Take Notice of a proposal by the Bureau of Insurance ("Bureau") to amend the Commission's regulations governing settlement agents, which are set forth in Chapter 395 of Title 14 of the Virginia Administrative Code, 14 VAC 5-395-10 et seq.[1] The Order to Take Notice and proposed regulations were published in the Virginia Register of Regulations on November 30, 2015, posted on the Commission's website, and sent to all licensed title insurance agents, agencies, and companies who are registered settlement agents, and other interested parties. Registrants and other interested parties were afforded the opportunity to file written comments or request a hearing on or before February 16, 2016.

Comments addressing nearly all aspects of the proposed regulations were filed by Virginia's largest title insurance trade association, the Virginia Land Title Association, as well as three title insurance companies, ten title insurance agencies or agents, four attorneys, and one consultant. Comments were also submitted by the Deputy Secretary of the Commonwealth and 176 Notaries Public.

The Bureau's proposed amendments added several definitions to the regulations, as well as numerous consumer protection provisions relating to, among other things, insurance and bonding requirements, escheatment of funds, audits, reporting requirements, and the use of independent contractors. The addition of the definition of "settlement agent" prompted the Deputy Secretary of the Commonwealth and Notaries Public to file comments expressing concerns that the proposed regulations would require a Notary Public who conducts settlement conferences without handling funds to become licensed and registered. General concerns were raised, as well as requests for clarification, with respect to other of the proposed amendments. The Commission did not receive any requests for a hearing.

The Bureau considered the comments filed and responded to them in its Statements of Position, which the Bureau filed with the Clerk of the Commission on April 29, 2016. The Bureau made changes to several of the definitions and consumer protection provisions in response to the comments. The Bureau also clarified that a Notary Public acting on behalf of a settlement agent may obtain signatures on closing documents without being licensed or registered provided that the Notary Public does not receive or handle money, and/or does not sell, solicit, or negotiate a contract of title insurance. The Bureau recommended that the Commission adopt the proposed regulations as modified.

NOW THE COMMISSION, having considered the proposed regulations, the comments filed, the Bureau's Statements of Position, the record herein, and applicable law, concludes that the proposed regulations should be modified to incorporate certain suggestions that were made by commenters and the Bureau. The Commission further concludes that the proposed regulations, as modified, should be adopted with an effective date of July 1, 2016.

Accordingly, IT IS ORDERED THAT:

(1) The proposed regulations, as modified herein and attached hereto, are adopted effective July 1, 2016.

(2) This Order and the attached regulations shall be posted on the Commission's website at: http://www.scc.virginia.gov/case.

(3) The Commission's Division of Information Resources shall provide a copy of this Order, including a copy of the attached regulations, to the Virginia Registrar of Regulations for publication in the Virginia Register of Regulations.

(4) This case is dismissed, and the papers filed herein shall be placed in the Commission's file for ended causes.

AN ATTESTED COPY hereof, together with a copy of the attached regulations, shall be sent by the Clerk of the Commission to the Commission's Office of General Counsel and the Commissioner of Insurance, who shall forthwith send by e-mail or U.S. mail a copy of this Order, together with a copy of the attached regulations, to all licensed and registered title insurance agents, title insurance agencies and title insurance companies providing escrow, closing or settlement services involving real property located in Virginia, and such other interested parties as she may designate.

[1] The amendments to the regulations were proposed in response to the legislative changes to §§ 38.2-1820, 55-525.16, 55-525.24, 55-525.25, and

55-525.26 of the Code of Virginia that will be effective July 1, 2016; to clarify the scope of the regulations; and to enhance consumer protections.

14VAC5-395-10. ~~Purpose~~ Applicability.

~~A. The purpose of this~~ This chapter ~~is to implement~~ implements Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia ~~B. This chapter~~ and applies to all title insurance agents, title insurance agencies, and title insurance companies providing escrow, closing, or settlement services involving the purchase of or lending on the security of any real ~~estate containing not more than four residential dwelling units~~ property in the Commonwealth of Virginia.

~~C. The Bureau of Insurance shall issue the necessary forms to carry out the provisions of Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia and this chapter.~~

14VAC5-395-20. Definitions.

~~Unless otherwise defined herein, all~~ The following words and terms when used in this chapter shall have the ~~meaning as set forth in Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia~~ following meanings unless the context clearly indicates otherwise:

"Agent" or "insurance agent" ~~shall have the same meaning as set forth in § 38.2-1800 of the Code of Virginia~~ means an individual or business entity that sells, solicits, or negotiates contracts of [title] insurance [~~or annuity~~] in the Commonwealth.

"Bureau" means the State Corporation Commission Bureau of Insurance.

"Business entity" means a partnership, limited partnership, limited liability company, corporation, or other legal entity other than a sole proprietorship [, professional corporation, or professional limited liability company].

["Chapter 27.3" means Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia.]

"Designated licensed producer" means an individual who (i) possesses a valid [~~Virginia title~~] license to sell, solicit, or negotiate contracts of [title] insurance [~~or annuity~~] in the Commonwealth; (ii) is appointed; (iii) is an [officer, director, or] employee of the business entity; and (iv) is responsible for the business [~~entity~~ entity's] compliance with the insurance laws, rules, and regulations of this Commonwealth.

"Employee" means an individual (i) whose manner and means of performance of work are subject to the right of control of, or are controlled by, a [~~business entity~~ person] and (ii) whose compensation for federal income tax purposes is reported, or required to be reported, on a W-2 form issued by the controlling [~~business entity~~ person].

"Escrow, closing, or settlement services" means the administrative and clerical services required to carry out the terms of contracts affecting real estate. These services include (i) placing orders for title insurance; (ii) receiving and issuing receipts for money received from the parties; (iii) ordering loan checks and payoffs; (iv) ordering surveys and inspections; (v) preparing settlement statements or Closing Disclosure forms; (vi) determining that all closing documents conform to the parties' contract requirements; (vii) setting the closing appointment; (viii) following up with the parties to ensure that the transaction progresses to closing; (ix) ascertaining that the lenders' instructions have been satisfied; (x) conducting a closing conference at which the documents are executed; (xi) receiving and disbursing funds; (xii) completing form documents and instruments selected by and in accordance with instructions of the parties to the transaction; (xiii) handling or arranging for the recording of documents; (xiv) sending recorded documents to the lender; (xv) sending the recorded deed and the title policy to the buyer; and (xvi) reporting federal income tax information for the real estate sale to the Internal Revenue Service.

"Lay real estate settlement agent" means a person who (i) is not licensed as an attorney under Chapter 39 (§ 54.1-3900 et seq.) of Title 54.1 of the Code of Virginia, (ii) is not a party to the real estate transaction, (iii) provides escrow, closing or settlement services in connection with a transaction related to any real estate in this Commonwealth, and (iv) is listed as the settlement agent on the settlement statement or Closing Disclosure for ~~such~~ the transaction.

"Settlement agent" ~~shall have the same meaning as set forth in § 55-525.16 of the Code of Virginia~~ means [~~any title insurance agent, title insurance agency, title insurance company, or~~ a] person, other than a party to the real estate transaction, who provides escrow, closing, or settlement services in connection with a transaction related to real estate in the Commonwealth and who is listed as the settlement agent on the settlement statement or Closing Disclosure for the transaction. Any person, other than a party to the transaction, who conducts the settlement conference and receives or handles money shall be deemed a "settlement agent" subject to the applicable requirements of Chapter 27.3 [~~(§ 55-525.16 et seq.) of the Code of Virginia~~] and this chapter.

~~"Title insurance agency" means a business entity licensed in this Commonwealth as a title insurance agent.~~

~~"Title insurance agent" shall have the same meaning as set forth in § 38.2-1800 of the Code of Virginia.~~

"Title insurance agency" or "title insurance agent" means any individual or business entity licensed in the Commonwealth, pursuant to Chapter 18 (§ 38.2-1800 et seq.) of Title 38.2 of the Code of Virginia, as a title insurance agent and appointed by a title insurance company licensed in the Commonwealth who shall perform all of the following services (for which liability arises) relevant to the issuance of title insurance policies, subject to the underwriting directives and guidelines of the agent's title insurance company. These services shall include (i) the evaluation of the title search to determine the insurability of the title; (ii) a determination of whether or not underwriting objections have been cleared; (iii) the actual issuance of a title commitment or binder and endorsements; and (iv) the actual issuance of the policy or

policies and endorsements on behalf of the title insurance company. A title insurance agent holding funds in escrow shall promptly deposit the funds in a trust account in a financial institution authorized to do business in this Commonwealth. This trust account shall be separate from all other accounts held by the agent.

"Title insurance company" means any company licensed to transact, or transacting, title insurance in this Commonwealth.

14VAC5-395-25. ~~Lay real estate settlement agents.~~ (Repealed.)

~~Notwithstanding any provision of this chapter to the contrary, and pursuant to § 55-525.18 of the Code of Virginia, a lay real estate settlement agent shall be required to comply with the provisions of this chapter, except as specifically set forth in 14VAC5-395-60.~~

14VAC5-395-30. Registration.

A. Every ~~title insurance agent, title insurance agency and title insurance company that acts as a~~ settlement agent shall ~~be required to be registered~~ register with the bureau in accordance with the provisions of § 55-525.30 of the Code of Virginia.

B. At the time of application for registration, a settlement agent [other than a title insurance company] shall provide to the bureau (i) its certificate of authorization or charter of a domestic limited liability company or corporation, or certificate of registration or certificate of authority of a foreign limited liability company or corporation, as applicable; (ii) an original surety bond; and (iii) [~~a~~ the name of the] designated licensed producer.

C. Within 30 days of registration a settlement agent shall furnish to the bureau:

1. Legal name;

2. Any fictitious [or assumed] names;

3. Principal place of business address;

4. Addresses of all other business locations;

5. Telephone numbers;

6. Escrow account numbers and financial institution addresses;

7. Employee and independent contractor list;

8. Website or websites;

9. Affiliated entities; and

10. Such other information as the bureau may require.

14VAC5-395-40. Insurance and bonding requirements.

A. At the time of registration, every ~~title insurance agent and title insurance agency acting as a~~ settlement agent [other than a title insurance company] shall file a certification on a form prescribed by the bureau, that the settlement agent has, and thereafter shall keep in force for as long as they are acting as a settlement agent, the following:

1. An errors and omissions insurance policy providing limits of at least $250,000 per occurrence or per claim and issued by an insurer authorized to do business in the Commonwealth of Virginia. A deductible is permitted but shall not hinder or delay the payment of a claim.

2. A blanket fidelity bond or employee dishonesty insurance policy covering persons employed by the settlement agent providing limits of at least $100,000 per occurrence or per claim and issued by an insurer authorized to do business in the Commonwealth of Virginia. Settlement agents that have no employees except the owners, partners, shareholders, or members may ~~request~~ apply for a waiver of this requirement on their certification form.

B. Every ~~title insurance agent and title insurance agency that acts as a~~ settlement agent [~~in the Commonwealth of Virginia~~ other than a title insurance company] shall file an original surety bond in an amount not less than $200,000 on a form prescribed by the bureau at the time of application for registration and, if such bond is canceled, at the time a replacement bond is issued.

14VAC5-395-50. Audits.

A. Every ~~title insurance agent and title insurance agency that acts as a~~ settlement agent [~~in the Commonwealth of Virginia~~ other than a title insurance company] shall, at its expense, have an audit of its escrow accounts conducted by an independent certified public accountant at least once each consecutive 12-month period. The audit month shall be prescribed by the bureau. Such audit shall conform with the standards established by the American Institute of Certified Public Accountants, ~~Statement on Auditing~~ AICPA Professional Standards, Volume 1, as of June 1, 2015, Special ~~Reports~~ Considerations - Audits of Single Financial Statements and Specific Elements, Accounts, or Items of a Financial Statement, and shall be filed by the settlement agent with the bureau no later than 60 days after the date on which the audit is completed. A title insurance company shall be subject to the requirements of this subsection unless such company's financial statements are audited annually by an independent certified public accountant.

B. Every ~~title insurance agent or title insurance agency acting as a~~ settlement agent [other than a title insurance company] shall file a copy of its audit report with each title insurance company it represents.

C. In lieu of an audit conducted by a certified public accountant, ~~a title insurance agent or title insurance agency acting as~~ a settlement agent [other than a title insurance company] shall allow each title insurance company for which it has an appointment to conduct an analysis of its escrow accounts at least once each consecutive 12-month period. The form of ~~such~~ the analysis and the analysis month shall be prescribed by the bureau. The title insurance company shall submit a copy of its analysis to the bureau no later than 60 days after the date on which the analysis is completed. With

the consent of the title insurance agent or agency, a title insurance company may share the results of its analysis with other title insurance companies that will accept the same in lieu of conducting a separate analysis.

D. Every settlement agent shall [~~(i)~~] make a good faith effort to disburse funds in its possession and return the funds to the rightful owner [~~; (ii)~~, and] escheat [~~unclaimed funds yearly~~ annually] to the Virginia Department of the Treasury [~~; and (iii) comply with The Uniform Disposition of Unclaimed Property Act (§ 55-210.1 et seq.) of Title 55 of the Code of Virginia~~ those funds for which the owner is unlocatable].

E. A settlement agent [other than a title insurance company] shall complete and file a close-out audit with the bureau in conformance with this chapter and the bureau's instructions within 180 days from the date the settlement agent ceases conducting settlements.

14VAC5-395-60. Separate fiduciary trust account.

A. Every ~~title insurance agent, title insurance agency and title insurance company that acts as a~~ settlement agent ~~in the Commonwealth of Virginia~~ shall maintain a separate fiduciary trust account for the purpose of handling funds received in connection with escrow, closing, or settlement services involving real estate located only in this Commonwealth. No other funds may be included in this escrow account except funds deposited to guarantee the adequacy of the account. Such trust account shall be with a financial institution authorized to do business in the Commonwealth of Virginia.

B. If the ~~agent, agency, or company acting as a lay real estate~~ settlement agent provides escrow, closing, or settlement services in transactions involving multiple parcels or tracts of real estate and any one of those tracts or parcels is located wholly or partially outside of this Commonwealth, ~~that~~ the settlement agent~~, agency, or company~~ shall maintain another separate fiduciary trust account for the purpose of handling funds received in connection with such transactions.

C. A settlement agent may utilize a general escrow account for the purpose of receiving funds in connection with an escrow, closing, or settlement involving real estate located in the Commonwealth, provided that the settlement agent (i) handles the funds in a fiduciary capacity and (ii) deposits the funds in a separate fiduciary trust account in compliance with subsection A of this section no later than the close of the second business day after receipt of the funds.

14VAC5-395-70. ~~Access to records~~ Reporting requirements.

A. Every ~~title insurance agent, title insurance agency and title insurance company that acts as a~~ settlement agent ~~in the Commonwealth of Virginia~~ shall make all escrow, closing, or settlement records available promptly upon request for examination by the bureau without notice during normal business hours.

B. A settlement agent shall maintain documentation that supports all entries on the settlement statement or Closing Disclosure.

C. A settlement agent shall promptly respond to a bureau request for books, records, documentation, or other information in connection with the bureau's investigation, enforcement, or examination of the settlement agent's compliance with applicable laws and regulations. If no time period is specified by the bureau, a written response as well as any requested books, records, documentation, or information shall be delivered by the settlement agent to the bureau not later than 30 days from the date of such request.

D. Within 30 days following the occurrence of any of the following events, a settlement agent [other than a title insurance company] shall report to the bureau if:

1. Any bankruptcy, reorganization, or receivership proceedings are filed by or against the settlement agent.

2. Any [~~local, state, or federal~~] governmental authority [~~institutes revocation, suspension, or other formal administrative,~~ enters a final disposition in a] regulatory, [administrative,] or enforcement [~~proceedings~~ action] against the settlement agent.

3. Any [~~local, state, or federal~~] governmental authority [~~(i)~~] revokes or suspends the settlement agent's registration, license, or other license for a similar business [~~; (ii) takes formal administrative, regulatory, or enforcement action against the settlement agent relating to its business; or (iii) takes any other action against the settlement agent relating to its business where the total amount of restitution or other payment from the settlement agent exceeds $2,500~~].

4. Based on allegations by any [~~local, state, or federal~~] governmental authority that the settlement agent violated any law or regulation applicable to the conduct of its licensed business, the settlement agent enters into, or otherwise agrees to the entry of, a settlement or consent order, decree, or agreement with or by such governmental authority.

5. The settlement agent surrenders its license in another state [~~in lieu of threatened or pending license revocation; license suspension; or other administrative, regulatory, or enforcement action~~].

6. The settlement agent is denied a license in another state.

7. The settlement agent or any of its members, partners, directors, officers, principals, employees, or independent contractors is [~~indicted or~~] convicted of a felony.

8. Any funds held by the settlement agent are (i) seized by or on behalf of any court or governmental instrumentality or (ii) forfeited to or on behalf of any court or governmental instrumentality. [The term "forfeited" shall not include the escheatment of funds in accordance with The Uniform Disposition of Unclaimed Property Act (§ 55-210.1 et seq. of Title 55 of the Code of Virginia) or

the interpleading of funds to a court of competent jurisdiction.]

E. A settlement agent shall immediately notify the bureau following the loss of (i) a designated licensed producer, (ii) required insurance coverage, or (iii) required bond coverage.

F. A settlement agent or former settlement agent [other than a title insurance company] shall provide the following information to the bureau within 10 days after such person's [title insurance] license is surrendered, terminated, suspended, or revoked or has lapsed by operation of law, or the licensed and registered business is otherwise closed: (i) the names, addresses, telephone numbers, fax numbers, and email addresses of a designated contact person; (ii) the location of the settlement agent's or former settlement agent's records; and (iii) any additional information that the bureau may reasonably require. A settlement agent or former settlement agent [other than a title insurance company] shall maintain current information with the bureau until all escrow funds are disbursed and all title policies are issued.

G. Sixty days prior to ceasing business, a settlement agent shall provide notice to the bureau of its intent to cease conducting settlements and the anticipated date of business termination.

H. The reports required by this section shall be in the format and contain such additional information as the bureau may reasonably require. The bureau may also require additional reports that it deems necessary.

14VAC5-395-75. Operating requirements.

A settlement agent shall comply with the following requirements:

1. A settlement agent shall continuously maintain the requirements and standards for licensure and registration.

2. A settlement agent shall reconcile its escrow accounts monthly.

3. A settlement agent shall not provide any information to the bureau or a consumer that is false, misleading, or deceptive.

4. A settlement agent shall not charge duplicative or [~~inflated~~ padded] fees for escrow, closing, or settlement services.

5. A settlement agent shall not engage in any activity that directly or indirectly results in an evasion of the provisions of Chapter 27.3 [~~(§ 55-525.16 et seq.) of the Code of Virginia~~] or this chapter.

6. Any person, other than a party to the transaction, who conducts the settlement conference and receives or handles money, including possessing wire transfer authority, shall be [~~properly licensed and shall be~~] deemed a "settlement agent" subject to the applicable requirements of Chapter 27.3 and this chapter.

7. A designated licensed producer shall be appointed by the same title insurance company as its employer settlement agent.

8. A settlement agent [~~may~~ shall] not use or accept the services of a title insurance agent [who is an] independent contractor unless the title insurance agent [~~(i) holds a title insurance license, (ii) is appointed, (iii) is registered, and (iv) maintains the insurance or bond coverages~~ is licensed and appointed. A settlement agent that permits an independent contractor to conduct one or more settlement conferences on behalf of the settlement agent shall ensure that the independent contractor is properly insured and bonded as] required by Chapter 27.3 and this chapter.

9. A settlement agent that uses the services of a title insurance agent [who is an] independent contractor shall be [~~(i)~~ considered] the legal principal of the [~~title insurance agent~~] independent contractor and [~~(ii)~~ shall be] liable for [~~all actions of the title insurance agent~~ any violations of Chapter 27.3 or this chapter committed by the] independent contractor, including unintentional conduct [~~, that occurs during the period services are utilized~~, within the scope of engagement].

10. A former settlement agent shall remain subject to the provisions of Chapter 27.3 and this chapter in connection with all settlements that the settlement agent performed while licensed and registered, notwithstanding the occurrence of any of the following events:

a. The settlement agent's license is surrendered, terminated, suspended, or revoked or has lapsed by operation of law; or

b. The settlement agent ceases conducting settlements.

11. If a settlement agent or former settlement agent disposes of records containing a consumer's personal financial information or copies of a consumer's identification documents, such records and copies shall be disposed of in a secure manner.

14VAC5-395-80. ~~Violations~~ Enforcement.

~~Any violation of~~ Failure to comply with any provision of Chapter 27.3 [~~(§ 55-525.16 et seq. of the Code of Virginia)~~] or this chapter ~~shall be punished as provided for in Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia~~ may result in penalties, license revocation or suspension, the entry of a cease and desist order, restitution, or other enforcement action.

14VAC5-395-100. Commission authority.

The commission may, at its discretion, waive or grant exceptions to any provision of this chapter for good cause shown.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with

a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (14VAC5-395)

Settlement Agent Official Registration Form for a Title Agent (eff. 3/2012)

Settlement Agent Official Registration Form for Licensed Title Insurance Company or Agency (eff. 3/2012)

Title Settlement Agency/Agency Financial Responsibility Certification (undated, filed 11/2015)

Waiver of Blanket Fidelity Bond or Employee Dishonesty Insurance Policy for Title Insurance Settlement Agents (undated, filed 11/2015)

Bond for Title Insurance Settlement Agent (undated, filed 11/2015)

Standard Report of Escrow Accounts Maintained by Title Insurance Agents (eff. 10/2010)

DOCUMENTS INCORPORATED BY REFERENCE (14VAC5-395)

~~Statement on Auditing Standards, Special Reports, July 1, 1989, American Institute of Certified Public Accountants.~~

AICPA Professional Standards, Volume 1, as of June 1, 2015, American Institute of Certified Public Accountants, New York, New York 10036-8775, http://www.aicpa.org

AICPA Professional Standards, Volume 2, as of June 1, 2015, American Institute of Certified Public Accountants, New York, New York 10036-8775, http://www.aicpa.org

VA.R. Doc. No. R16-4541; Filed June 7, 2016, 4:12 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF AUDIOLOGY AND SPEECH-LANGUAGE PATHOLOGY

Final Regulation

Title of Regulation: **18VAC30-20. Regulations Governing the Practice of Audiology and Speech-Language Pathology (amending 18VAC30-20-10; adding 18VAC30-20-241).**

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

Effective Date: July 27, 2016.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Audiology and Speech-Language Pathology, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4630, FAX (804) 527-4413, or email leslie.knachel@dhp.virginia.gov.

Summary:

Pursuant to Chapter 327 of the 2014 Acts of Assembly, the amendments provide a framework for safe practice of limited cerumen management by an audiologist including (i) a definition of "limited cerumen management," (ii) the education and specific training necessary to perform limited cerumen management on patients, (iii) the contraindications for performance by an audiologist of limited cerumen management on patients, and (iv) the conditions that require referral to a medical doctor.

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

Part I
General Provisions

18VAC30-20-10. Definitions.

A. The words and terms "audiologist," "board," "practice of audiology," "practice of speech-language pathology," "speech-language disorders," and "speech-language pathologist" when used in this chapter shall have the meanings ascribed to them in § 54.1-2600 of the Code of Virginia.

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

"Contact hour" means 60 minutes of time spent in continuing learning activities.

"Limited cerumen management" means the identification and removal of cerumen from the cartilaginous outer one-third portion of the external auditory canal in accordance with minimum standards and procedures set forth in this chapter.

"School speech-language pathologist" means a person licensed pursuant to § 54.1-2603 of the Code of Virginia to provide speech-language pathology services solely in public school divisions.

"Supervision" means that the audiologist or speech-language pathologist is responsible for the entire service being rendered or activity being performed, is available for consultation, and is providing regular monitoring and documentation of clinical activities and competencies of the person being supervised.

"Type 1" means continuing learning activities that must be offered by an accredited sponsor or organization as specified in 18VAC30-20-300.

"Type 2" means continuing learning activities that may or may not be approved by an accredited sponsor or organization but shall be activities considered by the learner to be beneficial to practice or to continuing learning. In Type 2 activities, licensees document their own participation on the Continued Competency Activity and Assessment Form and are considered self-learning activities.

18VAC30-20-241. Limited cerumen management.

A. In order for an audiologist to perform limited cerumen management, he shall:

1. Be a graduate of a doctoral program in audiology that is accredited by the Council on Academic Accreditation of the American Speech-Language-Hearing Association or other accrediting body recognized by the board and that included didactic education and supervised clinical experience in cerumen management as specified in subsection B of this section; or

2. Complete a course or workshop in cerumen management that provides training as specified in subsection B of this section and that is approved by the American Speech-Language Hearing Association or the American Academy of Audiology.

B. An audiologist shall maintain documentation evidencing satisfactory completion of training in cerumen management to include the following:

1. Recognizing the presence of preexisting contraindications that necessitate referral to a physician;

2. Recognizing patient distress and appropriate action to take if complications are encountered;

3. Use of infection control precautions;

4. Procedures for removal of cerumen, including cerumen loop, gentle water irrigation, suction, and the use of material for softening;

5. Observation of each type of cerumen management procedure performed by a qualified audiologist or physician; and

6. Successful performance, under direct supervision by an audiologist qualified to perform cerumen management or a physician, of each type of cerumen management procedure.

C. An audiologist shall not perform cerumen management on a patient who has any of the following preexisting contraindications:

1. A perforated tympanic membrane;

2. Inflammation, tenderness, drainage, or open wounds or traces of blood in the external ear canal;

3. History of ear surgery that results in distortion of the external ear canal;

4. HIV infection or bleeding disorders;

5. Actual or suspected foreign body in the ear, excluding hearing aid components that are located in the lateral one-third portion of the ear canal;

6. Stenosis or bony exostosis of the ear canal; or

7. Cerumen impaction that totally occludes the visualization of the tympanic membrane.

D. An audiologist performing cerumen management shall:

1. Obtain informed [~~written~~] consent of the patient or legally responsible adult and [~~maintain documentation of~~ document] such consent and the procedure performed in the patient record.

2. Refer patients to a physician if they exhibit contraindications or experience any complication, such as dizziness, during the procedure.

VA.R. Doc. No. R15-4115; Filed June 3, 2016, 2:57 p.m.

Final Regulation

Title of Regulation: **18VAC30-20. Regulations Governing the Practice of Audiology and Speech-Language Pathology (amending 18VAC30-20-240).**

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

Effective Date: July 27, 2016.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Audiology and Speech-Language Pathology, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4630, FAX (804) 527-4413, or email leslie.knachel@dhp.virginia.gov.

Summary:

The amendments establish provisions for the supervision of unlicensed assistants, including the (i) responsibility of the licensed speech-language pathologist for the training and assignment of duties of an assistant, (ii) qualifications of an assistant, (iii) duties that may be performed by an assistant, (iv) scope of practice of a speech-language pathologist that may not be delegated to an assistant, (v) level and limitation on supervision of assistants, and (vi) obligation of the licensee to provide the necessary level of supervision to ensure quality of care, including onsite observation of at least two client sessions for each assistant every 30 days and direct delivery of service to each client at least every 30 days. The amendments are made pursuant to Chapter 661 of the 2014 Acts of Assembly.

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

18VAC30-20-240. Supervisory responsibilities; supervision of unlicensed assistants.

A. Responsibility of a licensee.

1. A licensed audiologist ~~and speech-language pathologist shall provide documented supervision to~~ who supervises unlicensed assistants shall document such supervision, shall be held fully responsible for their performance and activities, and shall ensure that they perform only those activities ~~which~~ that do not constitute the practice of audiology ~~or speech-language pathology~~ and ~~which~~ that are commensurate with their level of training.

2. A licensed speech-language pathologist who supervises unlicensed assistants shall document such supervision, shall be held fully responsible for their performance and activities, and shall ensure that they perform only those activities that do not constitute the practice of speech-language pathology and that are commensurate with their level of training.

a. A speech-language pathologist shall not supervise an assistant without the speech-language pathologist's knowledge and consent by the assistant and the licensee documented prior to assumption of supervisory responsibilities.

b. The frequency in which the speech-language pathologist personally delivers treatment or services to a client who is receiving some services from an assistant shall be up to the professional judgment of the speech-language pathologist and shall be determined by the treatment needs of the client, the type of services being provided, and the setting in which the client is being served, but shall occur at least every 30 days.

~~B.~~ 3. The identity of the unlicensed assistant shall be disclosed to the client prior to treatment and shall be made a part of the client's file.

B. Qualifications of a speech-language pathologist assistant.

1. A person acting as a speech-language pathologist assistant shall have:

a. A bachelor's degree or associate's degree and documented training by a licensed speech-language pathologist in topics related to the client population to be served; or

b. Employment as a speech-language pathologist assistant in a United States jurisdiction within the last five years preceding [~~(the effective date of the regulations)~~ July 27, 2016].

2. A speech-language pathologist supervising an assistant shall be responsible for determining that the knowledge, skills, and clinical experience of the assistant are sufficient to ensure competency to perform all tasks to which the assistant is assigned. The speech-language pathologist shall document competency after training and direct observation of the assistant's performance of such tasks, and a record of skills and competencies shall be maintained.

C. Scope of practice of a speech-language pathologist assistant. After demonstration and documentation of competency for the duties to be assigned, an assistant shall only engage in those duties planned, designed, and supervised by a licensed speech-language pathologist, to include the following:

1. Assist with speech, language, and hearing screenings without clinical interpretation of results.

2. Assist during assessment of a client exclusive of administration or interpretation.

3. Perform activities for each session that are routine and do not require professional judgment, in accordance with a plan developed and directed by the speech-language pathologist who retains the professional responsibility for the client.

4. Document a client's performance and report information to the supervising speech-language pathologist.

5. Assist with programming augmentative and alternative communication devices and assist the client in repetitive use of such devices.

6. Sign or initial informal treatment notes and, upon request, co-sign formal documents with the supervising speech-language pathologist.

7. Engage in the following activities:

a. Preparing materials;

b. Scheduling appointments and activities;

c. Preparing charts, records, or graphs and performing other clerical duties;

d. Performing checks and maintenance of equipment; and

e. Assisting a client with transitioning to and from therapy sessions.

8. Perform duties not otherwise restricted to the practice of speech-language pathology.

D. A speech-language pathologist assistant shall not engage in the practice of speech-language pathology, including the following:

1. Represent himself as a speech-language pathologist.

2. Perform standardized or nonstandardized diagnostic tests or formal or informal evaluations.

3. Perform procedures that require a professional level of clinical acumen and technical skill.

4. Tabulate or interpret results and observations of feeding and swallowing evaluations or screenings performed by a speech-language pathologist.

5. Participate in formal conferences or meetings without the presence of the supervising speech-language pathologist.

6. Provide interpretative information to the client, the family of the client, or others regarding the client's status or service.

7. Write, develop, or modify a client's treatment plan.

8. Assist in or provide services as specified in subsection C of this section unless directed by the supervising speech-language pathologist.

9. Sign any formal documents in lieu of the supervising speech-language pathologist.

10. Select a client for service or discharge a client from service.

11. Make a decision on the need for additional services or make referrals for service.

12. Disclose clinical or confidential information either orally or in writing to anyone other than the supervising speech-language pathologist, unless mandated by law or authorized by the supervising speech-language pathologist.

13. Develop or determine the swallowing or feeding strategies or precautions for a client or provide feeding or swallowing treatment.

E. Supervision of an assistant in speech-language pathology.

1. The practice of an assistant shall only be supervised by a speech-language pathologist who retains full legal and ethical responsibility for the client. A speech-language pathologist shall only supervise the equivalent of two full-time assistants.

2. The speech-language pathologist shall provide the level of supervision to the speech-language pathologist assistant necessary to ensure quality of care to include on-site supervision of at least two client sessions for each assistant being supervised every 30 days to directly observe and evaluate the performance of the assistant. The speech-language pathologist shall document such on-site observation and evaluation in the client record for each session.

VA.R. Doc. No. R15-4179; Filed June 3, 2016, 2:58 p.m.

Notice of Extension of Emergency Regulation

Title of Regulation: **18VAC30-20. Regulations Governing the Practice of Audiology and Speech-Language Pathology (amending 18VAC30-20-10; adding 18VAC30-20-241).**

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

Expiration Date Extended Through: December 27, 2016.

The Governor has approved the Board of Audiology and Speech-Language Pathology request to extend the expiration date of the above-referenced emergency regulation for six months as provided for in § 2.2-4011 D of the Code of Virginia. Therefore, the emergency regulation will continue in effect through December 27, 2016. The emergency regulation was adopted pursuant to Chapter 327 of the 2014 Acts of Assembly and relates to the expansion of the practice of audiology to include limited cerumen management. The original emergency was published in 31:11 VA.R. 958-960 January 26, 2015, and an amended emergency regulation was published in 32:6 VA.R. 1100-1102 November 16, 2015.

Contact Information: Leslie L. Knachel, Executive Director, Board of Audiology and Speech-Language Pathology, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4630, FAX (804) 527-4413, or email leslie.knachel@dhp.virginia.gov.

VA.R. Doc. No. R15-4115; Filed June 3, 2016, 2:52 p.m.

BOARD FOR CONTRACTORS

Proposed Regulation

Title of Regulation: **18VAC50-22. Board for Contractors Regulations (amending 18VAC50-22-10, 18VAC50-22-40, 18VAC50-22-50, 18VAC50-22-60, 18VAC50-22-220, 18VAC50-22-230, 18VAC50-22-310).**

Statutory Authority: § 54.1-201 of the Code of Virginia.

Public Hearing Information:

July 11, 2016 - 10 a.m. - Commonwealth of Virginia Conference Center, Perimeter Center, 9960 Mayland Drive, Board Room 3, Richmond, VA 23233

Public Comment Deadline: August 26, 2016.

Agency Contact: Eric L. Olson, Executive Director, Board for Contractors, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-2785, FAX (866) 430-1033, or email contractors@dpor.virginia.gov.

Basis: Section 54.1-1102 of the Code of Virginia provides the authority for the Board for Contractors to promulgate regulations for the licensure of contractors in the Commonwealth. The content of the regulations is pursuant to the board's discretion, but shall not be in conflict with the purposes of the statutory authority.

Purpose: During the past 18 months, several instances involving the submission of false documentation, forged verification forms, and questionable identity have been brought to the attention of the Board for Contractors. The majority of these instances have resulted in disciplinary action being taken against the licensee, usually in the form of the revocation of the license and a monetary sanction. To date nearly 100 such cases have been adjudicated by the board or are scheduled to be heard by the board, and more than 100 currently are in the investigative stages.

A review of these cases has found that the board's current documentation requirements are insufficient to ensure that the information being provided by the applicant is valid. This includes, but is not limited to, verification of identification, experience documentation, determination of fiscal responsibility, and verification of employment status. The application process has been modified somewhat, in those areas that do not require an amendment of the regulations, but the board has identified other requirements that should be implemented to reduce the instances of application fraud.

The board is tasked with ensuring that contractors meet minimum competency standards as well as minimum financial standards to ensure that the public is protected from unqualified or incompetent contractors as well as to ensure that contractors have the fiscal health to enter into contracts that can be for hundreds of thousands of dollars. In order to ensure that these minimum standards are met, it is critical that the documentation reviewed by the board to determine license eligibility is accurate and trustworthy.

Substance: 18VAC50-22-10: Amendments add two definitions to the existing list of definitions.

18VAC50-22-40, 18VAC50-22-50, and 18VAC50-22-60: Provisions for submission of identification, experience verification, employment verification, credit checks, and verification of fiscal standing (as applicable) are amended as deemed necessary by the board to meet the statutory and regulatory requirements.

18VAC50-22-220 and 18VAC50-22-230: Documentation that must be submitted in order to ensure that a licensee meets the eligibility requirements to make changes to its license is amended.

18VAC50-22-310: Amendments are made to the requirements for pre-license education providers to attend training provided by the board.

Issues: The primary advantage to the public is that these regulations will help to ensure that the license holders actually meet the minimum competency requirements to get a license, and the public can feel more confident that the license was not acquired fraudulently. The only disadvantage to applicants applying for licenses is that they will need to provide licensing staff with more supporting paperwork.

The primary advantage to the agency is there will be fewer investigations on license holders for acquiring the license fraudulently. The disadvantage to the agency is that the licensing staff will need to do more research before issuing a license.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. In order to increase the integrity of information provided as a part of contractor licensure, the Board of Contractors (Board) proposes several new verification requirements for its licensees.

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

Estimated Economic Impact. Board staff reports that the Board is dealing with an increasing problem, over the last 18 months or so, involving the submission of false documentation, forged verification forms and questionable identity representations. Board staff reports that, to date, nearly 100 cases have been heard or are scheduled to be heard by the Board and that more than 100 additional cases are currently in some investigative stage.

To address these problems, the Board is proposing several new documentation requirements. The Board proposes that applicants for licensure that are subject to experience requirements must have that experience verified by a building official, building inspector, registered design professional, a licensee of this Board or another regulatory agency or by any other individual/organization approved by the Board. The Board also proposes to require firms that must supply information on past due debts, outstanding tax obligations and defaults, judgements and bankruptcies also supply a copy of their credit report to verify the information that they supply. Similarly, where the Board now requires firms to report and have a certain level of assets, the Board proposes to require verification that the reported assets are actually owned by, or titled to, the firm reporting them. The Board proposes to remove qualified individuals from the list of entities that must supply information on debts as any qualified individuals who are not also members of responsible management are just employees of the firm and their financial stability has no effect on the stability of the firm. People named by firms as qualified individuals (who are not also members of responsible management) will, however, have to provide proof that they are employed full time by the firm that has named them as qualifying individuals with submission of copies of I-9s, W-4s, insurance documents, or other documentation approved by the Board. The Board also proposes that firms be required to submit copies of a government issued photo ID for each member of responsible management and for each qualified individual for the firm. Members of responsible management and each qualified individual will also be required to sign the firm's application for licensure. If firms change members of responsible management or qualified individuals, the Board proposes to require the new individuals to provide the same information and documentation as required by members of responsible management and qualified individuals at the time of application for licensure. Lastly, the Board proposes to require all providers of pre-licensure education to send at least one representative every two years to attend a Board of Contractors remedial education course. These courses are held monthly.

Licensed firms would incur only minimal copying and postage costs for meeting most of the Board's proposed requirements. They may or may not incur slightly more than minimal costs to provide a credit report. Credit reports are available free at some websites but may cost as much as $12. Pre-licensure education providers will incur costs to send a representative to Board training once every two years roughly equal to the prorated salary of the individual sent plus travel expenses (gas, tolls if applicable and vehicle wear and tear allowances). These costs are likely outweighed by the benefits that will accrue from the Board taking steps to curb fraud and forgery amongst their applicants for licensure.

Businesses and Entities Affected. Board staff reports that the Board received approximately 5,000 applications for licensure per year over the last five years; approximately 4,000 of the 5,000 applications each year are from firms that qualify as small businesses.

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

Projected Impact on Employment. These proposed changes are unlikely to impact employment in any firm except those

that are unable to legitimately provide the documentation that the Board proposes to require.

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

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

Small Businesses:

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

Costs and Other Effects. Small businesses may incur minimal costs to meet the Board's new documentation requirements and pre-licensure education providers will likely incur moderate costs once every two years to send a representative to a Board remedial education course.

Alternative Method that Minimizes Adverse Impact. There are likely no alternative methods that would both meet the Board's goal of curbing fraud amongst their applicants and further minimize adverse impacts.

Adverse Impacts:

Businesses. Small businesses may incur minimal costs to meet the Board's new documentation requirements and pre-licensure education providers will likely incur moderate costs once every two years to send a representative to a Board remedial education course.

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

Other Entities. Other entities in the Commonwealth are unlikely to suffer any adverse impacts on account of this regulatory action.

Agency's Response to Economic Impact Analysis: The Board for Contractors concurs with the economic impact analysis prepared by the Department of Planning and Budget.

Summary:

The proposed amendments modify the documentation submitted as part of the application to verify requirements for experience level, net worth, examination, and employment, including submission of identification of the individuals listed on the application, third party verification of experience, verification of financial standing, and other criteria. The amendments also require all prelicense education providers to attend a board remedial education course once every two years.

Part I
Definitions

18VAC50-22-10. General definitions.

The following words and terms when used in this chapter, unless a different meaning is provided or is plainly required by the context, shall have the following meanings:

"Address of record" means the mailing address designated by the licensee to receive notices and correspondence from the board.

"Affidavit" means a written statement of facts, made voluntarily, and confirmed by the oath or affirmation of the party making it, taken before a notary or other person having the authority to administer such oath or affirmation.

"Business entity" means a sole proprietorship, partnership, corporation, limited liability company, limited liability partnership, or any other form of organization permitted by law.

"Change order" means any modification to the original contract including, but not limited to, the time to complete the work, change in materials, change in cost, and change in the scope of work.

"Controlling financial interest" means the direct or indirect ownership or control of more than 50% ownership of a firm.

"Credit report" means documentation from a nationally recognized credit agency that reflects the financial responsibility of the applicant; provides a current consumer credit score derived from the Fair Isaac Corporation's (FICO) scoring method; and includes information including payment history, credit rating, public filings in county, state, and federal courts, bankruptcies, business history, suits, liens, and judgments.

"Firm" means any business entity recognized under the laws of the Commonwealth of Virginia.

"Formal vocational training" means courses in the trade administered at an accredited educational facility; or formal training, approved by the department, conducted by trade associations, businesses, military, correspondence schools or other similar training organizations.

"Full-time employee" means an employee who spends a minimum of 30 hours a week carrying out the work of the licensed contracting business.

"Helper" or "laborer" means a person who assists a licensed tradesman and who is not an apprentice as defined in 18VAC50-30-10.

"Licensee" means a firm holding a license issued by the Board for Contractors to act as a contractor, as defined in § 54.1-1100 of the Code of Virginia.

"Nationally recognized credit agency" means an organization that obtains credit information on a nationwide basis; validates, updates, and maintains the accuracy of the credit information obtained; and obtains credit reports from at least two credit bureaus.

"Net worth" means assets minus liabilities. For purposes of this chapter, assets shall not include any property owned as tenants by the entirety.

"Prime contractor" means a licensed contractor that performs, supervises, or manages the construction, removal, repair, or improvement of real property pursuant to the terms of a primary contract with the property owner/lessee. The prime contractor may use its own employees to perform the work or use the services of other properly licensed contractors.

"Principal place of business" means the location where the licensee principally conducts business with the public.

"Reciprocity" means an arrangement by which the licensees of two states are allowed to practice within each other's boundaries by mutual agreement.

"Reinstatement" means having a license restored to effectiveness after the expiration date has passed.

"Renewal" means continuing the effectiveness of a license for another period of time.

"Residential building energy analyst firm" means any business entity wherein a residential building energy analysis, as defined in § 54.1-1144 of the Code of Virginia, is offered or practiced.

"Responsible management" means the following individuals:

1. The sole proprietor of a sole proprietorship;

2. The partners of a general partnership;

3. The managing partners of a limited partnership;

4. The officers of a corporation;

5. The managers of a limited liability company;

6. The officers or directors of an association or both; and

7. Individuals in other business entities recognized under the laws of the Commonwealth as having a fiduciary responsibility to the firm.

"Sole proprietor" means any individual, not a corporation, who is trading under his own name, or under an assumed or fictitious name pursuant to the provisions of §§ 59.1-69 through 59.1-76 of the Code of Virginia.

"Supervision" means providing guidance or direction of a delegated task or procedure by a tradesman licensed in accordance with Chapter 11 (§ 54.1-1100 et seq.) of Title 54.1 of the Code of Virginia, being accessible to the helper or laborer, and periodically observing and evaluating the performance of the task or procedure.

"Supervisor" means the licensed master or journeyman tradesman who has the responsibility to ensure that the installation is in accordance with the applicable provisions of the Virginia Uniform Statewide Building Code and provides supervision to helpers and laborers as defined in this chapter.

"Temporary license" means a license issued by the board pursuant to § 54.1-201.1 of the Code of Virginia that authorizes a person to engage in the practice of contracting until such time as the license is issued or 45 days from the date of issuance of the temporary license, whichever occurs first.

"Tenants by the entirety" means a tenancy which is created between a husband and wife and by which together they hold title to the whole with right of survivorship so that, upon death of either, the other takes whole to exclusion of the deceased's remaining heirs.

"Virginia Uniform Statewide Building Code" or "USBC" means building regulations comprised of those promulgated by the Virginia Board of Housing and Community Development in accordance with § 36-98 of the Code of Virginia, including any model codes and standards that are incorporated by reference and that regulate construction, reconstruction, alteration, conversion, repair, maintenance or use of structures, and building and installation of equipment therein.

Part II
Entry

18VAC50-22-40. Requirements for a Class C license.

A. A firm applying for a Class C license must meet the requirements of this section.

B. For every classification or specialty in which the firm seeks to be licensed, the firm shall name a qualified individual who meets the following requirements:

1. Is at least 18 years old;

2. Has a minimum of two years experience in the classification or specialty for which he is the qualifier~~,~~ verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board;

3. Is a ~~full-time employee of the firm as defined in this chapter or is a~~ member of the responsible management of the firm or is a full-time employee of the firm as verified by the submission of copies of an I-9, a W-4, insurance documents, or other documentation acceptable to the board; and

4. a. Has obtained the appropriate certification for the following specialties:

Blast/explosive contracting (Department of Fire Programs explosive use certification)

Fire alarm (NICET level III or higher certification in fire protection: fire alarm systems or completion of a board-approved examination)

Fire sprinkler ~~(NICET Sprinkler III certification)~~ (NICET level III or higher certification in fire protection: water based systems layout or completion of a board-approved examination)

Manufactured home contracting (completion of a U.S. Department of Housing and Urban Development or

Department of Housing and Community Development approved installers course)

Radon mitigation ~~(EPA or DEQ~~ (Virginia Department of Health accepted radon certification).

b. Has obtained, pursuant to the Individual Licensing and Certification Regulations (18VAC50-30), a master license for ~~Plumbing~~ plumbing, HVAC, ~~Electrical~~ electrical, ~~Gas Fitting~~ gas fitting, ~~Natural Gas Fitting Provider~~ natural gas fitting provider, and ~~Liquefied Petroleum Gas Contracting~~ liquefied petroleum gas contracting.

c. Has obtained, pursuant to the Individual Licensing and Certification Regulations, certification as an accessibility mechanic for accessibility services contracting, accessibility mechanic (LULA) for accessibility services contracting-LULA, ~~Elevator Mechanic~~ elevator mechanic for ~~Elevator Escalator Contracting~~ elevator escalator contracting and certification as a ~~Water Well Systems Provider~~ water well systems provider for ~~Water Well/Pump Contracting~~ water well/pump contracting.

d. Has obtained a lead supervisor license from the Virginia Board for Asbestos, Lead, and Home Inspectors for the lead abatement contracting specialty; an asbestos supervisor license from the Virginia Board for Asbestos, Lead, and Home Inspectors for the asbestos contracting specialty; and an onsite sewage systems professional installers license from the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals for the sewage disposal systems contracting specialty.

e. Has completed a board-approved examination for all other classifications and specialties that do not require other certification or licensure.

C. ~~The firm shall provide information for the past five years prior to application on any outstanding, past due debts and judgments; outstanding tax obligations; defaults on bonds; or pending or past bankruptcies. The firm and all members of the responsible management of the firm shall submit information on any past due debts and judgments or defaults on bonds directly related to the practice of contracting as defined in Chapter 11 (§ 54.1 1100 et seq.) of Title 54.1 of the Code of Virginia.~~ Each firm shall provide a credit report from a nationally recognized credit agency. The members of responsible management of the firm shall disclose information for the five years prior to the application on any outstanding past due debts or judgments, outstanding tax obligations, defaults on bonds related to the practice of contracting as defined in Chapter 11 (§ 54.1-1100 et seq.) of Title 54.1 of the Code of Virginia, or pending or past bankruptcies.

D. The firm and all members of the responsible management of the firm shall disclose at the time of application any current or previous contractor licenses held in Virginia or in other jurisdictions and any disciplinary actions taken on these licenses. This includes but is not limited to any monetary penalties, fines, suspensions, revocations, surrender of a license in connection with a disciplinary action, or voluntary termination of a license in Virginia or in any other jurisdiction.

E. In accordance with § 54.1-204 of the Code of Virginia, all applicants shall disclose the following information about the firm, all members of the responsible management, and the qualified individual or individuals for the firm:

1. All misdemeanor convictions within three years of the date of application; and

2. All felony convictions during their lifetimes.

Any plea of nolo contendere shall be considered a conviction for purposes of this subsection. The record of a conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt. The board, in its discretion, may deny licensure to any applicant in accordance with § 54.1-204 of the Code of Virginia.

F. A member of responsible management shall have successfully completed a board-approved basic business course.

G. The firm shall provide a copy of a government-issued photo identification for each member of responsible management and for each of the qualified individuals.

H. All members of responsible management and each qualified individual must sign the application.

18VAC50-22-50. Requirements for a Class B license.

A. A firm applying for a Class B license must meet the requirements of this section.

B. A firm shall name a designated employee who meets the following requirements:

1. Is at least 18 years old;

2. Is a ~~full-time employee of the firm as defined in this chapter, or is a member of responsible management as defined in this chapter~~ member of responsible management of the firm or is a full-time employee of the firm as verified by the submission of copies of an I-9, a W-4, insurance documents, or other documentation acceptable to the board;

3. Has passed a board-approved examination as required by § 54.1-1108 of the Code of Virginia or has been exempted from the exam requirement in accordance with § 54.1-1108.1 of the Code of Virginia; and

4. Has followed all rules established by the board or by the testing service acting on behalf of the board with regard to conduct at the examination. Such rules shall include any written instructions communicated prior to the examination date and any oral or written instructions given at the site on the date of the exam.

C. For every classification or specialty in which the firm seeks to be licensed, the firm shall name a qualified individual who meets the following requirements:

1. Is at least 18 years old;

2. Has a minimum of three years experience in the classification or specialty for which he is the qualifier verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board;

3. Is a ~~full-time employee of the firm as defined in this chapter or is a member of the responsible management of the firm~~ member of the responsible management of the firm or is a full-time employee of the firm as verified by the submission of copies of an I-9, a W-4, insurance documents, or other documentation acceptable to the board; and

4. a. Has obtained the appropriate certification for the following specialties:

Blast/explosive contracting (Department of Fire Programs explosive use certification)

Fire alarm (NICET level III or higher certification in fire protection: fire alarm systems or completion of a board-approved examination)

Fire sprinkler ~~(NICET Sprinkler III certification)~~ (NICET level III or higher certification in fire protection: water based systems layout or completion of a board-approved examination)

Manufactured home contracting (completion of a U.S. Department of Housing and Urban Development or Department of Housing and Community Development approved installers course)

Radon mitigation ~~(EPA or DEQ~~ (Virginia Department of Health accepted radon certification).

b. Has obtained, pursuant to the Individual Licensing and Certification Regulations (18VAC50-30), a master license for ~~Plumbing~~ plumbing, HVAC, ~~Electrical~~ electrical, ~~Gas Fitting~~ gas fitting, ~~Natural Gas Fitting Provider~~ natural gas fitting provider, and ~~Liquefied Petroleum Gas Contracting~~ liquefied petroleum gas contracting.

c. Has obtained, pursuant to the Individual Licensing and Certification Regulations, certification as an accessibility mechanic for accessibility services contracting, accessibility mechanic (LULA) for accessibility services contracting-LULA, ~~Elevator Mechanic~~ elevator mechanic for ~~Elevator Escalator Contracting~~ elevator escalator contracting and certification as a ~~Water Well Systems Provider~~ water well systems provider for ~~Water Well/Pump Contracting~~ water well/pump contracting.

d. Has obtained a lead supervisor license from the Virginia Board for Asbestos, Lead, and Home Inspectors for the lead abatement contracting specialty; an asbestos supervisor license from the Virginia Board for Asbestos, Lead, and Home Inspectors for the asbestos contracting specialty; and an onsite sewage systems professional installers license from the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals for the sewage disposal systems contracting specialty.

e. Has completed a board-approved examination for all other classifications and specialties that do not require other certification or licensure.

D. Each firm shall submit on a form provided by the board information on its financial position. ~~Excluding any property owned as tenants by the entirety, the firm shall state a net worth or equity of $15,000 or more.~~ Assets listed on this form must be verified as being titled or owned by the firm, and documentation must be less than 60 days old for liquid assets and less than one year old for fixed assets. Property owned or titled as tenants by the entirety shall not be included as an asset or liability. In lieu of this form, the firm may submit a review or an audit conducted by a certified public accountant in accordance with the provisions of the American Institute of Certified Public Accountants guidelines that was completed within one year of the date of application or the most recently filed U.S. Securities and Exchange Commission form 10-K. In order to qualify for a Class B license, the firm must have a net worth or equity of $15,000 or more.

E. Each firm shall provide ~~information for the five years prior to application on any outstanding, past due debts and judgments; outstanding tax obligations; defaults on bonds; or pending or past bankruptcies. The firm, its designated employee, and all members of the responsible management of the firm shall submit information on any past due debts and judgments or~~ a credit report from a nationally recognized credit agency. The members of responsible management of the firm shall disclose at the time of application information for the five years prior to the application on any outstanding, past due debts or judgments, outstanding tax obligations, defaults on bonds directly related to the practice of contracting as defined in Chapter 11 (§ 54.1-1100 et seq.) of Title 54.1 of the Code of Virginia, or pending or past bankruptcies.

F. The firm, the designated employee, and all members of the responsible management of the firm shall disclose at the time of application any current or previous substantial identities of interest with any contractor licenses issued in Virginia or in other jurisdictions and any disciplinary actions taken on these licenses. This includes but is not limited to any monetary penalties, fines, suspension, revocation, or surrender of a license in connection with a disciplinary action. The board, in its discretion, may deny licensure to any applicant when any of the parties listed above have had a substantial identity of interest (as deemed in § 54.1-1110 of the Code of Virginia) with any firm that has had a license suspended, revoked, voluntarily terminated or surrendered in connection with a disciplinary action in Virginia or any other jurisdiction.

G. In accordance with § 54.1-204 of the Code of Virginia, all applicants shall disclose the following information about the firm, designated employee, all members of the responsible management, and the qualified individual or individuals for the firm:

1. All misdemeanor convictions within three years of the date of application; and

2. All felony convictions during their lifetimes.

Any plea of nolo contendere shall be considered a conviction for purposes of this subsection. The record of a conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt. The board, in its discretion, may deny licensure to any applicant in accordance with § 54.1-204 of the Code of Virginia.

H. The designated employee or a member of responsible management shall have successfully completed a board-approved basic business course.

I. The firm shall provide a copy of a government-issued photo identification for each member of responsible management, for the designated employee, and for each of the qualified individuals.

J. All members of responsible management, the designated employee, and each qualified individual must sign the application.

18VAC50-22-60. Requirements for a Class A license.

A. A firm applying for a Class A license shall meet all of the requirements of this section.

B. A firm shall name a designated employee who meets the following requirements:

1. Is at least 18 years old;

2. Is a ~~full-time employee of the firm as defined in this chapter or is a~~ member of the responsible management of the firm ~~as defined in this chapter;~~ or is a full-time employee of the firm as verified by the submission of copies of an I-9, a W-4, insurance documents, or other documentation acceptable to the board;

3. Has passed a board-approved examination as required by § 54.1-1106 of the Code of Virginia or has been exempted from the exam requirement in accordance with § 54.1-1108.1 of the Code of Virginia; and

4. Has followed all rules established by the board or by the testing service acting on behalf of the board with regard to conduct at the examination. Such rules shall include any written instructions communicated prior to the examination date and any oral or written instructions given at the site on the day of the exam.

C. For every classification or specialty in which the firm seeks to be licensed, the firm shall name a qualified individual who meets the following requirements:

1. Is at least 18 years old;

2. Has a minimum of five years of experience in the classification or specialty for which he is the qualifier verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board;

3. Is a member of responsible management of the firm or full-time employee of the firm as ~~defined in this chapter or is a member of the firm as defined in this chapter or is a member of the responsible management of the firm;~~ verified by the submission of copies of an I-9, a W-4, insurance documents, or other documentation acceptable to the board; and

4. a. Has obtained the appropriate certification for the following specialties:

Blast/explosive contracting ~~(DHCD~~ (Department of Fire Programs explosive use certification)

Fire alarm (NICET level III or higher certification in fire protection: fire alarm systems or completion of a board-approved examination)

Fire sprinkler ~~(NICET Sprinkler III certification)~~ (NICET level III or higher certification in fire protection: water based systems layout or completion of a board-approved examination)

Manufactured home contracting (completion of a U.S. Department of Housing and Urban Development or Department of Housing and Community Development approved installers course)

Radon mitigation ~~(EPA or DEQ~~ (Virginia Department of Health accepted radon certification).

b. Has obtained, pursuant to the Individual Licensing and Certification Regulations (18VAC50-30), a master license for ~~Plumbing~~ plumbing, HVAC, ~~Electrical, Gas Fitting~~ electrical, gas fitting, ~~Natural Gas Fitting Provider~~ natural gas fitting provider, and ~~Liquefied Petroleum Gas Contracting~~ liquefied petroleum gas contracting.

c. Has obtained, pursuant to the Individual Licensing and Certification Regulations, certification as an accessibility mechanic for accessibility services contracting accessibility mechanic (LULA) for accessibility services contracting-LULA, ~~Elevator Mechanic~~ elevator mechanic for ~~Elevator Escalator Contracting~~ elevator escalator contracting and certification as a ~~Water Well Systems Provider~~ water well systems provider for ~~Water Well/Pump Contracting~~ water well/pump contracting.

d. Has obtained a lead supervisor license from the Virginia Board for Asbestos, Lead, and Home Inspectors for the lead abatement contracting specialty; an asbestos supervisor license from the Virginia Board for Asbestos, Lead, and Home Inspectors for the asbestos contracting specialty; and an onsite sewage systems professional installers license from the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System

Professionals for the sewage disposal systems contracting specialty.

e. Has completed a board-approved examination for all other classifications and specialties that do not require other certification or licensure.

D. Each firm shall submit on a form provided by the board information on its financial position. ~~Excluding any property owned as tenants by the entirety, the firm shall state a net worth or equity of $45,000.~~ Assets listed on this form must be verified as being titled or owned by the firm, and documentation must be less than 60 days old for liquid assets and less than one year old for fixed assets. Property owned or titled as tenants by the entirety shall not be included as an asset or liability. In lieu of this form, the firm may submit a review or an audit conducted by a certified public accountant in accordance with the provisions of the American Institute of Certified Public Accountants guidelines that was completed within one year of the date of application or the most recently filed U.S. Securities and Exchange Commission form 10-K. In order to qualify for a Class A license the firm must have a net worth or equity of $45,000 or more.

E. The firm shall provide ~~information for the five years prior to application on any outstanding, past due debts and judgments; outstanding tax obligations; defaults on bonds; or pending or past bankruptcies. The firm, its designated employee, and all members of the responsible management of the firm shall submit information on any past due debts and judgments or~~ a credit report from a nationally recognized credit agency. The members of responsible management of the firm shall disclose, at the time of application, information for the five years prior to the application on any outstanding, past due debts or judgments, outstanding tax obligations, defaults on bonds directly related to the practice of contracting as defined in Chapter 11 (§ 54.1-1100 et seq.) of Title 54.1 of the Code of Virginia, or pending or past bankruptcies.

F. The firm, the designated employee, and all members of the responsible management of the firm shall disclose at the time of application any current or previous substantial identities of interest with any contractor licenses issued in Virginia or in other jurisdictions and any disciplinary actions taken on these licenses. This includes but is not limited to, any monetary penalties, fines, suspensions, revocations, or surrender of a license in connection with a disciplinary action. The board, in its discretion, may deny licensure to any applicant when any of the parties listed above have had a substantial identity of interest (as deemed in § 54.1-1110 of the Code of Virginia) with any firm that has had a license suspended, revoked, voluntarily terminated, or surrendered in connection with a disciplinary action in Virginia or in any other jurisdiction.

G. In accordance with § 54.1-204 of the Code of Virginia, all applicants shall disclose the following information about the firm, all members of the responsible management, the designated employee and the qualified individual or individuals for the firm:

1. All misdemeanor convictions within three years of the date of application; and

2. All felony convictions during their lifetimes.

Any plea of nolo contendere shall be considered a conviction for purposes of this subsection. The record of a conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt. The board, in its discretion, may deny licensure to any applicant in accordance with § 54.1-204 of the Code of Virginia.

H. The designated employee or a member of responsible management shall have successfully completed a board-approved basic business course.

I. The firm shall provide a copy of a government-issued photo identification for each member of responsible management, for the designated employee, and for each of the qualified individuals.

J. All members of responsible management, the designated employee, and each qualified individual must sign the application.

18VAC50-22-220. Change of responsible management, designated employee, or qualified individual.

A. Any change in the officers of a corporation, managers of a limited liability company, or officers or directors of an association shall be reported ~~to the board in writing~~ on a form provided by the board within 90 days of the change. The new member of responsible management must provide the following:

1. A copy of a government-issued photo identification.

2. Information for the five years prior to the application on any outstanding past due debts or judgments, outstanding tax obligations, defaults on bonds related to the practice of contracting as defined in Chapter 11 (§ 54.1-1100 et seq.) of Title 54.1 of the Code of Virginia, or pending or past bankruptcies.

3. At the time of application, information regarding any current or previous contractor licenses held in Virginia or in other jurisdictions and any disciplinary actions taken on these licenses. This includes any monetary penalties, fines, suspensions, revocations, surrender of a license in connection with a disciplinary action, or voluntary termination of a license in Virginia or in any other jurisdiction.

4. In accordance with § 54.1-204 of the Code of Virginia, documentation of all misdemeanor convictions within three years of the date of the application and all felony convictions during his lifetime.

B. Any change of designated employee shall be reported on a form provided by the board within 90 days of the change. The new designated employee for a Class B licensee shall meet the requirements of 18VAC50-22-50 B. The new

designated employee for a Class A licensee shall meet the requirements of 18VAC50-22-60 B.

C. Any change of qualified individual shall be reported on a form provided by the board within 45 days of the change. The new qualified individual for a Class C licensee shall meet the requirements of 18VAC50-22-40 B. The new qualified individual for a Class B licensee shall meet the requirements of 18VAC50-22-50 C. The new qualified individual for a Class A licensee shall meet the requirements of 18VAC50-22-60 C.

18VAC50-22-230. Change of name or address.

A. A licensee must operate under the name in which the license is issued. Any name change shall be reported ~~in writing to the board~~ on a form provided by the board within 30 days of the change. The board shall not be responsible for the licensee's failure to receive notices or correspondence due to the licensee's not having reported a change of name.

B. Any change of the address of record or principal place of business shall be reported ~~in writing to the board~~ on a form provided by the board within 30 days of the change. The board shall not be responsible for the licensee's failure to receive notices or correspondence due to the licensee's not having reported a change of address.

18VAC50-22-310. Requirements for prelicense education providers.

A. Each provider of a prelicense education course shall submit an application for course approval on a form provided by the board. The application shall include but is not limited to:

1. The name of the provider;

2. Provider contact person, address and telephone number;

3. Course contact hours;

4. Schedule of courses, if established, including dates, time and locations;

5. Instructor information, including name, license ~~number(s)~~ number or numbers if applicable, and a list of other appropriate trade designations;

6. Course and material fees; and

7. Course syllabus.

B. All providers must establish and maintain a record for each student. The record shall include: the student's name and address; social security number or DMV control number; the course name and clock hours attended; the course syllabus or outline; the name or names of the instructor; the date of successful completion; and the board's course code. Records shall be available for inspection during normal business hours by authorized representatives of the board. Providers must maintain class records for a minimum of five years.

C. At least once every two calendar years, all providers must have at least one representative attend a monthly Board for Contractors remedial education course.

VA.R. Doc. No. R15-4414; Filed June 3, 2016, 9:55 a.m.

Proposed Regulation

Title of Regulation: **18VAC50-30. Individual License and Certification Regulations (amending 18VAC50-30-20, 18VAC50-30-30, 18VAC50-30-40).**

Statutory Authority: § 54.1-201 of the Code of Virginia.

Public Hearing Information:

July 11, 2016 - 10 a.m. - Commonwealth of Virginia Conference Center, Perimeter Center, 9960 Mayland Drive, Board Room 3, Richmond, VA 23233

Public Comment Deadline: August 26, 2016.

Agency Contact: Eric L. Olson, Executive Director, Board for Contractors, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-2785, FAX (866) 430-1033, or email contractors@dpor.virginia.gov.

Basis: Section 54.1-1102 of the Code of Virginia provides the authority for the Board for Contractors to promulgate regulations for the licensure of contractors in the Commonwealth. The content of the regulations is pursuant to the board's discretion, but shall not be in conflict with the purposes of the statutory authority.

Purpose: During the past 18 months, several instances involving the submission of false documentation, forged verification forms, and questionable identity have been brought to the attention of the Board for Contractors. The majority of these instances has resulted in disciplinary action being taken against the licensee or certificate holder, usually in the form of the revocation of the license or certificate, and a monetary sanction. To date nearly 100 such cases have been adjudicated by the board or are scheduled to be heard by the board, and there are more than 100 currently in the investigative stages.

A review of these cases has found that the board's current documentation requirements are insufficient to ensure that the information being provided by the applicant is valid. This includes, but is not limited to, verification of identification, experience documentation, determination of fiscal responsibility, and verification of employment status. The application process has been modified somewhat, in those areas that do not require an amendment of the regulations, but the board has identified other requirements that should be implemented to reduce the instances of application fraud.

The board is tasked with ensuring that individual licensees and certificate holders meet minimum competency standards to ensure that the public is protected from unqualified or incompetent individuals performing work that if done improperly can have a direct effect on the safety of the public. In order to ensure that these minimum standards are met it is critical that the documentation reviewed by the board to determine license and certification eligibility is accurate and trustworthy.

Substance: 18VAC50-30-20: The amendments clarify that the board may approve the applicant to take the applicable exam or issue the license or certificate.

18VAC50-30-30: The amendments add the requirement of submission of identification and a 2" x 2" photo deemed necessary by the board for proper identification of the applicant who is applying.

18VAC50-30-40: The amendments require submission of experience verification deemed necessary by the board to meet the statutory and regulatory requirements.

Issues: The primary advantage to the public is that the amendments help ensure that the license holders actually meet the minimum competency requirements to get a license, and the public can feel more confident that the license was not acquired fraudulently. The disadvantage to applicants applying for licenses is that they will need to provide licensing staff with more supporting paperwork.

The primary advantage to the agency is fewer investigations on license holders for acquiring the license fraudulently. The disadvantage to the agency is that the licensing staff will need to do more research before issuing a license.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. In order to increase the integrity of information provided as a part of tradesmen licensure/certification, the Board of Contractors (Board) proposes several new verification requirements for its individual tradesmen licensees/certificate holders.

Result of Analysis. Benefits likely outweigh costs for most proposed regulatory changes. For one proposed regulatory change, the benefits of the change could likely be ensured at a lower cost for regulated entities than would likely accrue under the current proposed language.

Estimated Economic Impact. Board staff reports that the Board is dealing with an increasing problem, over the last 18 months or so, involving the submission of false documentation, forged verification forms and questionable identity representations. Board staff reports that, to date, nearly 100 cases have been heard or are scheduled to be heard by the Board and that more than 100 additional cases are currently in some investigative stage.

To address these problems, the Board is proposing several new documentation requirements. The Board proposes that applicants for licensure or certification who are subject to experience requirements must have that experience verified by a building official, building inspector, registered design professional, a licensee of the Board or another regulatory agency or by any other individual/organization approved by the Board. Board staff reports that the Board is moving toward requiring that verification come from some licensed entity under some Board's authority because then the verifying entity can be disciplined if they falsely verify someone's experience. In most cases, this verification will be new. Applicants for journeyman or master status who are applying using 10 years of experience in a trade to qualify currently have to have their experience verified. Current regulation allows verification to come from the groups approved for verification in this proposed regulation plus former or current clients or former or current employers. While the proposed regulation allows the Board to approve additional entities (which may include current or former clients or employers on a case by case basis), some applicants may be worse off under the proposed regulation than they are under current the regulation which always allows them to use employer/client verification. All other applicants would likely incur only minimal copying and postage costs for meeting most of the Board's proposed requirements.

The Board also proposes that applicants for individual licensure be required to submit copies of a government issued ID and a 2 X 2 photograph that meets the requirements set forth by the U.S. Department of State for passports. These requirements include that the picture be:

1) In color,

2) Printed on matte or glossy photo quality paper,

3) 2 X 2 inches in size,

4) Sized such that the head is between 1" and 1 and 3/8" from the chin to the top of the head,

5) Taken within the last six months,

6) Taken in front of a white or off-white background,

7) Taken in full-face view looking directly at the camera, and

8) Taken with a neutral expression or a natural smile with both eyes open.

Board staff reports that the Board wants to require a government issued ID to verify the identity of the individuals who are submitting an application but that the Board also wants to require a photo that meets passport standards to 1) have an electronic copy of a photo for comparison with photos taken at exam sites during check-in and 2) because the Board is exploring the possibility of issuing photo licenses/certificates and requiring a passport compliant photo now will allow them to have photos to facilitate issuing such credentials. Board staff further reports that the Board will accept any photo that meets the State Department criteria. Assuming that individuals choose to take their own photos, they will incur likely fairly large time costs ensuring that their photo meets all criteria above and then will either have to print that photo in a standard available size (4 X 6 or 3 X 5, both available at most photo kiosks for less than 50 cents), and hand crop it while ensuring that head size in the photo matches requirements, or will have to pay to have 2 X 2 copies printed. Information found via internet search indicates that Walmart will print passport size photos from a customer's own electronic photo file for $7.44 per two photos (photos such as this can only be purchased in sets of two). Alternately, applicants can get a passport photo taken at a number of places including Walmart and Walgreens. Again

the photos are sold in sets of two and cost between $12 and $13.

While requiring individuals to submit a picture and ID with their application will likely decrease cases of applicants misrepresenting their identity or sending another individual to take their Board exam, it may not be the least costly way to affect that goal. Most people have a government issued photo ID, even if they do not have a driver's license, because they need a photo ID for many things (from proving identification when writing a check or using a credit card to voting). Just requiring a government issued ID that includes a photo would likely reduce the cost of complying with this proposed requirement. Also worth noting, the Board has not implemented photo license/certificates yet and it may be many months (or even years) before they can get such credentialing into place. As State Department rules require that a photo be taken within six months of its use, any delay in photo credentialing past a few months may see some applicants having to pay for and submit an additional photo when and if the Board changes licenses/certificates. While there is a very worthwhile benefit in the Board's efforts to curtail fraud, those benefits could likely be ensured at a lower cost for regulated entities by only requiring a government issued photo ID.

Finally, the Board is currently required to license/certify as a master any individual that successfully passed a Class A contractors trade examination prior to January 1, 1991. The Board proposes to change this so that they may issue a masters license or certificate only upon submission of verification of an individual's continuous work in the trade since he passed his exam. This change may mean fewer individuals in this category are able to obtain masters licensure/certification. To the extent that the contractors trade exam has undergone large changes in the information required to pass and to the extent that continuous or recent practice ensures competency, the benefits accrued by not licensing/certifying individuals who passed the exam approximately 25 years ago and who may not be competent to practice likely outweigh the costs for individuals who would have to meet current experience requirements and take an exam to get their masters designation.

Businesses and Entities Affected. Board staff reports that the Board received approximately 2,000 applications for licensure per year over the last five years. Some of these individuals may be (or may plan to be once licensed/certified) individual proprietor small businesses; some other of these individuals may work for small businesses that pay for their licensure.

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

Projected Impact on Employment. These proposed changes are unlikely to impact employment for any applicant tradesmen except those that are unable to legitimately provide the documentation that the Board proposes to require.

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

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

Small Businesses:

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

Costs and Other Effects. Small businesses that pay their applicant tradesmen's licensure/certification costs and fees, and individual applicant tradesmen who intend to be single proprietor small businesses once they are licensed or certified, will likely incur minimal costs to meet the Board's new verification requirements. These entities will likely also incur costs for meeting the proposed requirements for providing both a government issued ID and a State Department compliant passport size photo.

Alternative Method that Minimizes Adverse Impact. Costs for applicants could likely be decreased without decreasing benefits by requiring a copy of a government issued photo ID rather than requiring a government issued ID and a 2 X 2 photo.

Adverse Impacts:

Businesses. Businesses that pay their applicant tradesmen's Board costs and fees, and individual applicant tradesmen who intend to be single proprietor small businesses once they are licensed or certified, will likely incur minimal costs to meet the Board's new verification requirements. These entities will likely also incur costs for meeting the proposed requirements for providing both a government issued ID and a State Department compliant passport size photo.

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

Other Entities. Other entities in the Commonwealth are unlikely to suffer any adverse impacts on account of this regulatory action.

Agency's Response to Economic Impact Analysis: The Board for Contractors does not agree that the requirement to have an applicant provide a passport approved photograph would be overly burdensome or costly. The Department of Planning and Budget (DPB) indicates that the cost would be no greater than $13 or about 6.0% of the total cost of the application and examination ($130 and $85). The purpose of the passport photo is twofold: one to have an original photograph, not a scanned copy of a government identification (ID), for the purposes of ensuring exam site security; and secondly, to be incorporated into photographic licenses, which the board has indicated that it wishes to pursue. Scanned copies of

government IDs would not be acceptable for use to make photo licenses. While the statement that it may be months before the licenses are in place is certainly reasonable given the procurement process, the parenthetical that it may be years before they are implemented is not likely. Once the photo license program is initiated it will be much more economical to have a number of the photos already on file, where the board does not have to go through the time and expense to collect them.

With the exception of the statement that the requirement of passport photos may not be the most efficient way to achieve the benefits sought by the board, the agency concurs with the remainder of the economic impact analysis.

Summary:

The proposed amendments modify the documentation submitted as part of the application to verify requirements for experience level, education, and examination, including identification of the individual submitting the application, third party verification of experience, verification of education, and other requirements.

Part II
Entry

18VAC50-30-20. Requirements for licensure or certification.

Each applicant shall meet or exceed the requirements set forth in this section prior to issuance of the license or certification card.

The applicant shall be required to take an examination to determine his general knowledge of the regulated activity in which he desires licensure or certification. If the applicant successfully completes the examination, an application furnished by the department shall be completed. The application shall contain the applicant's name, home address, place of employment, and business address; information on the knowledge, skills, abilities, and education or training of the applicant; and a statement certifying that the information on the application is correct. If the application is satisfactory to the board, the applicant will be approved to take the applicable examination or a license or certification card shall be issued.

18VAC50-30-30. General qualifications for licensure or certification.

Every applicant to the Board for Contractors for licensure or certification shall meet the requirements and have the qualifications provided in this section.

1. The applicant shall be at least 18 years old.

2. Unless otherwise exempted, the applicant shall meet the current educational requirements by passing all required courses prior to the time the applicant sits for the examination and applies for licensure or certification.

3. Unless exempted, the applicant shall have passed the applicable examination provided by the board or by a testing organization acting on behalf of the board.

4. The applicant shall meet the experience requirements as set forth in 18VAC50-30-40.

5. In those instances where the applicant is required to take the license or certification examination, the applicant shall follow all rules established by the board with regard to conduct at the examination. Such rules shall include any written instructions communicated prior to the examination date and any instructions communicated at the site, either written or oral, on the date of the examination. Failure to comply with all rules established by the board and the testing organization with regard to conduct at the examination shall be grounds for denial of application.

6. ~~The~~ Each applicant shall (i) provide a copy of a government-issued identification, (ii) provide a 2 x 2-inch photograph that meets the requirements set forth by the U.S. Department of State for passports, and (iii) disclose his physical home address; a post office box alone is not acceptable.

7. Each nonresident applicant for a license or certification card shall file and maintain with the department an irrevocable consent for the department to serve as service agent for all actions filed in any court in this Commonwealth. In those instances where service is required, the director of the department will mail the court document to the individual at the address of record.

8. The applicant shall sign, as part of the application, a statement certifying that the applicant has read and understands Article 3 (§ 54.1-1128 et seq.) of Chapter 11 of Title 54.1 of the Code of Virginia and this chapter.

9. The board may make further inquiries and investigations with respect to the qualifications of the applicant or require a personal interview with the applicant.

10. In accordance with § 54.1-204 of the Code of Virginia, each applicant shall disclose a conviction, in any jurisdiction, of any misdemeanor or felony. Any plea of nolo contendere shall be considered a conviction for the purpose of this subdivision. The record of conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt. The board, at its discretion, may deny licensure or certification to any applicant in accordance with § 54.1-204 of the Code of Virginia.

11. The applicant shall report any suspensions, revocations, or surrendering of a certificate or license in connection with a disciplinary action or which has been the subject of discipline in any jurisdiction prior to applying for licensure or certification in Virginia. The board, at its discretion, may deny licensure or certification to any applicant based on prior suspensions, revocations, or surrender of

certifications or licenses based on disciplinary action by any jurisdiction.

18VAC50-30-40. Evidence of ability and proficiency.

A. Applicants for examination to be licensed as a journeyman shall furnish evidence that one of the following experience and education standards has been attained:

1. Four years of practical experience in the trade verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board and 240 hours of formal vocational training in the trade. Experience in excess of four years may be substituted for formal vocational training at a ratio of one year of experience for 80 hours of formal training, but not to exceed 200 hours;

2. Four years of practical experience verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board and 80 hours of vocational training for liquefied petroleum gas fitters and natural gas fitter providers except that no substitute experience will be allowed for liquefied petroleum gas and natural gas workers;

3. An associate degree or a certificate of completion from at least a two-year program in a tradesman-related field from an accredited community college or technical school as evidenced by a transcript from the educational institution and two years of practical experience in the trade for which licensure is desired verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board;

4. A bachelor's degree received from an accredited college or university in an engineering curriculum related to the trade and one year of practical experience in the trade for which licensure is desired verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board; or

5. An applicant with 10 years of practical experience in the trade, as verified by ~~reference letters of experience from any of the following: building officials, building inspectors, current or former employers, contractors, engineers, architects or current or past clients attesting to the applicant's work in the trade,~~ a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board, may be granted permission to sit for the journeyman's level examination without having to meet the educational requirements.

B. Applicants for examination to be licensed as a master shall furnish evidence that one of the following experience standards has been attained:

1. ~~Evidence that they have one year of experience as a licensed journeyman; or~~ Licensure as a journeyman in the applicable trade by the Board for Contractors for a period of a least one year; or

2. An applicant with 10 years of practical experience in the trade, as verified by ~~reference letters of experience from any of the following: building officials, building inspectors, current or former employers, contractors, engineers, architects or current or past clients, attesting to the applicant's work in the trade,~~ a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board, may be granted permission to sit for the master's level examination without having to meet the educational requirements.

C. Individuals who have successfully passed the Class A contractors trade examination prior to January 1, 1991, administered by the ~~Virginia~~ Board for Contractors in a certified trade ~~shall~~ may be deemed qualified as a master in that trade in accordance with this chapter upon submission of verification acceptable to the Board for Contractors or continuous work in the trade since the successful completion of the Class A contractors trade examination.

D. Applicants for examination to be certified as a backflow prevention device worker shall furnish evidence that one of the following experience and education standards has been attained:

1. Four years of practical experience in water distribution systems verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board and 40 hours of formal vocational training in a school approved by the board; or

2. Applicants with seven or more years of experience, as verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board, may qualify with 16 hours of formal vocational training in a school approved by the board.

The board accepts the American Society of Sanitary Engineers' (ASSE) standards for testing procedures. Other programs could be approved after board review. The board requires all backflow training to include instruction in a wet lab.

E. An applicant for certification as an elevator mechanic shall:

1. Have three years of practical experience in the construction, maintenance and service/repair of elevators, escalators, or related conveyances verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board; 144 hours of formal vocational training; and satisfactorily complete a written examination administered by the board. Experience in excess of four years may be substituted for formal vocational training at a ratio of one year of experience for 40 hours of formal training, but not to exceed 120 hours;

2. Have three years of practical experience in the construction, maintenance, and service/repair of elevators, escalators, or related conveyances verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board and a certificate of completion of the elevator mechanic examination of a training program determined to be equivalent to the requirements established by the board; or

3. Successfully complete an elevator mechanic apprenticeship program that is approved by the Virginia Apprenticeship Council or registered with the Bureau of Apprenticeship and Training, U.S. Department of Labor, as evidenced by providing a certificate of completion or other official document, and satisfactorily complete a written examination administered by the board.

F. Pursuant to § 54.1-1129.1 A of the Code of Virginia, an applicant for examination as a certified water well systems provider shall provide satisfactory proof to the board of at least:

1. One year of full-time practical experience in the drilling, installation, maintenance, or repair of water wells or water well systems under the supervision of a certified master water well systems provider or other equivalent experience as approved by the board to qualify for examination as a trainee water well systems provider;

2. Three years of practical experience in the drilling, installation, maintenance, or repair of water wells or water well systems under the supervision of a certified master water well systems provider or other equivalent experience as approved by the board and 24 hours of formal vocational training in the trade to qualify for examination as a journeyman water well systems provider; or

3. Six years of practical experience in the drilling, installation, maintenance, or repair of water wells or water well systems under the supervision of a certified master water well systems provider or other equivalent experience as approved by the board and 48 hours of formal vocational training in the trade to qualify for examination as a master water well systems provider.

G. An applicant for certification as an accessibility mechanic shall:

1. Have three years of practical experience in the construction, installation, maintenance, service, repair, and testing of wheelchair lifts, incline chairlifts, dumbwaiters, residential elevators, or related conveyances verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board; 80 hours of formal vocational training; and satisfactorily complete a written examination administered by the board. Experience in excess of four years may be substituted for formal vocational training at a ratio of one year of experience for 20 hours of formal training, but not to exceed 60 hours;

2. Have three years of practical experience in the construction, installation, maintenance, service, repair, and testing of wheelchair lifts, incline chairlifts, dumbwaiters, residential elevators, or related conveyances verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board and a certificate of completion of an accessibility mechanic examination of a training program determined to be equivalent to the requirements established by the board; or

3. Successfully complete an accessibility mechanic apprenticeship program that is approved by the Virginia Apprenticeship Council or registered with the Bureau of Apprenticeship and Training, U.S. Department of Labor, as evidenced by providing a certificate of completion or other official document, and satisfactorily complete a written examination administered by the board.

H. An applicant for a limited use/limited application (LULA) endorsement shall:

1. Hold a current certification as an accessibility mechanic issued by the board.

2. Have (i) one year of practical experience in the construction, installation, maintenance, service, repair, and testing of limited use/limited application elevators ~~and~~ verified by a building official, building inspector, registered design professional, licensee of the Board for Contractors, licensee of another regulatory agency, or other individual or organization approved by the board ~~complete~~; (ii) completed a vocational education program approved by the board; and (iii) either satisfactorily ~~complete~~ completed a written examination administered by the board; or ~~complete~~ completed a limited use/limited application elevator training program determined to be equivalent to the requirements established by the board.

VA.R. Doc. No. R15-4415; Filed June 3, 2016, 9:56 a.m.

BOARD OF MEDICINE

Final Regulation

Title of Regulation: **18VAC85-20. Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (amending 18VAC85-20-320, 18VAC85-20-340, 18VAC85-20-350, 18VAC85-20-370, 18VAC85-20-380).**

Statutory Authority: §§ 54.1-2400 and 54.1-2912.1 of the Code of Virginia.

Effective Date: July 27, 2016.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4621, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

Summary:

The amendments (i) define the administration of 300 milligrams or more of lidocaine as moderate sedation; (ii) address informed consent by patients, including knowledge about whether the physician is board certified or board eligible; (iii) require documentation of complications during surgery or recovery; (iv) establish a time limit on procedures that may be performed in an office setting; (v) address proximity to a hospital to which a patient may be transferred; and (vi) specify that the anesthesia provider or the doctor supervising the anesthesia must give the order for discharge.

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

18VAC85-20-320. General provisions.

A. Applicability of requirements for office-based anesthesia.

1. The administration of topical anesthesia, local anesthesia, minor conductive blocks, or minimal sedation/anxiolysis, not involving a drug-induced alteration of consciousness other than minimal preoperative tranquilization, is not subject to the requirements for office-based anesthesia in this part. A health care practitioner administering such agents shall adhere to an accepted standard of care as appropriate to the level of anesthesia or sedation, including evaluation, drug selection, administration, and management of complications.

2. The administration of moderate sedation/conscious sedation, deep sedation, general anesthesia, or regional anesthesia consisting of a major conductive block [~~are~~ is] subject to these requirements for office-based anesthesia in this part. The administration of 300 milligrams or more of lidocaine or equivalent doses of local anesthetics shall be deemed to be subject to these requirements for office-based anesthesia in this part.

3. Levels of anesthesia or sedation referred to in this chapter shall relate to the level of anesthesia or sedation intended and documented by the practitioner in the preoperative anesthesia plan.

B. A doctor of medicine, osteopathic medicine, or podiatry administering office-based anesthesia or supervising such administration shall:

1. Perform a preanesthetic evaluation and examination or ensure that it has been performed;

2. Develop the anesthesia plan or ensure that it has been developed;

3. Ensure that the anesthesia plan has been discussed with the patient or responsible party preoperatively and informed consent has been obtained;

4. Ensure patient assessment and monitoring through the ~~pre-, peri-~~ preprocedure, periprocedure, and post-procedure phases, addressing not only physical and functional status, but also physiological and cognitive status;

5. Ensure provision of indicated post-anesthesia care; ~~and~~

6. Remain physically present or immediately available, as appropriate, to manage complications and emergencies until discharge criteria have been met; and

7. Document any complications occurring during surgery or during recovery in the medical record.

C. All written policies, procedures, and protocols required for office-based anesthesia shall be maintained and available for inspection at the facility.

18VAC85-20-340. Procedure/anesthesia selection and patient evaluation.

A. A written protocol shall be developed and followed for procedure selection to include but not be limited to:

1. The doctor providing or supervising the anesthesia shall ensure that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.

2. The procedure or combined procedures shall be of a duration and degree of complexity that shall not exceed four hours and that will permit the patient to recover and be discharged from the facility in less than 24 hours. The procedure or combined procedures may be extended for up to eight hours if the anesthesia is provided by an anesthesiologist or a certified registered nurse [~~anesthesist~~ anesthetist].

3. The level of anesthesia used shall be appropriate for the patient, the surgical procedure, the clinical setting, the education and training of the personnel, and the equipment available. The choice of specific anesthesia agents and techniques shall focus on providing an anesthetic that will be effective~~,~~ and appropriate and will address the specific needs of patients while also ensuring rapid recovery to normal function with maximum efforts to control post-operative pain, nausea, or other side effects.

B. A written protocol shall be developed for patient evaluation to include but not be limited to:

1. The preoperative anesthesia evaluation of a patient shall be performed by the health care practitioner administering the anesthesia or supervising the administration of anesthesia. It shall consist of performing an appropriate history and physical examination, determining the patient's physical status classification, developing a plan of anesthesia care, acquainting the patient or the responsible individual with the proposed plan, and discussing the risks and benefits.

2. The condition of the patient, specific morbidities that complicate anesthetic management, the specific intrinsic risks involved, and the nature of the planned procedure shall be considered in evaluating a patient for office-based anesthesia.

3. Patients who have pre-existing medical or other conditions that may be of particular risk for complications shall be referred to a facility appropriate for the procedure and administration of anesthesia. Nothing relieves the licensed health care practitioner of the responsibility to make a medical determination of the appropriate surgical facility or setting.

C. Office-based anesthesia shall only be provided for patients in physical status classifications for Classes I, II and III. Patients in Classes IV and V shall not be provided anesthesia in an office-based setting.

18VAC85-20-350. Informed consent.

A. Prior to administration, the anesthesia plan shall be discussed with the patient or responsible party by the health care practitioner administering the anesthesia or supervising the administration of anesthesia. Informed consent for the nature and objectives of the anesthesia planned shall be in writing and obtained from the patient or responsible party before the procedure is performed. Such consent shall include a discussion of discharge planning and what care or assistance the patient is expected to require after discharge. Informed consent shall only be obtained after a discussion of the risks, benefits, and alternatives, contain the name of the anesthesia provider, and be documented in the medical record.

B. The surgical consent forms shall be executed by the patient or the responsible party and shall contain a statement that the doctor performing the surgery is board certified or board eligible by one of the American Board of Medical Specialties boards, the Bureau of Osteopathic Specialists of the American Osteopathic Association, or the American Board of Foot and Ankle Surgery. The forms shall either list which board or contain a statement that doctor performing the surgery is not board certified or board eligible.

C. The surgical consent forms shall indicate whether the surgery is elective or medically necessary. If a consent is obtained in an emergency, the surgical consent form shall indicate the nature of the emergency.

18VAC85-20-370. Emergency and transfer protocols.

A. There shall be written protocols for handling emergency situations, including medical emergencies and internal and external disasters. All personnel shall be appropriately trained in and regularly review the protocols and the equipment and procedures for ~~handing~~ handling emergencies.

B. There shall be written protocols for the timely and safe transfer of patients to a prespecified hospital or hospitals within a reasonable proximity. For purposes of this section, "reasonable proximity" shall mean that a licensed general hospital capable of providing necessary services is normally accessible within 30 minutes of the office. There shall be a written or electronic transfer agreement with such hospital or hospitals.

18VAC85-20-380. Discharge policies and procedures.

A. There shall be written policies and procedures outlining discharge criteria. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting.

B. Discharge from anesthesia care is the responsibility of the health care practitioner providing or the doctor supervising the anesthesia care and shall only occur when ~~patients have~~:

1. The patient has met specific physician-defined criteria; and

2. The health care practitioner providing or the doctor supervising the anesthetic care has given the order for discharge.

C. Written instructions and an emergency phone number shall be provided to the patient. Patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

D. At least one person trained in advanced resuscitative techniques shall be immediately available until all patients are discharged.

VA.R. Doc. No. R15-01; Filed June 3, 2016, 2:59 p.m.

BOARD OF PHARMACY

Fast-Track Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-540).**

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

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: July 27, 2016.

Effective Date: August 11, 2016.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4416, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia provides the Board of Pharmacy the authority to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) that are reasonable and necessary to administer effectively the regulatory system.

Purpose: The purpose of the planned regulatory action is to address an urgent problem. Omnicare, a CVS Health Company, provides long-term care pharmacy services to a diverse population of skilled nursing patients in Virginia to include subacute care for children. Specifically, the children in these facilities suffer from complex physical and neurological diseases and experience frequent seizures. As a result, nurses assigned to these pediatric units need immediate access to diazepam rectal gel in their emergency boxes. Limiting the access to this critical medication will most certainly threaten a successful patient outcome up to and including the survival of the patient. Unfortunately, current pharmacy regulation 18VAC110-20-550 does not allow a CIV rectal gel to be included in the contents allowed in the emergency box. The company requested the amendment to allow pharmacists to meet the needs of this fragile population. The request for limited access to the drug was approved to protect the health and safety of patients in a long-term care facility. Because 18VAC110-20-590 authorizes correctional facilities that employ one or more full-time physicians, nurses, or physician assistants to obtain an emergency kit in accordance with 18VAC110-20-540, patients in correctional facilities may also benefit from the inclusion of this drug in an emergency kit.

Rationale for Using Fast-Track Rulemaking Process: This action will not be controversial as it is limited to making a small dosage of a drug that can be lifesaving available in an emergency situation.

Substance: 18VAC110-20-540 is amended to allow a provider pharmacist, in consultation with medical and nursing staff, to include diazepam rectal gel in an emergency kit maintained in a long-term care facility. The amendment will also allow inmates in correctional facilities to potentially benefit from inclusion of this drug since 18VAC110-20-590 allows for an emergency kit under certain circumstances, consistent with 18VAC110-20-540.

Issues: The advantage to the public is availability of a drug that may be lifesaving to a small group of patients. There are no disadvantages to the public. There are no advantages or disadvantages to the agency.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Pharmacy (Board) proposes to amend this regulation to allow a provider pharmacist, in consultation with medical and nursing staff, to include diazepam rectal gel in an emergency kit maintained in a long-term care facility.

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

Estimated Economic Impact. The Regulations Governing the Practice of Pharmacy specify that pharmacists may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber under certain conditions.[1] The current regulation limits the contents of the kit to "drugs for administration by injection or inhalation only, except that Nitroglycerin SL may be included." The Board proposes to additionally allow diazepam rectal gel in the kit. Diazepam rectal gel is used in emergency situations to stop cluster seizures (episodes of increased seizure activity) in people who are taking other medications to treat epilepsy (seizures).[2]

Children and adults in long-term care facilities who suffer from complex physical and neurological diseases and experience frequent seizures would benefit from having immediate access to diazepam rectal gel in the facilities' emergency boxes. Under the current regulation the gel can only be obtained by prescription as needed. The proposed amendment will be beneficial in that it will likely help improve patient outcomes for patients having seizures by allowing for immediate access to the gel. Since the regulation authorizes correctional facilities that employ one or more full-time physicians, nurses, or physician assistants to obtain an emergency kit in accordance with the regulation, patients in correctional facilities may also benefit from the inclusion of this drug in an emergency kit. Since there is no apparent cost to the proposed amendment, the proposed addition of diazepam rectal gel to the allowable contents of emergency kits for long-term facilities creates a net benefit.

Businesses and Entities Affected. The proposed amendment potentially affects 162 skilled nursing facilities in the Commonwealth,[3] as well as correctional facilities.

Localities Particularly Affected. The proposed amendment does not disproportionately affect particular localities.

Projected Impact on Employment. The proposed amendment does not significantly affect employment.

Effects on the Use and Value of Private Property. The proposed amendment does not have significant effect on the use and value of private property.

Real Estate Development Costs. The proposed amendment does not affect real estate development costs.

Small Businesses:

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

Costs and Other Effects. The proposed amendment does not significantly affect costs for small businesses.

Alternative Method that Minimizes Adverse Impact. The proposed amendment does not adversely affect small businesses.

Adverse Impacts:

Businesses. The proposed amendment does not adversely affect businesses.

Localities. The proposed amendment does not adversely affect localities.

Other Entities. The proposed amendment does not adversely affect other entities.

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[1]http://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section540/

[2]Source: U.S. National Library of Medicine (https://www.nlm.nih.gov/medlineplus/druginfo/meds/a605033.html)

[3]The number of affected facilities was estimated by Omnicare, a CVS Health Company, which supplies the facilities.

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the analysis of the Department of Planning and Budget on proposed amended regulations for 18VAC110-20, Regulations Governing the Practice of Pharmacy.

Summary:

The amendments allow a provider pharmacist, in consultation with medical and nursing staff, to include diazepam rectal gel in an emergency kit maintained in a long-term care facility.

18VAC110-20-540. Emergency drug kit.

The pharmacist providing services may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.

2. The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.

3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.

a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication ~~and/or,~~ resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of ~~item(s)~~ items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

VA.R. Doc. No. R16-4671; Filed June 3, 2016, 4:25 p.m.

BOARD OF SOCIAL WORK

Fast-Track Regulation

Title of Regulation: **18VAC140-20. Regulations Governing the Practice of Social Work (amending 18VAC140-20-40, 18VAC140-20-45, 18VAC140-20-50 through 18VAC140-20-70, 18VAC140-20-110, 18VAC140-20-150, 18VAC140-20-160).**

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

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: July 27, 2016.

Effective Date: August 12, 2016.

Agency Contact: Jaime Hoyle, Executive Director, Board of Social Work, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4406, FAX (804) 527-4435, or email jaime.hoyle@dhp.virginia.gov.

Basis: Regulations are promulgated under the general authority of § 54.1-2400 of the Code of Virginia, which provides the Board of Social Work the authority to promulgate regulations to administer the regulatory system.

Purpose: The goals of the regulatory action are to address issues and a lack of clarity with some of the licensure requirements. More explicit but less restrictive application requirements may facilitate licensure for some clinical social workers who can provide mental health services in Virginia, but the requirement for a report from the national practitioner databank will ensure that applicants with a history of disciplinary action or malpractice will be carefully scrutinized before a licensure decision is made. Likewise, clarification of the regulations for supervised experience will ensure that supervisees are appropriately supervised in the provision of clinical services and therefore offer more protection for clients and the general public.

Rationale for Using Fast-Track Rulemaking Process: The amendments adopted are requested by the professional society, clarifying and intended to resolve issues with regulations, or are less restrictive for applicants and licensees. The amendments should not be controversial.

Substance: Licensure regulations are amended for (i) clarification of application requirements and inclusion of a requirement for submission of a current report from the national practitioner data bank about the disciplinary and malpractice history of the applicant; (ii) a reduction in the years of active practice required for endorsement or reinstatement; (iii) less restrictive and confusing requirement for hours of face-to-face client contact during supervision, for acceptance of supervision obtained in another U.S. jurisdiction, and fewer years of post-licensure experience required to be a supervisor; (iv) clarification about the requirement for registration of supervision whenever there is a change that affects the experience approved by the board; (v) more specificity about a request for extension of supervised practice and about the responsibilities of the supervisor; and (vi) clarification that the grounds for disciplinary action apply to registered supervisees as well as licensees.

Issues: The primary advantages to the public are greater clarity about the responsibilities of supervisees and supervisors so persons receiving social work services, especially those that are clinical in nature, have more assurance of appropriateness and competency. Additionally, a less stringent practice requirement may enable a few clinical social workers to qualify for licensure by endorsement or reinstatement; there are no disadvantages to the public.

The primary advantage to the agency is more clarity in regulation, which reduces questions and confusion; there are no disadvantages.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Social Work (Board) proposes to amend its regulation to: 1) require applicants for licensure to submit a current malpractice and disciplinary history report from the National Practitioner Data Bank, 2) decrease the number of months of active practice required to qualify for licensure by endorsement, 3) make rules for hours of face-to-face client contact during supervision, and for supervision in general, less restrictive and complicated and 4) clarify that disciplinary rules apply to registered supervisees as well as Board licensees.

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

Estimated Economic Impact. Current regulation requires applicants for licensure to submit varying types of documents/information depending on whether the applicant is seeking licensure by examination or licensure by endorsement. The Board proposes to require applicants on both licensure paths to additionally submit a current report from the U.S. Department of Health and Human Services National Practitioner Data Bank that will show their malpractice and disciplinary history (if any). This report will cost applicants $5 and is not duplicative of other information that is already required. Requiring this report will allow the Board to weed out potential licensees that might do harm to their future clients if licensed in Virginia. Given this, the benefits of requiring this report likely outweigh the costs of doing so.

Current regulation requires, in two of its experience options, that applicants for licensure by endorsement provide evidence of active practice for 36 of the 60 months immediately preceding application for licensure. The Board now proposes to lower this requirement so that applicants meeting one of these options will only have to have actively practiced for 24 of the preceding 60 months. This change will still allow the Board assurance that the applicant has practiced for a substantial period of time without issues while allowing a greater number of social workers from other states to qualify for licensure in Virginia. This will likely benefit those individuals as well as providing more choices to Virginians seeking these licensed services.

Currently, the Board requires individuals who are completing the supervised practice necessary for licensure to, among other things, 1) get pre-approval of supervision (so that supervision will count toward licensure requirements), 2) complete 15 hours of face-to-face client contact per 40 hours of work experience, 3) complete all supervised experience in the delivery of clinical social work services and 4) complete all required supervised work experience within four years unless the Board approves an extension for the supervisee. The Board currently requires supervisors to have at least three years of post-licensure work experience. In order to both simplify these rules and make them less restrictive, the Board proposes to 1) allow an exception for Board pre-approval of supervision for individuals who obtained their supervised work experience in another U.S. state or territory and met the requirements of that jurisdiction, 2) be less proscriptive about the ratio of face-to-face contact hours to total supervised experience by only specifying that face-to-face contact hours must be obtained throughout the hours of supervision, 3) allow supervised experience in ancillary services that support the delivery of clinical social work services to also count toward supervision requirements and 4) specify that supervisees may obtain an extension of 12 months to complete supervised experience requirements. The Board also proposes to only require licensees to have completed two (rather than three) years of post-licensure work experience in order to qualify to provide supervision. Taken together all of these changes will tend to make the rules of supervision easier to understand and easier to meet. Both supervisors and supervisees will benefit from these changes. In particular, decreasing the number of years of post-licensure work experience required will allow more licensees to qualify as supervisors which will, in turn, make it easier for individuals working to meet licensure requirements to find a supervisor. Allowing supervision completed in other U.S. jurisdictions to count toward licensure requirements will likely allow more individuals moving into the state to qualify for licensure more

quickly (as they would not have to re-do supervised experience already obtained in another state).

In addition to these substantive changes, the Board also proposes to clarify that supervisees, as individuals regulated by the Board, are also subject to Board discipline. Toward this end, the Board proposes to add supervisees to the disciplinary rule that discourages licensees from treating individuals with whom they have another pre-existing relationship so that supervisees know that they are also expected to follow this rule. No entity is likely to incur costs on account of this change. To the extent that this change reinforces to supervisees that they should not engage in dual relationships, this change will provide a benefit to those supervisees.

Businesses and Entities Affected. Board staff reports that the Board currently licenses 5,933 clinical social workers and 581 social workers. Additionally, the Board currently has 1,459 registered supervisees. All of these entities, as well as any future licensees and supervisees, will be affected by these regulatory changes. Based on survey data collected by the Healthcare Workforce Data Center at the Department of Health Professions, approximately 38% of clinical social workers (approximately 2,255 of the currently licensed clinical social workers) are in solo or group private practice and would likely qualify as small businesses.

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

Projected Impact on Employment. Requiring fewer months of active practice for licensure by endorsement may make a greater number of social workers and clinical social workers who have practiced in other states eligible for licensure in Virginia.

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

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

Small Businesses:

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

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

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

Adverse Impacts:

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

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

Other Entities. Individuals seeking licensure in the Commonwealth as social workers and clinical social workers will incur an additional $5 fee for obtaining a current malpractice and disciplinary history report from the National Practitioner Data Bank.

Agency's Response to Economic Impact Analysis. The Board of Social Work concurs with the economic impact analysis of the Department of Planning and Budget.

Summary:

The amendments (i) clarify application requirements and include a requirement for submission of a current report from the National Practitioner Data Bank about the disciplinary and malpractice history of the applicant; (ii) reduce the years of active practice required for endorsement or reinstatement; (iii) clarify and reduce a requirement for hours of face-to-face client contact during supervision, for acceptance of supervision obtained in another U.S. jurisdiction, and for years of post-licensure experience required to be a supervisor; (iv) clarify the requirement for registration of supervision whenever there is a change that affects the experience approved by the board; (v) specify requirements for a request for extension of supervised practice and the responsibilities of the supervisor; and (vi) clarify that the grounds for disciplinary action apply to registered supervisees as well as licensees.

Part II

Requirements for Licensure

18VAC140-20-40. Requirements for licensure by examination as a licensed clinical social worker.

Every applicant for examination for licensure as a licensed clinical social worker shall:

1. Meet the education requirements prescribed in 18VAC140-20-49 and experience requirements prescribed in 18VAC140-20-50.

2. Submit a completed application to the board office to include:

a. Documentation, on the appropriate forms, of the successful completion of the supervised experience requirements of 18VAC140-20-50 along with documentation of the supervisor's out-of-state license where applicable. Applicants whose former supervisor is deceased, or whose whereabouts is unknown, shall submit to the board a notarized affidavit from the present chief executive officer of the agency, corporation or partnership in which the applicant was supervised. The

affidavit shall specify dates of employment, job responsibilities, supervisor's name and last known address, and the total number of hours spent by the applicant with the supervisor in face-to-face supervision;

b. The application fee prescribed in 18VAC140-20-30;

c. Official transcript or documentation submitted from the appropriate institutions of higher education that verifies successful completion of educational requirements set forth in 18VAC140-20-49; ~~and~~

d. Documentation of ~~applicant's out-of-state~~ any other health or mental health licensure or certification ~~where~~, if applicable; and

e. A current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB).

3. Provide evidence of passage of the examination prescribed in 18VAC140-20-70. ~~If the examination was not passed within five years preceding application for licensure, the applicant may qualify by documentation of providing clinical social work services in an exempt setting for at least 360 hours per year for two of the past five years.~~

18VAC140-20-45. Requirements for licensure by endorsement.

A. Every applicant for licensure by endorsement shall submit in one package:

1. A completed application and the application fee prescribed in 18VAC140-20-30.

2. Documentation of active social work licensure in good standing obtained by standards required for licensure in another jurisdiction as verified by the out-of-state licensing agency ~~on a board-approved form~~. Licensure in the other jurisdiction shall be of a comparable type as the licensure that the applicant is seeking in Virginia.

3. Verification of a passing score on a board-approved national exam at the level for which the applicant is seeking licensure in Virginia.

4. Documentation of any other health or mental health licensure or certification, if applicable.

5. A current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB).

~~4.~~ 6. Verification of ~~active~~:

a. Active practice at the level for which the applicant is seeking licensure in another United States jurisdiction ~~or practice~~ for 24 out of the past 60 months;

b. Active practice in an exempt setting at the level for which the applicant is seeking licensure for ~~36~~ 24 out of the past 60 months; or ~~evidence~~

c. Evidence of supervised experience requirements substantially equivalent to those outlined in 18VAC140-20-50 A 2 and A 3 and 18VAC140-20-60 C 2 and C 3.

~~5.~~ 7. Certification that the applicant is not the respondent in any pending or unresolved board action in another jurisdiction or in a malpractice claim.

B. If an applicant for licensure by endorsement has not passed a board-approved national examination at the level for which the applicant is seeking licensure in Virginia, the board may approve the applicant to sit for such examination.

18VAC140-20-50. Experience requirements for a licensed clinical social worker.

A. Supervised experience. Supervised post-master's degree experience ~~in all settings obtained in Virginia~~ without prior written board approval will not be accepted toward licensure, except supervision obtained in another United States jurisdiction may be accepted if it met the requirements of that jurisdiction.

1. Registration. An individual who proposes to obtain supervised post-master's degree experience in Virginia shall, prior to the onset of such supervision:

a. Register on a form provided by the board and completed by the supervisor and the supervised individual; and

b. Pay the registration of supervision fee set forth in 18VAC140-20-30.

2. Hours. The applicant shall have completed a minimum of 3,000 hours of supervised post-master's degree experience in the delivery of clinical social work services and in ancillary services that support such delivery. A minimum of one hour and a maximum of four hours of face-to-face supervision shall be provided per 40 hours of work experience for a total of at least 100 hours. No more than 50 of the 100 hours may be obtained in group supervision, nor shall there be more than six persons being supervised in a group unless approved in advance by the board. The board may consider alternatives to face-to-face supervision if the applicant can demonstrate an undue burden due to hardship, disability or geography.

a. ~~Experience~~ Supervised experience shall be acquired in no less than two nor more than four consecutive years.

b. Supervisees shall ~~average no less than 15 hours per 40 hours of work experience in face-to-face client contact for~~ obtain throughout their hours of supervision a minimum of 1,380 hours of supervised experience in face-to-face client contact in the delivery of clinical social work services. The remaining hours may be spent in ancillary services supporting the delivery of clinical social work services.

3. An individual who does not complete the supervision requirement after four consecutive years of supervised experience ~~shall submit evidence to the board showing why the training should be allowed to continue~~ may request an extension of up to 12 months. The request for an extension shall include evidence that demonstrates

extenuating circumstances that prevented completion of the supervised experience within four consecutive years.

B. Requirements for supervisors.

1. The supervisor shall hold an active, unrestricted license as a licensed clinical social worker in the jurisdiction in which the clinical services are being rendered with at least ~~three~~ two years of post-licensure clinical social work experience. The board may consider supervisors with commensurate qualifications if the applicant can demonstrate an undue burden due to geography or disability or if supervision was obtained in another United States jurisdiction.

2. The supervisor shall have received professional training in supervision, consisting of a three credit-hour graduate course in supervision or at least 14 hours of continuing education offered by a provider approved under 18VAC140-20-105. The graduate course or hours of continuing education in supervision shall be obtained by a supervisor within five years immediately preceding registration of supervision.

3. The supervisor shall not provide supervision for a family member ~~of his immediate family~~ or provide supervision for anyone with whom he has a dual relationship.

4. The board may consider supervisors from jurisdictions outside of Virginia who provided clinical social work supervision if they have commensurate qualifications but were either (i) not licensed because their jurisdiction did not require licensure or (ii) were not designated as clinical social workers because the jurisdiction did not require such designation.

C. Responsibilities of supervisors. The supervisor shall:

1. Be responsible for the social work activities of the supervisee as set forth in this subsection once the supervisory arrangement is accepted;

2. Review and approve the diagnostic assessment and treatment plan of a representative sample of the clients assigned to the applicant during the course of supervision. The sample should be representative of the variables of gender, age, diagnosis, length of treatment and treatment method within the client population seen by the applicant. It is the applicant's responsibility to assure the representativeness of the sample that is presented to the supervisor;

3. Provide supervision only for those social work activities for which the supervisor has determined the applicant is competent to provide to clients;

4. Provide supervision only for those activities for which the supervisor is qualified by education, training and experience;

5. Evaluate the supervisee's knowledge and document minimal competencies in the areas of an identified theory base, application of a differential diagnosis, establishing and monitoring a treatment plan, development and appropriate use of the professional relationship, assessing the client for risk of imminent danger, understanding the requirements of law for reporting any harm or risk of harm to self or others, and implementing a professional and ethical relationship with clients;

6. Be available to the applicant on a regularly scheduled basis for supervision; ~~and~~

7. Maintain documentation, for five years post-supervision, of which clients were the subject of supervision; and

8. Ensure that the board is notified of any change in supervision or if supervision has ended or been terminated by the supervisor.

D. Responsibilities of supervisees.

1. Supervisees may not directly bill for services rendered or in any way represent themselves as independent, autonomous practitioners, or licensed clinical social workers.

2. During the supervised experience, supervisees shall use their names and the initials of their degree, and the title "Supervisee in Social Work" in all written communications.

3. Clients shall be informed in writing of the supervisee's status and the supervisor's name, professional address, and phone number.

4. Supervisees shall not supervise the provision of clinical social work services provided by another person.

18VAC140-20-51. Requirements for licensure by examination as a licensed social worker.

A. In order to be approved to sit for the board-approved examination for a licensed social worker, an applicant shall:

1. Meet the education requirements prescribed in 18VAC140-20-60 A.

2. Submit a completed application to the board office to include:

a. The application fee prescribed in 18VAC140-20-30; and

b. Official transcript or transcripts submitted from the appropriate institutions of higher education.

B. In order to be licensed by examination as a licensed social worker, an applicant shall:

1. Meet the education and experience requirements prescribed in 18VAC140-20-60; and

2. Submit, in addition to the application requirements of subsection A of this section, the following:

a. Documentation, on the appropriate forms, of the successful completion of the supervised experience requirements of 18VAC140-20-60 along with documentation of the supervisor's out-of-state license where applicable. An applicant whose former supervisor is deceased, or whose whereabouts is unknown, shall submit to the board a notarized affidavit from the present

chief executive officer of the agency, corporation or partnership in which the applicant was supervised. The affidavit shall specify dates of employment, job responsibilities, supervisor's name and last known address, and the total number of hours spent by the applicant with the supervisor in face-to-face supervision;

b. Verification of a passing score on the board-approved national examination; ~~and~~

c. Documentation of ~~applicant's out of state~~ any other health or mental health licensure or certification ~~where~~, if applicable; and

d. A current report from the U.S. Department of Health and Human Services National Practitioner Data Bank (NPDB).

3. Provide evidence of passage of the examination prescribed in 18VAC140-20-70. ~~If the examination was not passed within five years preceding application for licensure, the applicant may qualify by documentation of providing social work services in an exempt setting for at least 360 hours per year for two of the past five years.~~

18VAC140-20-60. Education and experience requirements for a licensed social worker.

A. Education. The applicant shall hold a bachelor's or a master's degree from an accredited school of social work. Graduates of foreign institutions must establish the equivalency of their education to this requirement through the Foreign Equivalency Determination Service of the Council on Social Work Education.

B. Master's degree applicant. An applicant who holds a master's degree may apply for licensure as a licensed social worker without documentation of supervised experience.

C. ~~Bachelor's degree applicant~~ Supervised experience requirement. Supervised experience ~~in all settings obtained in Virginia~~ without prior written board approval will not be accepted toward licensure, except supervision obtained in another United States jurisdiction may be accepted if it met the requirements of that jurisdiction.

1. Registration. Prior to the onset of supervision, an individual who proposes to obtain supervised experience in Virginia shall:

a. Register on a form provided by the board and completed by the supervisor and the supervised individual; and

b. Pay the registration of supervision fee set forth in 18VAC140-20-30.

~~1.~~ 2. Hours. Bachelor's degree applicants shall have completed a minimum of 3,000 hours of supervised post-bachelor's degree experience in casework management and supportive services under supervision satisfactory to the board. A minimum of one hour and a maximum of four hours of face-to-face supervision shall be provided per 40 hours of work experience for a total of at least 100 hours.

~~2. Experience~~ 3. Supervised experience shall be acquired in no less than two nor more than four consecutive years from the beginning of the supervised experience. An individual who does not complete the supervision requirement after four consecutive years of supervised experience may request an extension of up to 12 months. The request for an extension shall include evidence that demonstrates extenuating circumstances that prevented completion of the supervised experience within four consecutive years.

D. Requirements for supervisors.

1. The supervisor providing supervision shall hold an active, unrestricted license as a licensed social worker with a master's degree, or a licensed social worker with a bachelor's degree and at least three years of post-licensure social work experience or a licensed clinical social worker in the jurisdiction in which the social work services are being rendered. If this requirement places an undue burden on the applicant due to geography or disability, the board may consider individuals with comparable qualifications.

2. The supervisor shall:

a. Be responsible for the social work practice of the prospective applicant once the supervisory arrangement is accepted by the board;

b. Review and approve the assessment and service plan of a representative sample of cases assigned to the applicant during the course of supervision. The sample should be representative of the variables of gender, age, assessment, length of service and casework method within the client population seen by the applicant. It is the applicant's responsibility to assure the representativeness of the sample that is presented to the supervisor. The supervisor shall be available to the applicant on a regularly scheduled basis for supervision. The supervisor will maintain documentation, for five years post supervision, of which clients were the subject of supervision;

c. Provide supervision only for those casework management and support services activities for which the supervisor has determined the applicant is competent to provide to clients;

d. Provide supervision only for those activities for which the supervisor is qualified; ~~and~~

e. Evaluate the supervisee in the areas of professional ethics and professional competency; and

f. Ensure that the board is notified of any change in supervision or if the supervision has ended or has been terminated by the supervisor.

3. ~~Supervision between members of the immediate family (to include spouses, parents, and siblings) will not be approved~~ The supervisor shall not provide supervision for a family member or provide supervision for anyone with whom the supervisor has a dual relationship.

Part III
Examinations

18VAC140-20-70. Examination requirement.

A. An applicant for licensure by the board as a social worker or clinical social worker shall pass a written examination prescribed by the board.

1. The examination prescribed for licensure as a clinical social worker shall be the licensing examination of the Association of Social Work Boards at the clinical level.

2. The examination prescribed for licensure as a social worker shall minimally be the licensing examination of the Association of Social Work Boards at the bachelor's level.

B. A candidate approved by the board to sit for an examination shall take that examination within two years of the date of the initial board approval. If the candidate has not passed the examination by the end of the two-year period here prescribed, the applicant shall reapply according to the requirements of the regulations in effect at that time. After an applicant has failed the examination twice, he shall be required to register for supervision and complete one additional year as a supervisee before approval to re-take the examination is granted.

18VAC140-20-110. Late renewal; reinstatement; reactivation.

A. A social worker or clinical social worker whose license has expired may renew that license within one year after its expiration date by:

1. Providing evidence of having met all applicable continuing education requirements.

2. Paying the penalty for late renewal and the renewal fee as prescribed in 18VAC140-20-30.

B. A social worker or clinical social worker who fails to renew the license after one year and who wishes to resume practice shall apply for reinstatement and pay the reinstatement fee, which shall consist of the application processing fee and the penalty fee for late renewal, as set forth in 18VAC140-20-30. An applicant for reinstatement shall also provide documentation of having completed all applicable continued competency hours equal to the number of years the license has lapsed, not to exceed four years. An applicant for reinstatement shall also provide evidence of competency to practice by documenting:

1. Active practice in another ~~U.S.~~ United States jurisdiction for at least ~~three of the past five years~~ 24 out of the past 60 months immediately preceding application;

2. Active practice in an exempt setting for at least ~~three of the past five years~~ 24 out of the past 60 months immediately preceding application; or

3. Practice as a supervisee under supervision for at least 360 hours in the 12 months immediately preceding licensure in Virginia.

C. A social worker or clinical social worker wishing to reactivate an inactive license shall submit the renewal fee for active licensure minus any fee already paid for inactive licensure renewal~~,~~ and document completion of continued competency hours equal to the number of years the license has been inactive, not to exceed four years. An applicant for reactivation who has been inactive for four or more years shall also provide evidence of competency to practice by documenting:

1. Active practice in another ~~U.S.~~ United States jurisdiction for at least ~~three of the past five years~~ 24 out of the past 60 months immediately preceding application;

2. Active practice in an exempt setting for at least ~~three of the past five years~~ 24 out of the past 60 months immediately preceding application; or

3. Practice as a supervisee under supervision for at least 360 hours in the 12 months immediately preceding licensure in Virginia.

Part V
Standards of Practice

18VAC140-20-150. Professional conduct.

A. The protection of the public health, safety, and welfare and the best interest of the public shall be the primary guide in determining the appropriate professional conduct of all persons whose activities are regulated by the board. Regardless of the delivery method, whether in person, by telephone or electronically, these standards shall apply to the practice of social work.

B. Persons licensed as social workers and clinical social workers shall:

1. Be able to justify all services rendered to or on behalf of clients as necessary for diagnostic or therapeutic purposes.

2. Provide for continuation of care when services must be interrupted or terminated.

3. Practice only within the competency areas for which they are qualified by education and experience.

4. Report to the board known or suspected violations of the laws and regulations governing the practice of social work.

5. Neither accept nor give commissions, rebates, or other forms of remuneration for referral of clients for professional services.

6. Ensure that clients are aware of fees and billing arrangements before rendering services.

7. Inform clients of potential risks and benefits of services and the limitations on confidentiality and ensure that clients have provided informed written consent to treatment.

8. Keep confidential their therapeutic relationships with clients and disclose client records to others only with written consent of the client, with the following

exceptions: (i) when the client is a danger to self or others; or (ii) as required by law.

9. When advertising their services to the public, ensure that such advertising is neither fraudulent nor misleading.

10. As treatment requires and with the written consent of the client, collaborate with other health or mental health providers concurrently providing services to the client.

11. Refrain from undertaking any activity in which one's personal problems are likely to lead to inadequate or harmful services.

12. Recognize conflicts of interest and inform all parties of the nature and directions of loyalties and responsibilities involved.

C. In regard to client records, persons licensed by the board shall comply with provisions of § 32.1-127.1:03 of the Code of Virginia on health records privacy and shall:

1. Maintain written or electronic clinical records for each client to include identifying information and assessment that substantiates diagnosis and treatment plans. Each record shall include a diagnosis and treatment plan, progress notes for each case activity, information received from all collaborative contacts and the treatment implications of that information, and the termination process and summary.

2. Maintain client records securely, inform all employees of the requirements of confidentiality, and provide for the destruction of records that are no longer useful in a manner that ensures client confidentiality.

3. Disclose or release records to others only with clients' expressed written consent or that of their legally authorized representative or as mandated by law.

4. Ensure confidentiality in the usage of client records and clinical materials by obtaining informed consent from clients or their legally authorized representative before (i) videotaping, (ii) audio recording, (iii) permitting third-party observation, or (iv) using identifiable client records and clinical materials in teaching, writing or public presentations.

5. Maintain client records for a minimum of six years or as otherwise required by law from the date of termination of the therapeutic relationship with the following exceptions:

a. At minimum, records of a minor child shall be maintained for six years after attaining the age of majority or 10 years following termination, whichever comes later.

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

c. Records that have been transferred to another mental health professional or have been given to the client or his legally authorized representative.

D. In regard to dual relationships, persons licensed by the board shall:

1. Not engage in a dual relationship with a client or a ~~former client~~ supervisee that could impair professional judgment or increase the risk of exploitation or harm to the client or supervisee. (Examples of such a relationship include, but are not limited to, familial, social, financial, business, bartering, or a close personal relationship with a client or supervisee.) Social workers shall take appropriate professional precautions when a dual relationship cannot be avoided, such as informed consent, consultation, supervision, and documentation to ensure that judgment is not impaired and no exploitation occurs.

2. Not have any type of romantic relationship or sexual intimacies with a client or those included in collateral therapeutic services, and not provide services to those persons with whom they have had a romantic or sexual relationship. Social workers shall not engage in romantic relationship or sexual intimacies with a former client within a minimum of five years after terminating the professional relationship. Social workers who engage in such a relationship after five years following termination shall have the responsibility to examine and document thoroughly that such a relationship did not have an exploitive nature, based on factors such as duration of therapy, amount of time since therapy, termination circumstances, client's personal history and mental status, adverse impact on the client. A client's consent to, initiation of or participation in sexual behavior or involvement with a social worker does not change the nature of the conduct nor lift the regulatory prohibition.

3. Not engage in any romantic or sexual relationship or establish a therapeutic relationship with a current supervisee or student. Social workers shall avoid any nonsexual dual relationship with a supervisee or student in which there is a risk of exploitation or potential harm to the supervisee or student, or the potential for interference with the supervisor's professional judgment.

4. Recognize conflicts of interest and inform all parties of the nature and directions of loyalties and responsibilities involved.

5. Not engage in a personal relationship with a former client in which there is a risk of exploitation or potential harm or if the former client continues to relate to the social worker in his professional capacity.

E. Upon learning of evidence that indicates a reasonable probability that another mental health provider is or may be guilty of a violation of standards of conduct as defined in statute or regulation, persons licensed by the board shall advise their clients of their right to report such misconduct to the Department of Health Professions in accordance with § 54.1-2400.4 of the Code of Virginia.

18VAC140-20-160. Grounds for disciplinary action or denial of issuance of a license or registration.

The board may refuse to admit an applicant to an examination; refuse to issue a license or registration to an

applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke a license or registration for one or more of the following grounds:

1. Conviction of a felony or of a misdemeanor involving moral turpitude;

2. Procurement of license by fraud or misrepresentation;

3. Conducting one's practice in such a manner so as to make the practice a danger to the health and welfare of one's clients or to the public. In the event a question arises concerning the continued competence of a licensee, the board will consider evidence of continuing education.

4. Being unable to practice social work with reasonable skill and safety to clients by reason of illness, excessive use of alcohol, drugs, narcotics, chemicals or any other type of material or as a result of any mental or physical condition;

5. Conducting one's practice in a manner contrary to the standards of ethics of social work or in violation of 18VAC140-20-150, standards of practice;

6. Performing functions outside the board-licensed area of competency;

7. Failure to comply with the continued competency requirements set forth in 18VAC140-20-105; ~~and~~

8. Violating or aiding and abetting another to violate any statute applicable to the practice of social work or any provision of this chapter; and

9. Failure to provide supervision in accordance with the provisions of 18VAC140-20-50 or 18VAC140-20-60.

VA.R. Doc. No. R16-4473; Filed June 3, 2016, 4:27 p.m.

BOARD OF VETERINARY MEDICINE

Final Regulation

Title of Regulation: **18VAC150-20. Regulations Governing the Practice of Veterinary Medicine (amending 18VAC150-20-130; adding 18VAC150-20-173).**

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

Effective Date: July 27, 2016.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Veterinary Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4468, FAX (804) 527-4471, or email leslie.knachel@dhp.virginia.gov.

Summary:

The amendments (i) remove the requirement that a veterinary college student be in the final year of training to engage in a preceptorship or externship; (ii) require that whenever a veterinary preceptee or extern is performing surgery, the supervising veterinarian shall be in the operatory; and (iii) require disclosure whenever a veterinary preceptee or extern is practicing in the veterinary establishment.

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

18VAC150-20-130. Requirements for practical training in a preceptorship or externship.

A. The practical training and employment of qualified students of veterinary medicine or veterinary technology shall be governed and controlled as follows:

1. A veterinary student who is duly enrolled and in good standing in a veterinary college or school accredited or approved by the AVMA ~~and in the final year of his training or after completion of an equivalent number of hours as approved by the board~~ may be engaged in a preceptorship or externship. A veterinary preceptee or extern may perform duties that constitute the practice of veterinary medicine for which he has received adequate instruction by the college or school and only under the on-premises supervision of a licensed veterinarian.

2. A veterinary technician student who is duly enrolled and in good standing in a veterinary technology program accredited or approved by the AVMA may be engaged in a preceptorship or externship. A veterinary technician preceptee or extern may perform duties that constitute the practice of veterinary technology for which he has received adequate instruction by the program and only under the on-premises supervision of a licensed veterinarian or licensed veterinary technician.

B. Whenever a veterinary preceptee or extern is performing surgery on a patient, either assisted or unassisted, the supervising veterinarian shall be in the operatory during the procedure. Prior to allowing a preceptee or extern in veterinary medicine to perform surgery on a patient unassisted by a licensed veterinarian, a licensed veterinarian shall receive written approval from the ~~client~~ owner.

C. When there is a preceptee or extern practicing in the establishment, the supervising veterinarian shall disclose such practice to owners. The disclosure shall be by signage clearly visible to the public or by inclusion on an informed consent form.

D. A veterinarian or veterinary technician who supervises a preceptee or extern remains responsible for the care and treatment of the patient.

18VAC150-20-173. Informed consent for surgery.

A. Before surgery is performed, informed consent shall be obtained from the owner and documented in the patient record. Veterinarians shall inform an owner of the risks, benefits, and alternatives of the recommended surgery that a reasonably prudent practitioner in similar practice in Virginia would tell an owner.

B. An exception to the requirement for consent prior to performance of surgery may be made in an emergency

situation when a delay in obtaining consent would likely result in imminent harm to the patient.

C. If a veterinary student is to perform the surgery, the informed consent shall include that information.

VA.R. Doc. No. R14-14; Filed June 3, 2016, 3:02 p.m.

Final Regulation

Title of Regulation: **18VAC150-20. Regulations Governing the Practice of Veterinary Medicine (amending 18VAC150-20-10, 18VAC150-20-140).**

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

Effective Date: July 27, 2016.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Veterinary Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4468, FAX (804) 527-4471, or email leslie.knachel@dhp.virginia.gov.

Summary:

The amendments (i) define a specialist as a veterinarian who has been awarded and has maintained the status of diplomate of a specialty organization recognized by the American Board of Veterinary Specialties of the American Veterinary Medical Association, or any other organization approved by the board, and (ii) provide that representing oneself as a specialist without meeting that definition or representing a practice as a specialty practice without having a specialist on staff is unprofessional conduct.

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

Part I
General Provisions

18VAC150-20-10. Definitions.

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

"Animal shelter" means a facility, other than a private residential dwelling and its surrounding grounds, that is used to house or contain animals and that is owned, operated, or maintained by a nongovernmental entity including, but not limited to, a humane society, animal welfare organization, society for the prevention of cruelty to animals, or any other organization operating for the purpose of finding permanent adoptive homes for animals.

"Automatic emergency lighting" is lighting that is powered by battery, generator, or alternate power source other than electrical power, is activated automatically by electrical power failure, and provides sufficient light to complete surgery or to stabilize the animal until surgery can be continued or the animal moved to another establishment.

"AVMA" means the American Veterinary Medical Association.

"Board" means the Virginia Board of Veterinary Medicine.

"Companion animal" means any dog, cat, horse, 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 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 purposes of this chapter.

"CVMA" means the Canadian Veterinary Medical Association.

"Full-service establishment" means a stationary or ambulatory facility that provides surgery and encompasses all aspects of health care for small or large animals, or both.

"Immediate and direct supervision" means that the licensed veterinarian is immediately available to the licensed veterinary technician or assistant, either electronically or in person, and provides a specific order based on observation and diagnosis of the patient within the last 36 hours.

"Owner" means any person who (i) has a right of property in an animal; (ii) keeps or harbors an animal; (iii) has an animal in his care; or (iv) acts as a custodian of an animal.

"Pound" means a facility operated by the state or a locality for the purpose of impounding or harboring seized, stray, homeless, abandoned, or unwanted animals; or a facility operated for the same purpose under a contract with a locality or an incorporated society for the prevention of cruelty to animals.

"Preceptorship or externship" means a formal arrangement between an AVMA accredited college of veterinary medicine or an AVMA accredited veterinary technology program and a veterinarian who is licensed by the board and responsible for the practice of the preceptee. A preceptorship or externship shall be overseen by faculty of the college or program.

"Professional judgment" includes any decision or conduct in the practice of veterinary medicine, as defined by § 54.1-3800 of the Code of Virginia.

"Restricted service establishment" means a stationary or ambulatory facility which does not meet the requirements of a full-service establishment.

"Specialist" means a veterinarian who has [~~completed the requirements to become a~~ been awarded and has maintained the status of] diplomate of a specialty organization recognized by the American Board of Veterinary Specialties of the American Veterinary Medical Association, or any other organization approved by the board.

"Surgery" means treatment through revision, destruction, incision or other structural alteration of animal tissue. Surgery does not include dental extractions of single-rooted teeth or skin closures performed by a licensed veterinary technician upon a diagnosis and pursuant to direct orders from a veterinarian.

"Veterinarian in charge" means a veterinarian who holds an active license in Virginia and who is responsible for maintaining a veterinary establishment within the standards set by this chapter, for complying with federal and state laws and regulations, and for notifying the board of the establishment's closure.

"Veterinary establishment" means any fixed or mobile practice, veterinary hospital, animal hospital or premises wherein or out of which veterinary medicine is being conducted.

Part III
Unprofessional Conduct

18VAC150-20-140. Unprofessional conduct.

Unprofessional conduct as referenced in subdivision 5 of § 54.1-3807~~(5)~~ of the Code of Virginia shall include the following:

1. Representing conflicting interests except by express consent of all concerned given after a full disclosure of the facts. Acceptance of a fee from both the buyer and the seller is prima facie evidence of a conflict of interest.

2. Practicing veterinary medicine or equine dentistry where an unlicensed person has the authority to control the professional judgment of the licensed veterinarian or the equine dental technician.

3. Issuing a certificate of health unless he shall know of his own knowledge by actual inspection and appropriate tests of the animals that the animals meet the requirements for the issuance of such certificate on the day issued.

4. Revealing confidences gained in the course of providing veterinary services to a client, unless required by law or necessary to protect the health, safety or welfare of other persons or animals.

5. Advertising in a manner which is false, deceptive, or misleading or which makes subjective claims of superiority.

6. Violating any state law, federal law, or board regulation pertaining to the practice of veterinary medicine, veterinary technology or equine dentistry.

7. Practicing veterinary medicine or as an equine dental technician in such a manner as to endanger the health and welfare of his patients or the public, or being unable to practice veterinary medicine or as an equine dental technician with reasonable skill and safety.

8. Performing surgery on animals in an unregistered veterinary establishment or not in accordance with the establishment permit or with accepted standards of practice.

9. Refusing the board or its agent the right to inspect an establishment at reasonable hours.

10. Allowing unlicensed persons to perform acts restricted to the practice of veterinary medicine, veterinary technology or an equine dental technician including any invasive procedure on a patient or delegation of tasks to persons who are not properly trained or authorized to perform such tasks.

11. Failing to provide immediate and direct supervision to a licensed veterinary technician or an assistant in his employ.

12. Refusing to release a copy of a valid prescription upon request from a client.

13. Misrepresenting or falsifying information on an application or renewal form.

14. Failing to report suspected animal cruelty to the appropriate authorities.

15. Failing to release patient records when requested by the owner; a law-enforcement entity; or a federal, state, or local health regulatory agency.

16. Committing an act constituting fraud, deceit, or misrepresentation in dealing with the board or in the veterinarian-client-patient relationship.

17. Representing oneself as a "specialist" without meeting the definition set forth in 18VAC150-20-10 or using the words "specialist" or "specialty" in the name of a veterinary establishment unless there is a veterinarian on staff who meets the definition of a "specialist."

VA.R. Doc. No. R15-16; Filed June 3, 2016, 3:02 p.m.

BOARD FOR WASTE MANAGEMENT FACILITY OPERATORS

Final Regulation

Title of Regulation: **18VAC155-20. Waste Management Facility Operators Regulations (amending 18VAC155-20-10, 18VAC155-20-40, 18VAC155-20-110, 18VAC155-20-120, 18VAC155-20-130, 18VAC155-20-140, 18VAC155-20-160, 18VAC155-20-220, 18VAC155-20-230, 18VAC155-20-280; adding 18VAC155-20-235, 18VAC155-20-285; repealing 18VAC155-20-20, 18VAC155-20-30, 18VAC155-20-100, 18VAC155-20-150, 18VAC155-20-175).**

Statutory Authority: §§ 54.1-201 and 54.1-2211 of the Code of Virginia.

Effective Date: August 1, 2016.

Agency Contact: Eric L. Olson, Executive Director, Board for Waste Management Facility Operators, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8511, FAX (866) 430-1033, or email wastemgt@dpor.virginia.gov.

Summary:

The amendments (i) eliminate language that is duplicative of the Code of Virginia or board agreements, clarify existing sections, and consolidate duplicative sections; (ii) require that applicants for licensure follow the rules of facilities where they take their licensure exams; and (iii) simplify eligibility requirements by eliminating the application fee for training course approval, the

requirement that applicants for licensure who have failed the written examination twice recomplete all initial training, and the requirement that applicants for initial licensure have successfully completed high school or a college degree program or have received a generalized equivalency diploma.

Summary of Public Comments and Agency's Response: No public comments were received by the promulgating agency.

Part I
General

18VAC155-20-10. Definitions.

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

~~*~~"Board" means the Board for Waste Management Facility Operators.

[~~"Board-approved training course" means a course that has been approved by the board to provide appropriate training to an applicant in accordance with this chapter.~~]

"Class I license" means the authorization from the board to act as a waste management facility operator of a transfer station, a material recovery facility receiving mixed waste, an experimental facility, or a composting facility receiving yard waste.

"Class II license" means the authorization from the board to act as a waste management facility operator of a facility that composts municipal solid waste, a sanitary landfill, an industrial landfill, a construction landfill or a debris landfill.

"Class III license" means the authorization from the board to act as a waste management facility operator of an infectious waste incinerator or autoclave.

"Class IV license" means the authorization from the board to act as a waste management facility operator of a municipal waste combustor.

~~"Closed facility" means a solid waste management facility that has been properly secured in accordance with an approved facility closure plan.~~

~~"Closure" means an act of securing a solid waste management facility pursuant to the requirements established by the Virginia Department of Environmental Quality or appropriate regulatory authority.~~

"Contact hour" means 50 minutes of participation in a group program or 60 minutes of completion time for a project.

~~"Continuing professional education/training (CPE/T)" means an integral part of the lifelong learning process that enables a licensed solid waste management facility operator to maintain and increase the competence required to assure the public's protection, which shall be pursued through an organized program or project in compliance with this chapter.~~

"Department" means the Department of Professional and Occupational Regulation.

"Full-time employment" means 1,760 hours per year or 220 work days per year.

[~~"In charge" means the designation of any person by the owner to have duty and authority to operate or modify the operation of a waste management facility.~~]

"License" means an authorization issued by the board to an individual to practice as a waste management facility operator who meets the provisions of this chapter.

"Municipal solid waste ~~(MSW)~~" means that waste that is defined as "municipal solid waste" in [~~9VAC20-80-10~~ 9VAC20-81-10].

"Municipal waste combustor" means a mass burn or a refuse derived fuel incinerator or facility designed or modified for the purpose of noninfectious solid waste combustion.

"Operation" means any waste management facility that is under construction, treating, processing, storing or disposing of solid waste, or in the act of securing a facility for closure [as defined in 9VAC20-81-10].

"Organized program" means a formal learning process designed to permit a participant to learn a given subject or subjects through interaction with an instructor in a formal course, seminar or conference [as approved by the board].

"Owner" means the person who owns a solid waste management facility or part of a solid waste management facility.

~~*"Person" means an individual, corporation, partnership, association, governmental body, municipal corporation or any other legal entity.~~

[~~"Project" means a learning process designed to permit a participant to perform work assigned by the owner, operator or manager of a waste management facility under the supervision of a knowledgeable person that results in a specific, predetermined end result and that increases the participant's competence to practice as a waste management facility operator.~~

~~"Site" means within the vicinity of all land and structures, other appurtenances, and improvements thereon used for treating, storing, and disposing of solid waste. This term includes adjacent land within the property boundary used for the utility systems such as repair, storage, shipping or processing areas, or other areas incident to the management of solid waste.~~]

"Solid waste" means any of those materials [~~defined~~ identified] as nonhazardous solid waste in [~~regulations promulgated by the Virginia Department of Environmental Quality~~ 9VAC20-81-95].

[~~"Storage" means housing a solid waste as consistent with the regulations of the Virginia Waste Management Board.~~

~~"Substantial change" means a deviation from a specific course that decreases the approved time of the course by more than 30 minutes or modifies the topics of the approved course~~

~~to below the target levels of knowledge, as stated in the course application.~~]

~~*"Waste management facility" means a site used for planned treatment, storage, or disposal of nonhazardous solid waste.~~

~~*"Waste management facility operator" means any person, including an owner, who is in charge of the actual, on site operation of a waste management facility during any period of operation.~~

~~*As defined by Chapter 22.1 (§ 54.1 2209 et seq.) of Title 54.1 of the Code of Virginia.~~

18VAC155-20-20. ~~License required.~~ (Repealed.)

~~For the purposes of this chapter, the individual acting as a waste management facility operator is an individual employed or contracted by the facility owner whose responsibilities include supervision of on site activities and who, on and after January 1, 1993, has been licensed by the Board for Waste Management Facility Operators or is under the direct supervision of a waste management facility operator licensed by the Board for Waste Management Facility Operators.~~

18VAC155-20-30. ~~Disclosure.~~ (Repealed.)

~~A. Any individual seeking licensure shall disclose on the application any other operator or related license issued by any other state(s).~~

~~B. Any individual seeking licensure shall disclose on the application any felony convictions or any final order actions issued by an administrative body or court regarding environmental violations or crimes resulting in the significant harm or the imminent and substantial threat of significant harm to human health or the environment.~~

~~C. Each licensee shall notify the board in writing within 30 days of any felony convictions or final order actions issued by an administrative body or court regarding environmental violations or crimes resulting in the significant harm or the imminent and substantial threat of significant harm to human health or the environment.~~

18VAC155-20-40. Fees.

A. All fees are nonrefundable and shall not be prorated.

B. An application shall not be deemed complete and shall not be processed without the required fee.

1. The application fee for licensure shall be $75.

2. The fee for renewal of licensure shall be $50.

3. The fee for late renewal of licensure shall be $75.

4. The fee for reinstatement of licensure shall be $125.

5. The examination fee is charged to the applicant by an outside vendor competitively negotiated and contracted for in compliance with the Virginia Public Procurement Act (§ 2.2-4300 et seq. of the Code of Virginia). Fees may be adjusted and charged to the applicant in accordance with this contract.

~~6. The application fee for training course approval shall be $125.~~

C. All checks shall be made payable to the Treasurer of Virginia.

D. Receipt and deposit of fees submitted with applications do not indicate licensure.

Part II
Licensure

18VAC155-20-100. ~~Licensure required.~~ (Repealed.)

~~Licensure is required for all individuals acting as waste management facility operators after June 30, 1995.~~

18VAC155-20-110. License classification.

A. The applicant shall apply for at least one classification of license as outlined [~~below~~ in this subsection]:

1. An individual operating a facility that is defined [~~by the Department of Environmental Quality~~ in 9VAC20-81-10] as a transfer station, a [~~material~~ materials] recovery facility receiving mixed waste, an experimental facility, or a composting facility receiving yard waste shall hold a Class I license. An individual who has obtained a Class II, III or IV license may also operate a facility listed under Class I [~~, if the individual has completed the board-approved basic training course~~].

2. An individual operating a facility that composts municipal solid waste, or is defined [~~by the Department of Environmental Quality~~ in 9VAC20-81-10] as a sanitary [landfill], industrial [waste landfill], [~~construction or debris~~ constuction/demolition/debris (CDD)] landfill, shall hold a Class II license.

3. An individual operating a facility [~~defined by the Department of Environmental Quality as an infectious waste incinerator or an autoclave~~ regulated under 9VAC20-120, Regulated Medical Waste Management Regulations,] shall hold a Class III license.

4. An individual operating a facility defined [~~by the Department of Environmental Quality~~ in 9VAC5-40-6560] as a municipal waste [~~combustor~~ combustion unit] shall hold a Class IV license.

B. A licensee may not operate a facility outside of his classification other than that defined by subdivision A 1 of this section.

C. An individual operating a solid waste management facility that has been issued a permit by the Department of Environmental Quality but for which the board has not established training and licensure requirements shall hold a Class I license until the board establishes the training and licensing requirements by regulation.

18VAC155-20-120. Qualifications for licensure.

~~A. The board shall issue a license only after an individual has met, through a completed application and addendum, all training, testing, and experience requirements for at least one specific class as set forth in this chapter.~~

~~B. The applicant shall meet the following requirements for licensure for all classes of licenses:~~

A. Every applicant to the Board for Waste Management Facility Operators for licensure shall meet the requirements and have the qualifications provided in this subsection.

1. The applicant shall be at least 18 years of age.

~~2. The applicant shall provide proof of high school or college graduation, or of having a General Equivalency Diploma (GED).~~

~~3. An applicant who cannot fulfill the requirement outlined in subdivision 2 of this subsection shall document at least five years of verified experience with a waste management facility during the preceding seven years, with at least three years of experience in at least one of the following activities:~~

~~a. Supervision;~~

~~b. Research;~~

~~c. Construction;~~

~~d. Project development;~~

~~e. Site development;~~

~~f. Compliance and enforcement of a permit or regulations;~~

~~g. Operation; or~~

~~h. Review of materials for permitting purposes.~~

~~4. Except for applicants that qualify pursuant to subdivision 3 of this subsection, each applicant shall document one year of verified operational experience with a waste management facility.~~

~~5. All applicants shall successfully complete the basic training course as defined in 18VAC155-20-220 B.~~

~~6. An applicant may use employment responsibilities in lieu of facility specific training as defined in subsections D through F of this section provided that:~~

~~a. The applicant has been a full-time employee at a waste facility specific to the desired license classification for at least three of the past seven years.~~

~~b. The employment responsibilities include at least one of those activities enumerated in subdivision 3 of this subsection.~~

~~7. Experience requirements claimed on the application for licensure shall be verified by the individual's supervisor(s) or personnel officer. Individuals who are under contract with a facility owner may obtain a letter from the facility owner to verify experience.~~

~~8. Education requirements claimed on the application for licensure shall be verified by the attendee's educational institution or authorizing jurisdiction on the provided form or in the form of an official transcript or letter. Diplomas will not be accepted for verification of degree or graduation.~~

~~9. The applicant holding a valid license from another state or jurisdiction may qualify by reciprocity under the provisions of 18VAC155-20-150.~~

~~C. The specific requirements for Class I licensure are as follows:~~

~~1. Complete a board-approved basic training course; and~~

~~2. Pass the board-approved examination for Class I.~~

~~D. The specific requirements for Class II licensure are as follows:~~

~~1. Complete a board-approved basic training course and an approved training course specific to Class II facilities; and~~

~~2. Pass the board-approved examination for Class II.~~

~~E. The specific requirements for Class III licensure are as follows:~~

~~1. Complete a board-approved basic training course and an approved training course specific to Class III facilities and pass the board-approved examination for Class III; or~~

~~2. Complete the training and examination requirement of a federal or state agency under the federal Clean Air Act, as amended, as of the date applicable to an interpretation of a regulation or adjudication of a case decision and complete the board-approved basic training course within one year after licensure.~~

~~F. The specific requirements for Class IV licensure are as follows:~~

~~1. Complete a board-approved basic training course and an approved training course specific to Class IV facilities and pass the board-approved examination for Class IV; or~~

~~2. Complete the training and examination requirement of a federal or state agency under the federal Clean Air Act, as amended, as of the date applicable to an interpretation of a regulation or adjudication of a case decision and complete the board-approved basic training course within one year after licensure.~~

2. Unless otherwise exempt, the applicant shall have successfully completed a basic training course approved by the board. [~~Additonally~~ Additionally], an applicant for a Class II, III, or IV license shall complete a training course approved by the board specific to the license for which he applies.

3. Unless exempt, the applicant shall have passed the applicable examination provided by the board or by a testing organization acting on behalf of the board.

4. Each applicant shall document a minimum of one year of verified operational experience with a waste management facility of the same class for which he applies. Experience claimed on the application for licensure shall be verified by the individual's supervisor or personnel officer. Individuals who are under contract with a facility owner may obtain a letter from the facility owner to verify experience.

5. Applicants certified or licensed as [~~a~~] waste management facility [~~operator~~ operators] by governing bodies outside of the Commonwealth of Virginia shall be considered to be in compliance with this chapter if the

board or its designee has determined the certifying system to be substantially equivalent to the Virginia system.

6. In accordance with § 54.1-204 of the Code of Virginia, each applicant shall disclose a conviction, in any jurisdiction, of any misdemeanor or felony. Any plea of nolo contendere shall be considered a conviction for the purpose of this subdivision. The record of conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt. The board, at its discretion, may deny licensure to any applicant in accordance with § 54.1-204 of the Code of Virginia.

7. The applicant shall report suspensions, revocations, or surrendering of a certificate or license in connection with a disciplinary action [~~or that have~~. The applicant shall report if a license has] been the subject of discipline in any jurisdiction prior to applying for licensure in Virginia. The board, at its discretion, may deny licensure to any applicant based on prior suspensions, revocations, or surrender of certifications or licenses based on disciplinary action by any jurisdiction.

B. The board may make further inquiries and investigations with respect to the qualifications of the applicant.

18VAC155-20-130. Application procedures.

~~A.~~ Application shall be made on forms supplied by the department, and application forms shall be completed in accordance with the instructions on the forms. Failure to provide a complete application and all applicable addenda may result in a denial of approval. The failure to provide complete information may be interpreted as misrepresentation and may result in disciplinary action as [~~defined by~~ described in] 18VAC155-20-280.

~~B. Those already licensed who desire to add another classification or classifications to their license shall apply under the provisions of 18VAC155-20-110.~~

18VAC155-20-140. Examinations.

~~A. Initial examination.~~

~~1. An individual may not take the board-approved examination until all training requirements have been completed and are verified to the board unless qualifying under 18VAC155-20-120 B 6.~~

~~2. All applicants approved for the examination by the board will be notified in writing with a request for the examination fee defined in 18VAC155-20-40 B 5. The applicant will be scheduled for the next available examination upon receipt of the examination fee.~~

~~3. The examination fee will be required at least 30 days before the scheduled date of the examination.~~

~~4. All applicants shall achieve a passing score on the examination as determined by the board.~~

~~5. An individual unable to take an examination at the time scheduled shall notify the board prior to the date of the examination; such an individual shall be rescheduled for the next examination. Failure to notify the board may require the submittal of a new examination fee.~~

~~B. Reexamination.~~

~~1. An individual may retake the board-approved examination as many times as necessary to pass except those who have been waived from training requirements.~~

~~2. If the applicant has been waived from training under 18VAC155-20-120 B 6 and fails, the applicant may retake the examination once. After failing twice, the applicant shall complete the required training before retaking the examination.~~

~~3. Reexamination shall require the submission of the reexamination fee as defined in 18VAC155-20-40 B 5.~~

A. Applicants will be approved to sit for the examination for licensure once all [~~education~~ training] and experience requirements have been satisfied and documentation pertaining to all other qualifications [~~have~~ has] been received by the board.

B. An applicant must follow all rules established by the board or by the testing service acting on behalf of the board with regard to the conduct at the examination site. Such rules shall include any written instructions communicated prior to the examination date and any oral or written instructions given at the site on the date of the exam.

18VAC155-20-150. ~~Reciprocity.~~ (Repealed.)

~~A. Any individual holding a valid license in another state may apply for licensure based on reciprocity.~~

~~B. The board will certify an individual who submits a completed application and the initial application fee and is in compliance with 18VAC155-20-280.~~

~~C. All applicants licensed through reciprocity shall complete the basic training course within one year after being licensed in Virginia.~~

~~D. If the licensee fails to complete the basic course and fails to properly notify the board of such failure within one year after licensure, the board may begin disciplinary action to suspend or revoke the license.~~

Part III
Renewal of License

18VAC155-20-160. Procedures for renewal.

A. Licenses issued under this chapter shall expire two years from the last day of the month in which they were issued as indicated on the license. ~~biennially. Licensees shall be notified by mail of the fee and the procedures for license renewal. Each licensee desiring to renew his license shall ensure that the department receives the renewal notice; evidence of completion of continuing professional education/training; a statement that the license renewal applicant is in compliance with all facility specific operator training and examination requirements of federal and Virginia law and regulations, and of the facility operating permit(s); and the appropriate fee before the license expires.~~

B. ~~Licenses shall be renewed for a period of 24 months from the date of the expiring license.~~ The board will mail a renewal notice to the licensee at the address on file with the board outlining the fee and procedures for license renewal. Failure to receive written notice from the department does not relieve the licensee from the requirement to renew his license. If the license holder fails to receive the renewal notice, a copy of the license may be submitted with evidence of completion of the continuing education requirements and the appropriate fee.

~~C. Failure to receive written notice from the department does not relieve the regulant from the requirement to renew his license. If the license holder fails to receive the renewal notice, a copy of the license may be submitted with evidence of completion of the continuing education/training and the appropriate fee.~~

~~D.~~ C. The date the required fee is received by the department or its agent will be used to determine whether a penalty fee or the requirement for reinstatement of a license is applicable.

~~E. Revoked or suspended licenses are not renewable until reinstated by the board.~~

D. As a condition of renewal or reinstatement all individuals holding a license shall be required to satisfactorily complete eight hours of continuing education from a provider approved by the board in accordance with the provisions of this chapter [, except that no continuing education shall be required for the first renewal after the issuance of the initial license to an individual].

18VAC155-20-175. ~~Continuing professional education/training.~~ (Repealed.)

~~A. Each applicant for license renewal shall provide evidence of the completion of at least eight contact hours of continuing professional education/training, as defined in 18VAC155-20-10 and in accordance with this section, except that no continuing professional education/training shall be required for the first renewal after the issuance of the initial license to an individual.~~

~~B. All CPE/T contact hours must be specific to the operation of a waste management facility.~~

~~C. Renewal applicants shall submit one or both of the following to document completion of the hours of CPE/T required by subsection A of this section:~~

~~1. For an organized program, a document with:~~

~~a. The name, address and telephone number of the sponsor;~~

~~b. The date(s) the applicant participated in the organized program;~~

~~c. A copy of the syllabus or other descriptive material of the information presented during the organized program; and~~

~~d. Verification of the number of contact hours completed that were specific to the operation of a waste management facility.~~

~~2. For a project, a document with:~~

~~a. The name and address of the waste management facility where the project was conducted;~~

~~b. The name of the owner, operator or manager of the facility who assigned the project;~~

~~c. The name, address and telephone number of the knowledgeable person assigned to supervise the license renewal applicant during the project;~~

~~d. A brief description of how the project's specific predetermined end result increased the license renewal applicant's competence; and~~

~~e. A statement of the number of contact hours required for the license renewal applicant to satisfactorily complete the project, which is signed by the owner, operator or manager of the facility where the project was conducted or by the knowledgeable person supervising the project.~~

~~D. The board shall advise the license renewal applicant of the approval of his CPE/T by issuing the renewed license provided all of the other renewal requirements of this chapter have been met. The board shall advise the license renewal applicant in writing of the deficiencies it finds in the CPE/T submitted and shall allow a reasonable amount of time for the renewal applicant to correct the deficiencies and respond.~~

~~E. Each licensee shall maintain evidence of the satisfactory completion of CPE/T for a period of three years. Such documentation shall be in the form required by subsection C of this section and shall be provided to the board or its duly authorized agents upon request.~~

~~F. CPE/T contact hours taken after the expiration of the individual's license to meet the CPE/T requirement of the prior license term shall not be reported for any future renewal.~~

Part IV
Training Requirements

18VAC155-20-220. ~~Training course curriculum.~~ Education courses.

A. ~~The board shall approve only training courses that document that their instruction meets the minimum curriculum standards contained in this section.~~ All training and continuing education courses must be completed through accredited colleges, universities, junior and community colleges, Virginia Apprenticeship Council programs, proprietary schools approved by the Virginia Department of Education, or other programs approved by the board.

~~B. A board-approved basic training course shall at a minimum include the following topics as they relate to nonhazardous solid waste management facilities:~~

~~1. Definitions.~~

~~2. Authority for regulations.~~

3. Purpose of regulations.

4. Administration of regulations.

5. Applicability of regulations.

6. Prohibitions.

7. Open dumps.

8. Unpermitted facilities.

9. Enforcement and appeal.

10. Penalties and enforcement.

11. Public participation.

12. Relationship with other regulations promulgated by the Virginia Waste Management Board, the State Water Control Board, and the Virginia State Air Pollution Control Board.

13. Identification of solid waste.

a. Purpose and scope.

b. Definitions of solid waste.

c. Special wastes.

d. Exclusions.

e. Conditional exemptions.

14. Identification of unauthorized waste.

15. Overview of open dumps and unpermitted facilities.

16. Permitting of solid waste management facilities.

17. Review of Department of Environmental Quality Inspection Form.

18. Overview of permitted solid waste management facilities.

a. Transfer stations.

b. Material recovery facilities.

c. Experimental facilities.

d. Sanitary landfills.

e. Infectious waste incinerators.

f. Mass burn facilities.

g. Refuse derived fuel facilities.

h. Yard waste composting facilities.

i. Autoclaves.

19. Overview of general OSHA requirements.

20. Neighbor relations.

21. Recordkeeping and financial assurance.

C. A board approved training course specific to Class II facilities shall include at a minimum the following topics:

1. Definitions.

2. Special wastes.

a. General.

b. Asbestos wastes.

c. Wastes containing polychlorinated biphenyls.

d. Liquids.

e. Tires.

f. Drums.

g. White goods.

h. Soil contaminated with petroleum products.

i. Lead acid batteries.

j. Other prohibited wastes.

k. Hazardous wastes.

l. Screening for prohibited wastes.

m. Handling procedures for special or hazardous wastes.

n. Recordkeeping and notification requirements.

3. Sanitary landfills.

a. Design/construction.

b. Operation.

c. Groundwater monitoring.

d. Control of decomposition gases and landfill gas recovery systems.

e. Leachate control system and monitoring.

f. Leachate control system appurtenances.

g. Large landfill air operating permits.

4. Construction/demolition debris standards.

5. Industrial waste disposal standards.

6. Other solid waste management facility standards.

a. Compost facilities.

b.. Surface impoundments and lagoons.

c. Waste piles.

d. Miscellaneous units.

7. Permitting of solid waste management facilities.

a. Solid waste.

b. Virginia Pollution Discharge Elimination System (VPDES) permits and related water and wastewater permits.

c. Air.

8. Financial assurance documentation.

a. Closure regulations.

b. Post-closure regulations.

c. Corrective action.

9. Rulemaking petitions and procedures.

D. A board approved training course specific to Class III facilities shall include at a minimum the following topics:

1. Identification and listing of infectious waste.

a. General.

b. Exemption to regulations.

c. Exclusions.

d. Characteristics of infectious waste.

e. Controlled infectious waste.

2. General requirements.

a. Permits and permits by rule.

b. Packaging and labeling requirements.

c. Management of spills.

d. Methods of treatment and disposal.

e. Approved test method.

f. Recordkeeping requirements.

3. Requirements for storage facilities.

a. Sanitation.

b. Access.

c. Temperature control and storage period.

d. Drainage and ventilation.

4. Requirements for transportation.

a. Sanitation.

b. Access.

c. Temperature and storage period.

d. Drainage.

e. Packaging, labeling and placards.

f. Management of spills.

g. Loading and unloading.

h. Registration of transportation.

5. Requirements for incineration.

a. Performance standards.

b. Analysis and management of ash residue.

c. Unloading operation.

d. Facility air operating permits.

e. Compliance with other regulatory requirements.

6. Requirements for steam sterilization.

a. Performance standards.

b. Compliance with other regulatory requirements.

7. Medical waste combustor regulations.

8. Financial assurance documentation.

a. Closure regulations.

b. Corrective action.

E. A board-approved training course specific to Class IV facilities shall include at a minimum the following topics:

1. Solid Waste Management Regulations.

a. Siting.

b. Design and construction.

c. Operation.

d. Waste characteristics.

2. Emissions formation and control.

a. Type of emissions.

b. Environmental effect.

c. Control techniques.

3. Emissions monitoring.

a. Parameters monitored.

b. Types of monitors.

c. Data acquisition.

d. Monitor calibration, certification and testing.

4. Combustion and gas reactions.

a. Combustion components.

b. Optimizing solid waste combustion.

c. Gas reactions related to combustor construction materials.

5. Solid waste materials handling.

a. Front end processing equipment.

b. Combustion enhancement.

c. Back end processing.

d. Recycling benefits.

6. Waste combustion residue handling and disposal.

a. Types of residue.

b. Characteristics.

c. Regulations.

d. Monitoring.

e. Handling and transportation.

f. Disposal.

g. Alternative uses.

7. Safety.

a. Employer/employee obligations.

b. OSHA.

c. Hazard communication.

d. Equipment tagout.

e. Respiratory protection.

8. Recordkeeping.

a. Engineering log keeping.

b. Maintenance.

c. Solid waste.

9. Virginia pressure vessel regulation.

10. Air pollution control regulations for waste combustors.

11. Facility air operating permits.

12. Plant operations.

a. Thermal fluids theory.

b. Boiler plant operations.

13. Financial assurance documentation.

a. Closure regulations.

b. Corrective action.

B. [~~All continuing education courses must be specific to the operation of the class of waste management facility for which the course is being offered and must be approved by the board.~~ All courses for which credit for pre-license education is sought shall be related to the operation of the class of waste management facility for which the course is being offered and shall be approved by the board.

C. All courses for which credit for continuing education is sought shall be related to the operation of the class of waste management facility for which the course is being offered and may be reviewed by the board.

~~C.~~ D.] Each provider of a [~~training~~ pre-license education course] or [person submitting a course for] continuing education [~~course~~ credit] shall submit an application for approval on a form provided by the board. The application shall include, but is not limited to:

1. The name of the provider;

2. Provider contact person, address, and telephone number;

3. Course contact hours;

4. Schedule of courses, if established, including dates, times, and locations;

5. Course syllabus; [and]

6. Instructor information, including name, license number if applicable, education and training background, and a list of other appropriate trade designations or training certifications.

18VAC155-20-230. ~~Approval of training course.~~ Training records.

~~A. Each applicant for training course approval shall meet the requirements established by this chapter before being granted approval by the board. Those desiring approval of a training course shall apply on a form provided by the department. The form shall be completed in accordance with the instructions supplied, and shall be accompanied by three copies of the materials which document that the training course meets the requirements of this chapter and by the fee required by 18VAC155-20-40 B 6. Receipt and deposit of the required fee does not indicate board approval.~~

~~B. Training courses shall be approved by the board prior to the training activity in accordance with the following:~~

~~1. Training providers.~~

~~a. Organizations. The board may approve training courses offered by a sponsor who is an identifiable organization which can demonstrate the capability to teach environmental or engineering material. The organization shall have a mission statement outlining its functions, structure, process and philosophy, and a staff of one or more persons that has the authority to administer and coordinate the training program.~~

~~b. Schools. The board may approve training courses offered by an accredited academic institution which can demonstrate the capability to teach environmental or engineering material.~~

~~c. Businesses. The board may approve training courses offered by a business entity which can demonstrate the capability to teach environmental or engineering material.~~

~~2. Instructors. The training course provider shall ensure training is only conducted by personnel who have demonstrated competence in the subject being taught, an understanding of the learning objective, a knowledge of the teaching process to be used, and a proven ability to communicate.~~

~~3. Objectives. The training course provider shall ensure that the course has a series of stated objectives that are consistent with the type of facility, operator job requirements, and state and federal regulation. The training course shall be consistent with training criteria outlined in 18VAC155-20-220.~~

~~4. The board shall only approve courses which provide the participants a complete tour of a facility appropriate to the course emphasizing operator responsibilities. The basic training course is exempt from this requirement.~~

~~5. Course completion requirements. For successful completion of a training program, participants must attend 90% or more of the class contact time and the tour of the facility.~~

~~6. The training provider shall provide an effective means for evaluation of the quality of the course and the instructor(s).~~

~~7. The training provider shall ensure the number of participants and physical facilities are appropriate for the course content and teaching method specified by the developer of the course.~~

~~8. The training provider shall ensure all course materials are technically accurate, current and sufficient to meet the program's learning objectives.~~

~~C. Training records.~~

~~1. An approved training provider shall retain records for all participants for a period of 10 years and shall maintain a written policy on the retention and release of records.~~

~~2. All records pertaining to the approved training and participants shall be made available to the board immediately upon request.~~

~~D. The board shall consider the following information before deciding to approve or disapprove an application for training provider approval:~~

~~1. Course information.~~

~~a. Course title.~~

~~b. Planned audience.~~

~~c. Name of sponsor.~~

d. Name, address and telephone number of contact person.

e. Scheduled presentation dates.

f. Detailed course schedule on an hour-by-hour basis.

g. List of planned breaks.

h. Scheduled presentation locations.

i. Scheduled tour locations.

j. Instructor(s) resume.

2. Training materials.

a. Course objectives. A listing of the course objectives stated in terms of the skills and knowledge the participant will be able to demonstrate as a result of the training.

b. Course outline. A detailed outline showing the planned activities that will occur during the training program, including major topics, planned presentation sequence, tour activities, audio-visual presentations and other major activities.

c. Course reference materials. A list of name, publisher, and publication date of commercially available publications; for material developed specifically for the course, a copy of the reference material.

d. Audio-visual support materials. A list of any commercially available audio-visual support material that will be used in the course; a brief description of any audio-visual material generated by the sponsor or instructor.

e. Handouts. Identification of all commercially available handout material including regulations; copies of other handouts generated by the sponsor or instructor.

E. The board shall approve all substantial changes to the course before the changes may be implemented.

F. The board reserves the right to withdraw approval if the board determines the course is not adequately teaching participants, or the sponsor or an instructor violates this chapter.

An approved training provider shall retain records for all participants for a period of 10 years and shall maintain a written policy on the retention and release of records. All records pertaining to the approved training and participants shall be made available to the board immediately upon request.

18VAC155-20-235. Denial or withdrawal of approval.

The board may deny or withdraw the approval of any training or continuing education course for the following reasons:

1. Courses being offered no longer meet the standards established by the board;

2. The course provider, through an agent or otherwise, advertises its services in a fraudulent or deceptive way;

3. The course provider, instructor, or designee of the provider falsifies any information relating to the application for approval, course information, or student records or fails to produce records required by the Board for Waste Management Facility Operators.

4. The course provider fails to maintain student course completion records for a minimum of 10 years.

Part V
Disciplinary Action

18VAC155-20-280. Grounds for denial of application, denial of renewal, or discipline.

A. The board shall have the authority to (i) deny an application for and to deny renewal of a license or training course approval, and to (ii) revoke or suspend the license or training course approval as well as to, and (iii) discipline a licensee or an approved training provider for the following reasons: who is found to be in violation of the statutes or regulations governing the practice of licensed waste management facility operators.

1. Violating or inducing another to violate any provisions of Chapters 1 (§ 54.1-100 et seq.), 2 (§ 54.1-200 et seq.), 3 (§ 54.1-300 et seq.) or 22.1 (§ 54.1-2209 et seq.) of Title 54.1 of the Code of Virginia, or any provision of this chapter.

2. Obtaining or renewing a license or training course approval through fraudulent means or misrepresentation.

3. Having been found guilty by the board, an administrative body or by a court of any material misrepresentation in the course of performing his operating duties.

4. Subject to the provisions of § 54.1-204 of the Code of Virginia, having been convicted or found guilty, regardless of jurisdiction, of any felony, or of any violation that resulted in the significant harm or the imminent and substantial threat of significant harm to human health or the environment, there being no appeal pending therefrom or the time of appeal having elapsed. Any plea of nolo contendere shall be considered a conviction for the purposes of this chapter. A certified copy of the final order, decree or case decision by a court or regulatory agency with lawful authority to issue such order, decree or case decision shall be admissible as prima facie evidence of such conviction.

5. Failing to inform the board in writing within 30 days of pleading guilty or nolo contendere or being convicted or found guilty of any felony, or of any violation that resulted in the significant harm or the imminent and substantial threat of significant harm to human health or the environment.

6. Gross negligence, or a continued pattern of incompetence, in the practice as a waste management facility operator.

~~7. Violating the permit conditions for the facility, or violating any federal, state or local laws or regulations which that resulted in the significant harm or the imminent and substantial threat of significant harm to human health or the environment.~~

B. Any individual whose license is revoked under this section shall not be eligible to apply for licensure for a period of one year from the effective date of the final order of revocation. After the one-year period, the individual shall meet all education, examination, experience and training requirements, complete the application and submit the required fee for consideration as a new applicant.

C. The board shall conduct disciplinary procedures in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

18VAC155-20-285. Prohibited acts.

Any of the following are cause for disciplinary action:

1. Violating or inducing another to violate any provisions of Chapter 1 (§ 54.1-100 et seq.), 2 (§ 54.1-200 et seq.), 3 (§ 54.1-300 et seq.) or 22.1 (§ 54.1-2209 et seq.) of Title 54.1 of the Code of Virginia, or any provision of this chapter.

2. Obtaining or renewing a license through fraudulent means or misrepresentation.

3. Having been found guilty by the board, an administrative body, or by a court of any material misrepresentation in the course of performing his operating duties.

4. Subject to the provisions of § 54.1-204 of the Code of Virginia, having been convicted or found guilty, regardless of jurisdiction, of any felony or any violation that resulted in the significant harm or the imminent and substantial threat of significant harm to human health or the environment, there being no appeal pending therefrom, or the time of appeal having elapsed. Any plea of nolo contendere shall be considered a conviction for the purposes of this chapter. A certified copy of the final order, decree, or case decision by a court or regulatory agency with lawful authority to issue such order, decree, or case decision shall be admissible as prima facie evidence of such conviction.

5. Failing to inform the board in writing within 30 days of pleading guilty to, pleading nolo contendere to, being convicted of, or being found guilty of (i) any felony or (ii) any violation that resulted in the significant harm or the imminent and substantial threat of significant harm to human health or the environment.

6. Gross negligence, or a continued pattern of incompetence, in the practice of a waste management facility operator.

7. Violating the permit conditions for the facility, or violating federal, state, or local laws or regulations, which resulted in the significant harm or the imminent and substantial threat of significant harm to human health or the environment.

8. Failure to comply with all rules established by the board and the testing organization with regard to conduct at the examination.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (18VAC155-20)

~~License Application, 46LICPKG (rev. 5/05)~~

~~Experience Verification Form, 46EXP (rev. 5/00)~~

~~Education Verification Form, 46ED (rev. 5/00)~~

~~Application for Training Course Approval, 46CRS (rev. 5/00)~~

[~~License Application, A438-4605LIC-v8 (rev. 8/15)~~

~~Training Course Approval Application, A438-46CRS-v4 (rev. 8/15)~~

Experience Verification Form, A438-46EXP-v5 (rev. 10/2013)

Examination Site Conduct Agreement Form (rev. 2/2013)

Education Verification Form, A438-46ED (rev. 7/2012)

License Application, A438-4605LIC v10 (rev. 8/2016)

Training Course Approval Application, A438-46CRS-v4 (rev. 8/2016)]

VA.R. Doc. No. R13-3737; Filed June 1, 2016, 12:53 p.m.

TITLE 23. TAXATION

DEPARTMENT OF TAXATION

Fast-Track Regulation

Title of Regulation: **23VAC10-55. Virginia Corn Excise Tax (amending 23VAC10-55-40; repealing 23VAC10-55-50).**

Statutory Authority: § 58.1-203 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: August 26, 2016.

Effective Date: September 12, 2016.

Agency Contact: Joe Mayer, Lead Policy Analyst, Department of Taxation, P.O. Box 27185, Richmond, VA 23261-7185, telephone (804) 371-2299, FAX (804) 371-2355, or email joseph.mayer@tax.virginia.gov.

Basis: Section 58.1-203 of the Code of Virginia authorizes the Tax Commissioner to issue regulations relating to the interpretation and enforcement of the laws governing taxes administered by the Department of Taxation. Section 3.2-1412 of the Code of Virginia authorizes the Tax Commissioner to administer the corn excise tax.

Purpose: The amendments are needed to update the corn excise tax rate to the rate provided in statute (one cent per bushel) and strike language that provides no guidance beyond the plain meaning of the statutes as it is not necessary to protect the public health, safety, or welfare. The regulatory action does not reflect any change in current tax policy and will have no impact on the administration of the corn excise tax.

Rationale for Using Fast-Track Process: The department is using the fast-track rulemaking process because amending Virginia Corn Excise Tax, 23VAC10-55, to update the tax rate and to repeal language that provides no guidance beyond the plain meaning of the statute is expected to be noncontroversial.

Substance: The amendments update the tax rate and repeal language that provides no guidance beyond the plain meaning of the statute. The corn excise tax is levied on corn produced in Virginia for sale. The tax is remitted quarterly and the revenues deposited into The Corn Fund. The Corn Board uses these funds to provide for programs of market development, education, publicity, research, and the promotion of the sale and use of corn. This regulatory action does not reflect any change in current tax policy and will have no impact on the administration of the corn excise tax.

Issues: The primary advantage to the public, the Department of Taxation, and the Commonwealth of this action is that it will conform Virginia Corn Excise Tax, 23VAC10-55, to a rate change in the statutory law and thereby assist taxpayers with voluntary compliance with the tax, ease administration of the tax by the Department of Taxation, and help ensure the steady flow of tax revenues to the Commonwealth. As the regulation will update the tax rate to the rate provided in statute and repeal language that provides no additional guidance to statutes that are clear and unambiguous, there are no issues or disadvantages to the public or the Commonwealth associated with this regulatory action.

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

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Department of Taxation (Department) proposes to update the corn excise tax rate in the regulation to reflect the rate that has been in effect since 1989. The Department also proposes to amend other language for clarity.

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

Estimated Economic Impact. The current regulation states that the corn excise tax rate is one-quarter cent per bushel. The Code of Virginia (§ 3.2-1405 and § 3.2-1406) establishes that the excise tax rate may be changed or eliminated by virtue of referenda of corn producers. An October 1, 1989 tax bulletin reported that "On September 7, 1989, Virginia corn producers voted 136 to 51 in favor of increasing the corn assessment from one-quarter cent to one cent per bushel of corn…" In practice, the tax has been assessed at one cent per bushel ever since. The Department proposes to amend this regulation to indicate that the tax is one cent per bushel. This amendment will be beneficial in that the regulation will reflect the actual tax rate that is assessed, significantly improving clarity.

Businesses and Entities Affected. The regulation affects corn farmers, processors, dealers, shippers, country buyers, and exporters. According to the Department, there were 63 corn excise tax payers in 2015.

Localities Particularly Affected. The regulation particularly affects localities where corn is grown and processed for profit.

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

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

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

Small Businesses:

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

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

Alternative Method that Minimizes Adverse Impact. The proposed amendments do not create adverse impact for small businesses.

Adverse Impacts:

Businesses. The proposed amendments will not adversely affect businesses.

Localities. The proposed amendments will not adversely affect localities.

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

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

Summary:

The amendments update the tax rate and repeal language that provides no guidance beyond the plain meaning of the statute. This regulatory action does not reflect any change in current tax policy and will have no impact on the administration of the corn excise tax.

23VAC10-55-40. ~~Handler to deduct assessment from payment to farmer; report~~ Report and payment by handler.

A. Definition. The following word or term when used in this section shall have the following meaning unless the context clearly indicates otherwise:

"Handler" means any person, firm, corporation or any other business entity that is a processor, dealer, shipper, country buyer, exporter that handles corn produced in Virginia, or farmer who sells his corn out of state or to anyone other than a "handler."

B. Generally. The handler of corn is liable for remitting the ~~one-quarter cent~~ $ .01 per bushel corn excise tax to the Tax Commissioner ~~as regulated herein~~. If the handler purchases, from farmers, corn subject to the excise tax, the handler must deduct the excise tax from any payment made to the farmer for the corn. All corn handlers must register with the Tax Commissioner for receiving the quarterly corn excise tax returns and reporting the corn excise tax. ~~Application for registration should be submitted to the Department of Taxation, Registration Unit, P.O. Box 1880, Richmond, VA 23282-1880.~~

~~B. Handler defined. The term "handler" means any person, firm, corporation or any other business entity who is a processor, dealer, shipper, country buyer, exporter who handles corn produced in Virginia or a farmer who sells his corn out of state or to anyone other than a "handler."~~

C. Examples.

Example 1: Farmer A grows corn in Virginia and sells the harvested crop for processing to Processor B located in North Carolina. Farmer A is the "handler" and responsible for remitting the Virginia Corn Excise Tax to the Virginia Department of Taxation.

Example 2: Farmer E grows corn in Virginia and sells the harvested corn for processing to Processor F located in Virginia. Processor F is the "handler" and is responsible for collecting from the farmer and remitting the Virginia Corn Excise Tax to the Virginia Department of Taxation.

Example 3: Farmer G grows corn in Virginia and sells the harvested crop for seed to Farmer H. Farmer G is the "handler" and is responsible for remitting the Virginia Corn Excise Tax to the Virginia Department of Taxation.

~~C. Handler return. The corn excise tax returns must be filed by the handler quarterly and are due on or before the last day of the month following the end of the period. The quarters are January 1 through March 31, April 1 through June 30, July 1 through September 30 and October 1 through December 31. Each return shall report the gross volume of corn which has been handled by the handler during the quarter. Each handler must file the return with the Department of Taxation, P.O. Box 1880, Richmond, VA 23282-1880.~~

~~D. Payment of tax by handler. Each handler must pay the corn excise tax. The return, with applicable tax payment, is due by the last day of the month following the end of each quarter. (Due dates are April 30, July 31, October 31, and January 31). The tax receipts shall be deposited by the Tax Commissioner into the State Treasury and credited to the Virginia Corn Fund.~~

23VAC10-55-50. ~~Records to be kept by handlers.~~ (Repealed.)

~~A. Generally. Every handler of corn subject to the corn excise tax must keep complete records on the corn handled by him. The handler must keep and preserve the records for at least three years following the date the tax is reported on such corn.~~

~~Note: While § 3.1-1045 of the Code of Virginia specifies records must be preserved for a period not less than two years from the time the corn was handled, the statute of limitations under § 58.1-1812 of the Code of Virginia provides for a three year period for assessment of deficiencies. In order to prevent any undue burden upon the taxpayer, in the event of audit, the record retention period has been extended to the same limitation as the assessment statute of limitations.~~

~~B. Examination by Commissioner. The Tax Commissioner, or his duly authorized agents, may examine during the usual business hours of the day records, books, papers, or other documents of the handler to verify the truth and accuracy of any return, statement, or other relevant information.~~

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (23VAC10-55)

~~Virginia Corn Assessment Return Instructions, Form CO-AR W (rev. 5/06).~~

~~Business Registration Application, Form R-1 (rev. 3/08).~~

Form CO-1, Virginia Corn Assessment Return and Instructions (CO-AR W) (rev. 5/2006)

Form R-1, Business Registration Form (1501220) and Instructions (1501228) (rev. 3/2015)

VA.R. Doc. No. R16-4608; Filed May 31, 2016, 3:26 p.m.

Fast-Track Regulation

Title of Regulation: **23VAC10-210. Retail Sales and Use Tax (amending 23VAC10-210-940).**

Statutory Authority: § 58.1-203 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: August 26, 2016.

Effective Date: September 12, 2016.

Agency Contact: Kristen Peterson, Analyst, Department of Taxation, 600 East Main Street, Richmond, VA 23219, telephone (804) 371-2340, FAX (804) 371-2355, or email kristen.peterson@tax.virginia.gov.

Basis: Section 58.1-203 of the Code of Virginia authorizes the Tax Commissioner to issue regulations relating to the interpretation and enforcement of the laws of the Commonwealth governing taxes administered by the Department of Taxation. The authority for the current regulatory action is discretionary.

Purpose: The current regulation does not reflect numerous statutory changes that have been made regarding the retail sales and use tax. Chapters 331 and 361 of the 2006 Acts of Assembly changed the application of the retail sales and use tax for veterinarians purchasing medicines and drugs. Prior to this legislative change, a veterinarian was deemed the user and consumer of any medicine or drug used in his operation and was required to pay his suppliers the sales and use tax when purchasing these items. The 2006 Session of the General Assembly amended this statute by exempting a veterinarian's purchase of medicines and drugs that are either used by the veterinarian in treating agricultural production animals or sold to a farmer for direct use in producing an agricultural product for market. The current regulation does not reflect this statutory change, as it explicitly excludes veterinarians from the "licensed physician" definition.

The General Assembly also enacted Chapter 217 of the 2006 Acts of Assembly, which expanded the exemption to allow for-profit nursing homes, clinics, and similar corporations to purchase medicines and drugs tax free. This change is not reflected in the current regulation.

In 1999, the General Assembly expanded the sales and use tax exemption available for eyeglasses and related items to include eyeglass cases, contact lens storage containers, solutions or sterilization kits, and other similar devices when distributed free of charge by optometrists, ophthalmologists, and opticians. This legislative change is not reflected in the current regulation.

In 1998, the department released a tax bulletin (VTB 98-4) to explain a legislative change that exempted nonprescription drugs as well as samples of nonprescription drugs distributed free of charge by the manufacturer (Chapter 696 of the 1997 Acts of Assembly), from sales and use tax. The tax bulletin identified categories of taxable items and provided a detailed list of items falling under the exempt nonprescription drug classification. The department updated this tax bulletin in 2013 (VTB 13-5) to provide clarification to retailers and purchasers of nonprescription drugs. These statutory and administrative changes are not reflected in the current regulation.

In addition, the regulation clarifies the tax treatment of various items not specifically identified in the statute or current regulation, but frequently utilized in the provision of health care services, including, for example, eyeglasses, durable medical equipment, or other medical devices.

Because the existing regulation does not reflect current law and requires clarification regarding the tax treatment of certain items, it does not provide the sufficient guidance needed to ensure that taxpayers comply with Virginia's sales and use tax laws. This regulatory action is necessary to ensure a predictable and adequate revenue stream for the government to provide for the health, safety, and welfare of citizens.

Rationale for Using Fast-Track Rulemaking Process: The fast-track rulemaking process is intended for proposed regulations that are expected to be noncontroversial. As the regulation will be amended to reflect current law and will not make any changes to the department's current policy regarding medicines and drugs, this action is not expected to be controversial. The department has issued numerous published ruling letters, tax bulletins, and other public documents (PD) that address the retail sales and use tax as it applies to the purchase of medicines, drugs, medical devices, durable medical equipment, and other medical-related items. These PDs and recent law changes form the basis for the proposed changes to this regulation.

Substance: This regulatory action amends 23VAC10-210-940 to reflect changes made during the 1997 and 2006 Sessions of the General Assembly and to incorporate policy set forth in numerous PDs. Substantive changes or new provisions to the regulation are as follows:

1. Controlled drugs. While the current regulation provides an exemption to licensed physicians for controlled drug purchases, this exemption also extends to licensed optometrists, licensed nurse practitioners, and licensed physician assistants. Moreover, the Code of Virginia defines controlled drug, but this regulatory action expands that definition by explaining that the manufacture, distribution, and dispensation are heavily regulated by the state and federal government because of the drug's potential for abuse and physical or psychological dependence. The regulation also describes the documentation that may be used to demonstrate that the exemption requirements have been satisfied.

2. Durable medical equipment. In addition to the exemption available for durable medical equipment, items specifically designed for use with durable medical equipment or devices are exempt from the retail sales and use tax. General purpose supplies do not qualify for this exemption. Additional items have been added to the current list of qualifying durable medical equipment. Durable medical equipment and related items must be purchased by or on behalf of an individual and may not

be purchased in bulk and then dispensed to individual patients. If the purchaser of these items has no blanket exemption for his purchases and no certificate of exemption or other exemption notice from the department applies, the taxpayer must obtain a signed statement from the purchaser certifying that the durable medical equipment or related items are purchased on behalf of a specific patient through a doctor's prescription or hospital's work order and is for sole use by that patient. Taxpayers are obligated to keep records documenting that the purchase was for a specific patient, but they may redact identifying information regarding each patient in order to comply with federal and state privacy laws.

3. Eyeglasses. Optometrists, ophthalmologists, and opticians are engaged in the provision of professional services and must pay the tax to their suppliers at the time they purchase tangible personal property used in performing their professional services or remit the use tax directly to the department. When these practitioners provide eyeglass cases, contact lens storage containers, solutions or sterilization kits, or other similar devices to their patients free of charge, they may purchase these specified items exempt of the tax.

4. Hemodialysis and peritoneal dialysis equipment. Hemodialysis and peritoneal dialysis equipment, supplies, and drugs used in dialysis are not subject to the retail sales and use tax, regardless of the nature of the purchaser.

5. Licensed hospitals and nursing homes. Licensed hospitals and nursing homes may purchase medicines and drugs for use and consumption exempt from the retail sales and use tax.

6. Medical supplies purchased by Medicaid recipients. Medicaid recipients may purchase otherwise taxable medical products and supplies exempt from the retail sales and use tax provided the purchase is made through a Department of Medical Assistance Services provider agreement.

7. Nonprescription drugs. Nonprescription medicines and drugs and proprietary medicines and drugs purchased for the cure, mitigation, treatment, or prevention of disease in human beings are exempt from retail sales and use tax, regardless of the nature of the purchaser. In addition, samples of nonprescription drugs distributed free of charge by the manufacturer, as well as the packaging materials and constituent elements, are also exempt. The exemption does not extend to cosmetics; toilet articles; food products and supplements; vitamins and mineral concentrates sold as dietary supplements or adjuncts; devices; certain products listing natural or herbal ingredients; and items containing nonprescription drugs that serve a secondary function to the intended use of the product. A list of exempt nonprescription medicines and taxable items that do not qualify for the nonprescription drug exemption is provided.

8. Prosthetic devices. Implants used for cosmetic purposes do not qualify for exemption from the tax because their main function is not to replace a missing body part, but rather, to promote beauty.

9. Samples of prescription drugs. Pharmaceutical manufacturers are authorized to distribute samples of prescription drugs and medicines and their packaging free of charge to certain medical care providers and are not required to remit use tax for these items.

10. Veterinarians. Veterinarians have been added to the list of medical providers on whose written prescription medicines and drugs may be purchased exempt of the retail sales and use tax. A separate section has been added to indicate that, while veterinarians are deemed the users or consumers of medicines and drugs and must pay the retail sales and use tax on such purchases, they may purchase medicines and drugs used in caring for agricultural production animals exempt of the retail sales and use tax.

Issues: This regulatory action will ease voluntary taxpayer compliance and the department's administration of the state tax laws by amending a regulation that does not reflect current law. By clarifying the retail sales and use tax treatment for medicines and drugs, the department ensures uniform application of the tax laws to taxpayers, particularly physicians, optometrists, ophthalmologists, veterinarians, audiologists, and other medical service providers, as well as purchasers of these services. In addition, business taxpayers will be better equipped to predict the tax consequences of transactions and avoid unanticipated tax assessments as the result of audits.

This regulatory action poses no disadvantages to the public or the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Department of Taxation (Department) proposes several amendments to reflect statutory changes and long-standing policy concerning the tax treatment of purchases of medicines and drugs by medical service providers and consumers.

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

Estimated Economic Impact. The current regulation does not reflect numerous statutory changes that have been made regarding the Retail Sales and Use Tax. Legislation enacted by the 2006 General Assembly (2006 Acts of Assembly, Chapters 331, 361) changed the application of the Retail Sales and Use Tax for veterinarians purchasing medicines and drugs. Prior to this legislative change, a veterinarian was deemed the user and consumer of any medicine or drug used in his operation, and was required to pay his suppliers the

sales and use tax when purchasing these items. The 2006 General Assembly amended this statute by exempting a veterinarian's purchase of medicines and drugs that are either used by the veterinarian in treating agricultural production animals or sold to a farmer for direct use in producing an agricultural product for market. The current regulation does not reflect this statutory change, as it explicitly excludes veterinarians from the "licensed physician" definition.

The General Assembly also enacted law in 2006 (2006 Acts of Assembly, Chapter 217) that expanded the exemption to allow for-profit nursing homes, clinics, and similar corporations to purchase medicines and drugs tax-free. This change is not reflected in the current regulation.

In 1999, the General Assembly expanded the sales and use tax exemption available for eyeglasses and related items to include eyeglass cases, contact lens storage containers, solutions or sterilization kits and other similar devices, when distributed free of charge by optometrists, ophthalmologists, and opticians. This legislative change is not reflected in the current regulation.

In 1998, the Department released a Tax Bulletin (VTB 98-4) to explain a legislative change that exempted nonprescription drugs, as well as samples of nonprescription drugs distributed free of charge by the manufacturer (1997 Acts of Assembly, Chapter 696), from sales and use tax. The Tax Bulletin identified categories of taxable items and provided a detailed list of items falling under the exempt nonprescription drug classification. The Department updated this Tax Bulletin in 2013 (VTB 13-5) to provide clarification to retailers and purchasers of nonprescription drugs. These statutory and administrative changes are not reflected in the current regulation.

The Department proposes to update the regulation to reflect the above statutory and administrative changes. The proposed changes will not affect tax rules and policy, but will be beneficial by increasing clarity and reducing potential confusion for readers of the regulation concerning the rules in effect.

Businesses and Entities Affected. The proposed amendments pertain to the 40,146 physicians, 1,621 optometrists, 4,042 veterinarians, and other health care providers currently licensed in the Commonwealth, as well as their associated employers.

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

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

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

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

Small Businesses:

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

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

Alternative Method that Minimizes Adverse Impact. The proposed amendments do not create adverse impact for small businesses.

Adverse Impacts:

Businesses: The proposed amendments will not adversely affect businesses.

Localities: The proposed amendments will not adversely affect localities.

Other Entities: The proposed amendments will not adversely affect other entities.

Agency Response to Economic Impact Analysis: The Department of Taxation agrees with the Department of Planning and Budget's economic impact analysis regarding its update to 23VAC10-210-940, regarding medicines, drugs, eyeglasses, and related items.

Summary:

The amendments reflect statutory changes and long-standing policy concerning the tax treatment of purchases of medicines and drugs by medical service providers and consumers.

23VAC10-210-940. Medicines, drugs, eyeglasses, and related items.

~~A. Generally. The tax does not apply to medicines, drugs, hypodermic syringes, artificial eyes, contact lenses, eyeglasses and hearing aids dispensed by or sold on prescriptions or work orders of licensed physicians, dentists, optometrists, audiologists, hearing aid dealers and fitters or ophthalmologists, and controlled drugs purchased by a licensed physician for use in his professional practice.~~

~~The tax does not apply to wheelchairs and repair parts, braces, crutches, prosthetic devices, orthopedic appliances, catheters, urinary accessories, insulin and insulin syringes, and equipment, devices or chemical reagents which may be used by a diabetic to test or monitor blood or urine and other durable medical equipment and devices, related parts and supplies specifically designed for such equipment when such items or parts are purchased by or on behalf of an individual using these items. Purchases of these items by a hospital or licensed nursing home conducted for profit or by a licensed physician for use in his professional practice are subject to tax.~~

~~B.~~ A. Definitions. ~~As used in this regulation, the~~ The following words and ~~phrases set forth below~~ terms when used

in this section shall ~~be given~~ have the following meanings unless the context clearly indicates otherwise:

~~1. Prosthetic devices. "Prosthetic devices" shall mean devices which replace a missing part or function of the body and shall include any supplies physically connected to such devices.~~

~~2. Controlled drugs.~~ "Controlled drugs" ~~shall mean those~~ means medicines or drugs for which the manufacture, distribution, and dispensation are strictly regulated by both state and federal laws due to the potential for abuse and physical and psychological dependence. Controlled drugs are separated into six schedules and itemized under ~~§ 54.1-3400~~ et seq. Article 5 (§ 54.1-3443 et seq.) of Title 54.1 of the Code of Virginia ~~but shall include only medicines and drugs and not devices~~. For purposes of this definition, "controlled drugs" does not include devices.

"Cosmetics" means articles applied to the body for cleansing, beautifying, promoting attractiveness, or altering the appearance including makeup, body lotions, cold creams, and hair restoration products.

"Devices" means instruments, apparatuses, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or to affect the structure or any function of the human body. A partial list of devices that the federal Food and Drug Administration recognizes is provided at 21 CFR Part 862.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii) of this definition; or (v) a biological product. For purposes of this definition, "drug" includes oxygen and other medical gases, but does not include devices or their components, parts, or accessories.

"Durable medical equipment" means medical equipment that meets all of the following requirements: (i) can withstand repeated use; (ii) is primarily and customarily used to serve a medical purpose; (iii) generally is not useful to a person in the absence of illness or injury; and (iv) is appropriate for use in the home.

"Glycolic acid products" means cosmetic items used to smooth or lighten skin or to remove age spots and wrinkles for the purpose of promoting attractiveness or altering the appearance.

"Hemodialysis" means a renal replacement therapy method of removing waste products as well as free water from the blood when the kidneys are incapable of removing these wastes.

"Homeopathic product" means a product derived from the system of medical practice that treats a disease by the administration of minute doses of a remedy that would, in larger amounts, produce in healthy persons, symptoms similar to those of the disease.

~~3. Licensed physician.~~ "Licensed physician" ~~shall include only those persons~~ means a person licensed as a medical ~~doctors and shall~~ doctor. For purposes of this definition, a "licensed physician" does not include ~~veterinarians~~ a veterinarian, ~~chiropractors~~ chiropractor, ~~opticians~~ optician, ~~optometrists and~~ optometrist, or similar ~~persons~~ person.

"Nonprescription drug" means a substance or mixture of substances containing medicines or drugs for which no prescription is required and that is generally sold for internal or topical use in the cure, mitigation, treatment, or prevention of disease in human beings.

"Peritoneal dialysis" means a renal replacement therapy method of removing waste from the blood, as well as excess fluid, when the kidneys are incapable of removing these wastes, by instilling a specially formulated dialysis fluid around the peritoneal membrane that surrounds the intestine.

"Prescription" means an order for drugs or medical supplies written or signed or transmitted by word of mouth, telephone, telegraph, Internet, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer drugs or medical supplies.

"Proprietary medicine" means any nonprescription drug that is sold to the general public under the brand name or trade name of the manufacturer and that does not contain any controlled substance or marijuana.

"Prosthetic device" means any device that replaces a missing part or function of the body. For purposes of this section, a prosthetic device includes any supplies physically connected to the device.

"Toilet articles" means articles advertised or held out for sale for grooming purposes including toothpastes, hairsprays, shaving products, colognes, and deodorants.

B. Generally. Purchases of the following items are exempt from the retail sales and use tax:

1. Controlled drugs that a licensed physician, licensed optometrist, licensed nurse practitioner, or licensed physician assistant purchases for use in his professional practice;

2. Medicines, drugs, hypodermic syringes, artificial eyes, contact lenses, eyeglasses, and hearing aids that a licensed physician, dentist, optometrist, ophthalmologist, optician, audiologist, hearing aid dealer or fitter, nurse practitioner, physician assistant, or veterinarian dispenses or sells on prescriptions or work orders;

3. Medicines and drugs that a licensed hospital, nursing home, clinic, or similar corporation purchases for its use and consumption;

4. Medicines and drugs that a retailer purchases in order to fill a prescription, provided the purchase is made under a certificate of exemption, Form ST-10;

5. Nonprescription medicines or drugs and proprietary medicines or drugs regardless of the nature of the purchaser;

6. Samples of nonprescription drugs and proprietary medicines that a manufacturer distributes free of charge;

7. Eyeglass cases, contact lens storage containers, all solutions or sterilization kits, or other devices applicable to the wearing or maintenance of contact lenses or eyeglasses, provided these items are purchased by optometrists, ophthalmologists, and opticians and distributed free of charge to their patients;

8. Eyeglasses that a consumer purchases on prescription of a licensed physician, ophthalmologist, or optometrist;

9. Eyeglass frames sold in connection with the repair or replacement of prescription eyeglasses;

10. Durable medical equipment, devices, and related parts and supplies, provided the equipment, parts, and supplies are purchased by or on behalf of an individual for use by that individual. Purchases of durable medical equipment, parts, and supplies made by a licensed hospital or nursing home conducted for profit or by a licensed physician for use in his professional practice remain subject to tax;

11. Hemodialysis and peritoneal dialysis equipment, supplies, and drugs used in dialysis regardless of the nature of the purchaser;

12. Samples of prescription drugs that a pharmaceutical manufacturer distributes to licensed physicians, hospitals, pharmacies, and other health care facilities pursuant to a written request;

13. Medicines and drugs that a veterinarian purchases for use in caring for, medicating, or treating agricultural production animals; and

14. Medical products and supplies that a Medicaid recipient purchases through a Department of Medical Assistance Services provider agreement.

C. Medicines and drugs, specifically.

1. ~~Sales of~~ Medicines and drugs sold on prescriptions. Consumers may purchase medicines or drugs~~, including oxygen,~~ on ~~written~~ prescriptions ~~of~~ issued by licensed physicians~~,~~ ~~or~~ dentists ~~are~~, optometrists, ophthalmologists, opticians, audiologists, hearing aid dealers and fitters, nurse practitioners, physician assistants, and veterinarians exempt from the sales and use tax. ~~Sales of medicines~~ Medicines and drugs ~~on a physician's or dentist's telephone (oral)~~ purchased pursuant to an oral prescription made by any of these licensed professionals are exempt from the tax, provided the prescription is reduced to writing, signed by the pharmacist, and filed in the same manner as an original written prescription. Medicines or drugs sold pursuant to the refilling of a ~~physician's or dentist's~~ prescription by any of these licensed professionals are also exempt from the tax. ~~Vendors~~ Sellers making sales of medicines or drugs pursuant to ~~physician's or dentist's~~ these prescriptions or ~~in refilling the same~~ refills must keep sales records segregating the prescription sales. All original prescriptions must be filed and kept available for ~~inspection by~~ the Department of ~~Taxation~~ Taxation's inspection. When a ~~sale is made to refill~~ pharmacist refills a prescription, the seller's records of the refill must carry the number of the original prescription for reference.

2. ~~Sales of controlled~~ Controlled drugs sold to ~~a licensed physician~~ certain health care providers. A licensed physician, licensed optometrist, licensed nurse practitioner, or licensed physician assistant may purchase controlled drugs for use in his professional practice ~~are~~ exempt from the retail sales and use tax. The Department of Taxation will look to the purchasers on the invoice that supports the transaction to determine whether the controlled drug exemption applies. When an invoice includes any of the licensed practitioners as the purchaser, this is sufficient to demonstrate that the purchase was made by the qualifying party for use in his professional practice. The use of a Drug Enforcement Agency number is also sufficient.

3. ~~Sales of medicines or drugs to users or consumers, except when the sales are made pursuant to a prescription of a physician or dentist or as a refill of a written prescription, as referred to in paragraph (A) are subject to the tax. Sales of medicines~~ Medicines and drugs sold to licensed hospitals and ~~nursing homes conducted for profit are subject to the~~ similar facilities. Licensed hospitals, nursing homes, clinics, and similar facilities may purchase medicines and drugs for their use and consumption exempt from the retail sales and use tax ~~unless the sales are made as a result of a written prescription of a licensed physician for a particular patient under the care of the hospital or nursing home. Sales to hospitals or licensed nursing homes conducted not for profit, however, are not subject to the tax~~. For more information ~~about~~ concerning hospitals and nursing homes, see 23VAC10-210-720.

4. ~~Purchases of drugs by the dealer for filling prescriptions are not subject to the tax and must be made under certificate of exemption.~~ Medicines and drugs purchased for resale. A retailer may purchase drugs that will be used to fill or refill prescriptions exempt of the retail sales and use tax, provided the retailer presents the supplier with a certificate of exemption, Form ST-10, at the time of purchase.

D. Nonprescription drugs and proprietary drugs.

1. Nonprescription medicines or drugs and proprietary medicines and drugs purchased for the cure, mitigation,

treatment, or prevention of disease in human beings may be purchased exempt of the retail sales and use tax regardless of the nature of the purchaser. No certificate of exemption is necessary to utilize the exemption.

2. In order to be deemed an exempt nonprescription drug, the item at issue must (i) contain a nonprescription drug or proprietary medicine; (ii) be sold for internal or topical use; (iii) be sold for the cure, mitigation, treatment, or prevention of disease in human beings; and (iv) fall outside of the excluded categories set forth in subdivision 3 of this subsection. Products that require over-the-counter registration are deemed exempt nonprescription drugs or medicines if they meet these requirements.

3. The exemption for nonprescription drugs and proprietary medicines does not apply to the following categories of items:

a. Cosmetics;

b. Toilet articles;

c. Food products and supplements classified as such by the federal Food and Drug Administration;

d. Vitamins and mineral concentrates sold as dietary supplements or adjuncts, except when sold pursuant to a written prescription by a licensed physician, nurse practitioner, or physician's assistant;

e. Devices, including contraceptive items, birth control preparations, and testing kits. However, a separate exemption is available for diabetic testing kits under subsection F of this section;

f. Products listing natural or herbal ingredients as the active components unless the items contain a nonprescription drug or proprietary medicine and treat, cure, or prevent disease in human beings.

g. Items containing nonprescription drugs or other medicinal ingredients that serve a secondary function to the intended use of the product, such as toothpaste with nonprescription drugs added to prevent gingivitis.

4. Following is a list of nonprescription drugs and proprietary medicines that qualify for exemption based on their status as nonprescription drugs or proprietary medicines. This list is intended as a guide and is not intended to be all inclusive.

Acne products	Headache relief aid products
Alcohol, rubbing	Hemorrhoidal treatments
Alcohol swabs	Hydrogen peroxide
Allergy relief products	Ibuprofen
Analgesics	Insect bite and sting preparations
Anesthetics	Iodine
Antacids	Itch and rash relievers
Antibiotic ointments	Laxatives
Antifungals	Lice products used to kill lice that infect humans
Antihistamines	Liniments
Antimalarials	Lip balms, ice and salves, medicated
Antinauseants	Lotions, medicated
Antiseptics	Menstrual cramp relievers
Aspirin	Mercurochrome
Asthma preparations	Milk of Magnesia
Baby powder, medicated	Mineral oil
Bandages, gauze, or swabs, provided these items contain antiseptic or bacterial control products in the pad	Motion sickness remedies
Bee sting relievers	Mouthwashes containing antiseptic
Benzoin	Muscle ache relievers
Boric acid ointment	Nasal drops and sprays
Burn remedies	Nicotine supplements that treat nicotine withdrawal symptoms
Calamine lotion	Oil of wintergreen
Camphor	Pain relievers, oral or topical
Castor oil	Parasiticides for humans
Cathartics	Peroxide, medicinal
Cold or canker sore preparations	Poison ivy and oak preparations
Cold capsules and remedies	Powder, medicated
Contact lens lubricating and wetting solutions for insertion directly into the eye	Rectal preparations
Contraceptive creams containing nonprescription drugs and intended to treat a disease	Shampoos, medicated

Cough and cold items, cough drops, cough syrups	Sinus relievers
Dandruff and seborrhea preparations	Sitz bath solutions
Decongestants	Skin irritation relievers
Diarrhea remedies	Sleep aids and sleep inducers
Digestive aids	Soap, including germicidal, surgical, therapeutic, or other soaps used for medical treatment
Disinfectant for use on or about the human body	Styptic pencils
Diuretics	Sunburn lotions
Earache and earwax removal preparations	Sunscreen containing SPF protection
Eczema preparations	Suppositories, excluding contraceptives
Epsom salts	Teething preparations
Expectorants	Throat lozenges, medicated
Eye drops, lotions, ointments, and washes for healing, treatment, or therapeutic use	Tooth desensitizers
Fever blister aids	Toothache relievers
First aid healing agents, cleaners	Upset stomach relievers
Fluoride rinses and antiseptic dental washes	Vaginal infection remedies
Foot care products for treatments of infections, medicated callous or corn removers, ingrown toenail preparations, and athlete's foot treatments	Wart removers
Fungicides for human use	Witch hazel
Glucose tablets	Worming treatments for human use humans
Glycerine products intended for medical use	Zinc oxide ointments
Hay fever aid products	

5. Following is a list of items that do not qualify as nonprescription drugs or proprietary medicines. These items may qualify for another retail sales and use tax exemption. This list is intended as a guide and is not intended to be all inclusive.

Adhesive bandages, dressings, and cotton	Household disinfectants and insecticides
Adhesive removers	Infant formula
Adhesive tape	Insect repellant
Ammonia	Mouthwashes, excluding antiseptic mouthwashes
Appetite suppressants	Nutraceutical products
Bath crystals, milks, oils and powder	Oral electrolyte mixtures for rehydration
Birth control preparations	Pet medical supplies
Breath fresheners and sweeteners	Pet medicines
Bubble bath	Petroleum jelly
Bunions or corn pads, unless medicated	Powders, nonmedicated
Cleaning creams and lotions	Prophylactics
Cod liver oil	Pumice powder
Contact lens cleaning solutions and disinfectants, unless designed to be applied directly in the eye	Saline solution
Cosmetics, whether or not containing medicinal properties or acne treatments	Sanitary napkins, tampons, and similar items
Cotton applicators, rolls, balls, and swabs	Shampoos, nonmedicated
Cuticle softener	Shaving products
Denture adhesives, cleaners, and preparations	Skin bleaches
Deodorants and antiperspirants	Soaps for general use
Depilatories	Stimulants
Dental floss and threaders	Suntan lotion without SPF protection

Diet aids	Talcum powder
Dietary foods, supplements, and substitutes	Testing kits
Distilled water	Thermometers
Exfoliants	Toothpastes, polishes, powders, and whiteners, including products containing fluoride or peroxide
Glycolic acid products	Vitamins and mineral supplements
Hair restoration products	Wax
Hand sanitizers, sprays, foams, gels, soaps or wipes, including antibacterial items	Weight control preparations
Herbal teas, drinks, pills, or powder supplements	Wrinkle removing and concealing preparations

6. If a homeopathic product is classified as a drug by the federal Food and Drug Administration, is used internally or topically, and is used for the cure, treatment, mitigation, or prevention of disease in human beings, the product is exempt from the retail sales and use tax.

7. Nonprescription items packaged with items that would not qualify for exemption as nonprescription drugs, such as items found in a first-aid kit, are subject to the retail sales and use tax. The tax is computed on the total sales price.

8. Items identified as "sensitive care products" range from lotions and soap-free cleaners to medicated products that treat a number of medical conditions. The taxability of these items must be determined on a case-by-case basis, based on the ingredients the item contains and the intended purpose of the product.

9. Retailers making sales of nonprescription drugs must include exempt nonprescription drugs with all other exempt sales on the retailer's regular sales tax return, Form ST-9. Retail dealers making sales of such items must keep records segregating purchases and sales of exempt items.

~~D.~~ E. Eyeglasses and other ophthalmic aids and supplies.

1. Optometrists, ophthalmologists, and opticians are engaged in the provision of professional services and must pay the tax to their suppliers at the time they purchase instruments, supplies, equipment, and other tangible personal property used in performing their professional services or remit the use tax directly to the Department of Taxation on these items. However, when optometrists, ophthalmologists, and opticians provide eyeglass cases, contact lens storage containers, solutions, sterilization kits, or other similar devices related to wearing or maintaining contact lenses or eyeglasses to their patients free of charge, the practitioners may purchase these specified items exempt of the tax.

~~1. Sales of eyeglasses~~ 2. Eyeglasses ground on prescription of physicians, ophthalmologists, or optometrists~~, including~~ as well as frames ~~as an~~ that are an integral part of the glasses are ~~not subject to the tax~~ exempt from the retail sales and use tax. Eyeglass frames sold in connection with the repair or replacement of prescription eyeglasses are also exempt from the tax, provided the prescription for the glasses is on file with the person replacing or repairing the eyeglass frames.

~~2. Eyeglass frames sold in connection with the repair or replacement of eyeglasses ground on prescription of physicians, ophthalmologists or optometrists are not subject to the tax.~~

3. ~~Sales of~~ Dealers, including ophthalmologists and optometrists, are not subject to the retail sales and use tax on purchases of eyeglass frames, optical merchandise, and optical supplies ~~by~~ that are purchased for resale and may present the optical ~~supply houses to dealers, including ophthalmologists and optometrists, for resale are not subject to the tax until sold at retail by such purchasers at which time the rules set forth in this section apply~~ supplier with an exemption certificate, Form ST-10, at the time of purchase.

~~4. Sales of ophthalmic instruments and supplies to physicians, ophthalmologists, optometrists and other users are subject to the tax.~~

~~5. All sales to users or consumers of eyeglass~~ 4. Eyeglass frames, nonprescription sunglasses ~~not ground on prescription~~, cases, solutions for cleaning eyeglasses, barometers, telescopes, binoculars, opera glasses, and similar items are subject to the tax when sold to users or consumers. All persons~~, including opticians, optometrists and ophthalmologists~~ making ~~such~~ sales of these items, including opticians, optometrists, and ophthalmologists, are required to register as dealers and collect and pay the tax due. ~~However, sales of eyeglass frames or repair parts for prescription eyeglasses are exempt from the tax if the prescription for the glasses is on file with the person replacing or repairing the eyeglass frames~~.

~~6.~~ 5. The exemptions outlined in this ~~regulation~~ subsection have no application ~~whatever~~ to the retail sales of eyeglasses or other optical goods not prescribed by licensed optometrists or ophthalmologists. All ~~such~~ of these sales are subject to the tax.

~~E. Wheelchairs, braces, prosthetic devices, orthopedic appliances, etc.~~ F. Durable medical equipment, devices, and certain products for diabetics.

1. Generally. The tax does not apply to wheelchairs and their repair parts, braces, crutches, prosthetic devices, orthopedic appliances, catheters, urinary accessories, other

durable medical equipment and devices, insulin and insulin syringes, and equipment devices and chemical reagents ~~which~~ that may be used by a diabetic to test or monitor blood or urine~~,~~ when ~~such~~ these items are purchased by or on behalf of an individual ~~using these items~~ for the individual's exclusive use. ~~For example, if individual A purchases a wheelchair for use by individual B, no tax will apply to the transaction since the wheelchair is purchased on behalf of individual B. However, purchases of these items by a profit hospital, licensed nursing home, home for adults or by a licensed physician for use in his professional practice are deemed to be purchases on behalf of an individual only if purchased for a specific individual. Items withdrawn from an inventory of items purchased in bulk are not deemed to be purchased on behalf of an individual. (See subsection (G) below.)~~ The fact that an item is purchased from a medical equipment supplier or on a physician's prescription is not dispositive of its exempt status.

In addition, parts or supplies that are specifically designed for use with the items outlined in this subdivision are exempt from retail sales and use tax. For example, because hearing aids qualify as durable medical equipment, hearing aid batteries also are exempt durable medical equipment because these items are a part or supply specifically designed for use with hearing aids. General purpose medical supplies such as tape, gauze, dressings, alcohol swabs, and sharps containers for disposal of used needles and waste bags are not designed for use with durable medical equipment; therefore, they do not qualify for the exemption.

2. Prosthetic devices. Generally, implants satisfy the definition of prosthetic devices and may be purchased exempt of the tax when purchased by or on behalf of specific individuals. However, implants used for cosmetic purposes are not used to replace missing body parts or functions and, as such, do not qualify for exemption from the tax, regardless of whether they are purchased by or on behalf of an individual. For dentures and other prosthetic devices relating to the practice of dentistry, see 23VAC10-210-500.

3. Following is a list of the types of items that are deemed durable medical equipment or other qualifying equipment or devices under this subsection. This is a listing of general categories of products; specific items must meet all of the requirements for durable medical equipment or other qualifying items, as outlined in subdivision 1 of this subsection. The listing is intended to be exemplary and not all inclusive.

Aerosol compressors, stationary and portable	Oxygen concentrators
Air oxygen mixers	Oxygen conserving devices
Alternating pressure pads	Oxygen cylinders
Alternating pressure pumps, if used with alternate pressure pads	Oxygen equipment
Apnea monitors and accessories	Oxygen fittings and accessories
Aspirators	Oxygen humidifiers
Bed rails	Oxygen tubing
Bedside commodes	Oxygen
Bone fracture therapy devices	Paraffin baths
Catheter devices and supplies	Patient care equipment for physical and occupational therapy
Colostomy supplies and devices	Patient lifts
Communication aids for physically impaired	Patient lift slings
Continuous passive motion devices	Patient transport devices and boards
Continuous positive airway pressure (CPAP) and CPAP accessories	Percussors and vibrators
Crawlers	Physical therapy items such as wrist and ankle weights, shoulder braces, supports and braces when rehabilitative related
Crutches, crutch pads, and tips	Phototherapy lights, provided they are used to serve a medical purpose and not for sun tanning purposes
Cylinder stands and support devices	Pneumatic compression units and accessories
Cylinder transport devices, sheaths and carts	Posture back supports, including back supports for seating
Decubitus seating pads and bed pads	Raised toilet seats
Dressing aids, button loops, zipper aids, etc.	Reaching aids
Eating and drinking aids	Regulators and flowmeters
Emergency oxygen delivery units	Respiratory accessories, such as PFLEX or Peak Flow items

Enteral and parenteral feeding equipment and supplies, including tubes, pumps, and containers	Respiratory therapy equipment
Face masks	Restraints
Fitted stroller	Room humidifiers with script
Foam seating pads	Shampoo trays
Foam wedges	Shower seating and bath benches
Gas oxygen refills and tanks	Shower grip bars
Geriatric chairs	Sitting and sleeping cushions
Glucose monitors and supplies, except batteries	Specialized seating, desks, and work stations
Grooming aids and dental aids	Specially designed hand utensils
Hand exercise equipment putty	Splints and holders
Heating pads	Stairglides and lifts in home
Hospital beds	Standing frames, devices, and accessories
Hospital bed mattresses and egg crates	Stethoscope
Household aids for the impaired	Tank wrench
Hydro-collators	Transcutaneous electrical nerve stimulator (TENS) unit and muscle stimulators
Hydro-therm heating pads	TENS accessories (electrodes, wiring specifically for use with TENS units)
Ice bags	Toilet safety frames
Intermittent positive pressure breathing (IPPB) circuits, devices and supplies	Tracheotomy and suction supplies
Intravenous (IV) stands	Traction stands, pulleys, etc.
IV supplies such as catheters and tubing	Trapeze bars and bar stands
Leg weights, related to rehabilitation	Ultrasonic nebulizers
Lift recliners	Vaporizer
Liquid and gas oxygen systems, stationary and portable	Volume ventilators, respirators, and related device supplies
Manual resuscitators	Walker accessories
Muscle stimulators	Walkers
Nasal cannulas	Walking canes, quad canes, accessories
Nebulizers and tubing	Wheelchairs
Overbed tables	Wheel walkers
Oximeters	Writing and speech aids for the impaired

4. Following are examples that demonstrate whether the definition for durable medical equipment is met:

Example 1: A physician purchases a disposable capsule for a specific patient that must be ingested to capture internal images of the body. Because the capsule is disposable, it is not able to withstand repeated use. Therefore, the capsule does not qualify as durable medical equipment.

Example 2: A physician offering gynecological services purchases intrauterine copper contraceptive devices for a specific patient. Because the contraceptive devices are not useful in the absence of illness or injury, they are not durable medical equipment. Although there are instances of pregnancy that may threaten the health of a patient, and in which the patient may not be able to use other forms of contraceptive, the devices are designed for contraceptive use. Therefore, they are not exempt durable medical equipment.

5. The exemption in this subsection is available only for items purchased by or on behalf of an individual for his use. In order to be deemed a purchase on behalf of an individual, the item must be specifically purchased for the individual. If items are purchased in bulk and then dispensed to individual patients, the exemption does not apply, even if the items are modified or fitted for a specific individual.

Example 1: A physician maintains an inventory of crutches or ace bandages that are dispensed to individual patients as needed. The physician must pay sales or use tax on these items because the original purchase was not made on behalf of a specific patient.

Example 2: A physician determines that a patient needs a brace and purchases a brace specifically designed for that patient. The purchase is made on behalf of the individual and is exempt from the tax.

The Department of Taxation has not prescribed a certificate of exemption to use when durable medical equipment and other exempt items under subdivision 1 of this subsection are purchased on behalf of a specific person. When the purchaser has no blanket exemption for its purchases and no certificate of exemption or other exemption notice from the Department of Taxation applies, the dealer must get a signed statement from the medical service provider making the purchase, such as the hospital, nursing home, licensed physician, or infusion service business, certifying that the durable medical equipment is purchased on behalf of a specific patient through a doctor's prescription or hospital's work order and is for sole use by that patient. The purchaser is also responsible for retaining a copy of the doctor's prescription or hospital work order as part of the record of the transaction for tax auditing purposes. The fact that a purchaser can trace durable medical equipment back to a specific patient after the fact is not sufficient to establish that the durable medical equipment was purchased for a specific individual; therefore, the purchaser's documentation must have included patient identification information at the time of purchase in order for the purchase to be deemed made on behalf of an individual. For purposes of proving that the sale was for a specific individual in the event of a sales and use tax audit, the purchaser may redact any identifying information in order to comply with federal and state privacy laws.

~~2. Hemodialysis and peritoneal dialysis.~~

~~Hemodialysis and peritoneal dialysis equipment, supplies and drugs used in dialysis are not subject to the tax. This exemption is applicable regardless of the nature of the purchaser. Therefore such dialysis equipment, supplies and drugs may be purchased exempt by physicians, individuals, profit and nonprofit hospitals, and other entities.~~

~~F. Durable medical equipment. The tax does not apply to durable medical equipment purchased by or on behalf of an individual. Durable medical equipment is that which (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to a person in the absence of illness or injury; and (4) is appropriate for use in the home. In order for an item to be exempt from the tax, it must meet all of the above criteria. The fact that an item is purchased from a medical equipment supplier is not dispositive of its exempt status; the item must satisfy the definition of durable medical equipment.~~

~~Following is a list of those types of items which constitute durable medical equipment. This is a listing of general categories of products; specific items must still meet the definition set forth above. The listing is intended to be exemplary and not all inclusive.~~

~~Oxygen equipment~~

~~Oxygen cylinders~~

~~Cylinder transport devices (sheaths, carts)~~

~~Cylinder stands, support devices~~

~~Regulators, flowmeters~~

~~Tank wrench~~

~~Oxygen concentrators~~

~~Liquid oxygen base dispenser~~

~~Liquid oxygen portable dispenser~~

~~Oxygen tubing~~

~~Nasal cannulas~~

~~Face masks~~

~~Oxygen humidifiers~~

~~Oxygen fittings, accessories~~

~~Respiratory therapy equipment~~

~~Room humidifiers (with script)~~

~~Aspirators~~

~~Aerosol compressors (stationary and portable)~~

~~Ultrasonic nebulizers~~

~~Volume ventilators, respirators and related device supplies~~

~~Percussors, vibrators~~

~~IPPB, circuits, devices and supplies~~

~~Air-oxygen mixers~~

~~Manual resuscitators~~

~~Nebulizers, tubing~~

~~Emergency oxygen delivery units~~

~~Patient care equipment, physical and occupational therapy~~

~~Hospital beds~~

~~Trapeze bars - bar stand~~

~~Bed rails~~

~~Geriatric chairs~~

~~Lift recliners~~

~~Bedside commodes~~

~~Overbed tables~~

~~Patient lifts~~

~~Patient lifts slings~~

~~Traction stands, pulleys, etc.~~

~~Shower seating~~

~~Shower grip bars~~

~~Raised toilet seats~~

~~Toilet safety frames~~

~~Walking canes, quad canes, accessories~~

~~Walkers~~

~~Wheel walkers~~

~~Walker accessories~~

~~I.V. stands~~

~~Crawlers~~

~~Posture back supports for seating~~

~~Posture back supports~~

~~Wheelchairs~~

~~Crutches, crutch pads, tips~~

~~Restraints~~

~~Standing frames, devices and accessories~~

~~Colostomy supplies and devices~~

~~Enteral and parenteral feeding equipment and supplies (tubes, pumps, containers)~~

~~Catheter devices and supplies~~

~~Hand exercise equipment putty~~

~~Specially designed hand utensils~~

~~Leg weights (rehab. related)~~

~~Paraffin baths~~

~~Hydro-collators~~

~~Hydro-therm heating pads~~

~~Communication aids for physically impaired~~

~~Specialized seating, desks, work stations~~

~~Foam wedges~~

~~Writing and speech aids for the impaired~~

~~Dressing aids, button loops, zipper aids, etc.~~

~~Grooming aids, dental aids~~

~~Eating and drinking aids~~

~~Splints, holders~~

~~Household aids for the impaired~~

~~Shampoo trays~~

~~Reaching aids~~

~~Foam seating pads~~

~~Decubitis seating pads, bed pads~~

~~Fitted stroller~~

~~Alternating pressure pads~~

~~Stethoscope~~

~~Sitting and sleeping cushions~~

~~Patient transport devices, boards~~

~~Stairglides, lifts in home~~

~~Transcutaneous nerve stimulators~~

~~Muscle stimulators~~

~~Bone fracture therapy devices~~

~~G. Purchases on behalf of an individual. The exemption for wheelchairs and repair parts, braces, crutches, prosthetic devices, orthopedic appliances, catheters, urinary accessories, insulin and insulin syringes, equipment, devices or chemical reagents used by a diabetic to test or monitor blood or urine, and durable medical equipment and devices and related parts and supplies specifically designed for such equipment extends to items purchased "on behalf of" an individual for his use. In order to be deemed a purchase on behalf of an individual, the item must be specifically bought for the individual. If items are purchased in bulk and then dispensed to individual patients, no exemption is applicable even if the item is modified or fitted for a specific individual.~~

~~For example if a physician maintains an inventory of crutches or ace bandages which are dispensed to individual patients as needed, the purchase of these items is not exempt since the original purchase was not made on behalf of a specific patient. Conversely, if a physician determines that a patient needs a brace and purchases a brace specifically designed for that patient, the purchase is made on behalf of the individual and will not be subject to the tax.~~

~~For dentures and other prosthetic devices relating to the practice of dentistry, see 23VAC10-210-500.~~

G. Hemodialysis and peritoneal dialysis equipment, supplies, and drugs. Hemodialysis and peritoneal dialysis equipment, supplies, and drugs used in dialysis are not subject to the tax. This exemption is applicable regardless of the nature of the purchaser. Therefore, hemodialysis and peritoneal dialysis equipment, supplies, and drugs may be purchased exempt by physicians, individuals, for-profit and nonprofit hospitals, and other entities.

H. Samples distributed to authorized recipients. Pharmaceutical manufacturers are not subject to sales and use tax for samples of prescription drugs and medicines or the packaging when distributed free of charge to licensed physicians, hospitals, pharmacies, and other health care facilities upon the written request of these medical providers in accordance with the federal Food, Drug, and Cosmetic Act (21 USC § 301 et seq.).

I. Purchases of medicines and drugs by veterinarians. Veterinarians who dispense medicines or drugs on prescription are deemed the users or consumers of all such medicines and drugs and must pay the retail sales and use tax on these purchases; however, veterinarians may purchase exempt of the sales and use tax all medicines and drugs that will be used in caring for, medicating, or treating agricultural production animals. For additional information on the taxability of drugs dispensed by veterinarians, see 23VAC10-210-6050.

J. Purchases of medical products and supplies by certain Medicaid recipients. Medicaid recipients are authorized to purchase medical products and supplies that are otherwise taxable, such as bandages, gauze dressings, incontinence products, and wound care products exempt from the retail sales and use tax, provided the purchase is made through a Department of Medical Assistance Services (DMAS) provider agreement. This exemption applies to any type of medical product or supply, incontinence, or wound care product, provided DMAS pays for the product or supply. Sellers must maintain sufficient documentation to verify that the purchase transaction meets the criteria of the exemption. The documentation must (i) identify the item sold; (ii)

identify that the purchaser is a Medicaid recipient; and (iii) verify that the transaction is billed in accordance with a DMAS provider agreement.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (23VAC10-210)

Business Registration Application, Form R-1 (rev. 3/08).

5% Virginia Sales Tax Table (rev. 9/04).

2.5% Virginia Qualifying Food Sales Tax Table (rev. 4/05).

Certificate of Registration, Form ST-4 (rev. 2/08).

Virginia Direct Payment Permit Sales and Use Tax Return, Form ST-6 (rev. 9/05).

Virginia Direct Payment Permit Sales and Use Tax Return Worksheet (Instructions), Form ST-6A (rev. 9/05).

Virginia Schedule of Local Taxes, Form ST-6B (rev. 7/05).

Virginia Business Consumer's Use Tax Return, Form ST-7 (rev. 7/05).

Virginia Business Consumer's Use Tax Return Worksheet and Instructions, Form ST-7A (rev. 6/05).

Virginia Out-of-State Dealer's Use Tax Return, Form ST-8 (rev. 9/05).

Virginia Out-of-State Dealer's Use Tax Return Worksheet and Instructions, Form ST-8A (rev. 9/05).

~~Virginia Retail Sales and Use Tax Return, Form ST-9 (rev. 11/06).~~

~~Virginia Retail Sales and Use Tax Worksheet and Instructions, Form ST-9A (rev. 9/05).~~

~~Schedule of Local Sales and Use Taxes, Form ST-9B (rev. 7/05).~~

Virginia Retail Sales and Use Tax Return, Form ST-9 (6210051) (rev. 3/2013)

Virginia Retail Sales and Use Tax Return for Consolidated Filers, Form ST-9 (6210051) (rev. 3/2013); includes:

Virginia Schedule of Local Sales and Use Taxes, Form ST-9B (6202053) (rev. 3/2013)

Virginia Retail Sales and Use Tax, ST-9A Worksheet (6201052) (rev. 3/2013)

Virginia Schedule of Regional State Sales and Use Tax, Form ST-9R (6201055) (rev. 2013)

Application for Sales and Use Tax Exemption for Nonprofit Organizations, Form NPO Appl (rev. 1/08).

~~Sales and Use Tax Certificate of Exemption (For dealers who purchase tangible personal property for resale, lease or rental), Form ST-10 (rev. 10/99).~~

Sales and Use Tax Certificate of Exemption, Form ST-10 (6201056) (rev. 9/2015) - For a Virginia dealer who purchases tangible personal property for resale, or for lease or rental, or who purchases materials or containers to package tangible personal property for sale

Sales and Use Tax Certificate of Exemption (For catalogs and other printed materials distributed outside of Virginia; property delivered to factor or agent for foreign export; advertising for placement in media; advertising supplements), Form ST-10A (rev. 6/95).

Sales and Use Tax Certificate of Exemption (for use by handicapped persons for purchase of special equipment for installation on a motor vehicle), Form ST-10B (rev. 7/78).

Sales and Use Tax Certificate of Exemption (For manufacturing, processing, refining, converting, mining, basic research and research and development in experimental or laboratory sense, or certified pollution control equipment; equipment, materials or supplies used in the production of a publication issued at least quarterly; high speed electrostatic duplicators; materials, containers, etc. for future used for packaging tangible personal property for shipment or sale), Form ST-11 (rev. 6/06).

Sales and Use Tax Certificate of Exemption (For use by construction contractors and non-manufacturers when purchasing tangible personal property for usage directly in manufacturing products for sale or resale which are exempt from the tax; incorporation into real property in another state or foreign country which could be purchased free from the tax in such state or country; agricultural production, to be affixed to real property owned or leased by a farmer engaged in agricultural production for market), Form ST-11A (rev. 5/06).

Sales and Use Tax Certificate of Exemption (For use by a semiconductor manufacturer), Form ST-11B (rev. 5/06).

Sales and Use Tax Certificate of Exemption (For use by the Commonwealth of Virginia, a political subdivision of the Commonwealth of Virginia, or the United States), Form ST-12 (rev. 10/06).

Sales and Use Tax Certificate of Exemption (For use by certain medical related organizations), Form ST-13 (rev. 10/06).

Sales and Use Tax Certificate of Exemption (For use by nonprofit churches), Form ST-13A (rev. 6/07).

Sales and Use Tax Certificate of Exemption (For use exclusively by an out-of-state dealer who purchases tangible personal property in VA for immediate transportation out of VA in his own vehicle for resale outside VA), Form ST-14 (rev. 3/99).

Sales and Use Tax Certificate of Exemption (For use exclusively by an out-of-state dealer who purchases livestock

in VA for immediate transportation out of VA for resale outside VA.) Form ST-14A (rev. 1/99).

Sales and Use Tax Certificate of Exemption (For use by individuals purchasing heating oil, artificial or propane gas, firewood or coal for domestic consumption), Form ST-15 (rev. 9/05).

Sales and Use Tax Certificate of Exemption (For use by watermen who extract fish, bivalves, or crustaceans from waters for commercial purposes.), Form ST-16 (rev. 9/05).

Sales and Use Tax Certificate of Exemption (For use by harvesters of forest products.), Form ST-17 (rev. 7/99).

Sales and Use Tax Certificate of Exemption (For use by farmers engaged in agricultural production), Form ST-18 (rev. 5/06).

Sales and Use Tax Certificate of Exemption (For use by shipping lines engaged in interstate or foreign commerce, and by shipbuilding companies engaged in building, converting or repairing ships or vessel), Form ST-19 (rev. 6/05).

Sales and Use Tax Certificate of Exemption (For use by certain public service corporations, commercial radio, and television companies, cable television systems, taxicab operators and certain airlines.), Form ST-20 (rev. 9/04).

Sales and Use Tax Certificate of Exemption (For use by production companies, program producers, radio, television and cable T.V. companies, and other entities engaged in the production and creation of exempt audiovisual works and the licensing, distribution and broadcasting of same), Form ST-20A (rev. 9/05).

Sales and Use Tax Certificate of Exemption (For use when purchasing or leasing railroad rolling stock from a manufacturer), Form ST-22 (rev. 4/07).

Sales and Use Tax Certificate of Exemption (For use by individuals purchasing multi-fuel heating stoves for resident heating, Form ST-23 (rev. 8/07).

Virginia Consumers Use Tax Return for Individuals, Form CU-7 (rev. 6/07).

Virginia Vending Machine Dealer's Sales Tax Return, Form VM-2 (rev. 8/05).

Virginia Vending Machines Dealer's Sales Tax Return Worksheet, Form VM-2A (rev. 9/05).

Schedule of Local Vending Machine Sales Tax, Form VM-2B (rev. 7/05).

VA.R. Doc. No. R16-650; Filed May 31, 2016, 11:34 a.m.

Fast-Track Regulation

Title of Regulation: **23VAC10-210. Retail Sales and Use Tax (amending 23VAC10-210-160, 23VAC10-210-220, 23VAC10-210-250, 23VAC10-210-340, 23VAC10-210-450, 23VAC10-210-485, 23VAC10-210-630, 23VAC10-210-680, 23VAC10-210-2070, 23VAC10-210-3080, 23VAC10-210-6041, 23VAC10-210-6042, 23VAC10-210-6043).**

Statutory Authority: § 58.1-203 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: August 26, 2016.

Effective Date: September 12, 2016.

Agency Contact: Andrea Muse, Department of Taxation, 600 East Main Street, Richmond, VA 23261-7185, telephone (804) 371-2336, FAX (804) 371-2355, or email andrea.muse@tax.virginia.gov.

Basis: Section 58.1-203 of the Code of Virginia authorizes the Tax Commissioner to issue regulations relating to the interpretation and enforcement of the laws governing taxes administered by the Department of Taxation. The retail sales and use tax is administered by the Department of Taxation.

Purpose: Statutory rate change and legislative changes. This regulatory action is needed to (i) update the retail sales and use tax rate to the rate provided in statute, (ii) reflect the legislative change allowing dealers to absorb the sales and use tax during the sales tax holiday period, and (iii) reflect the legislative change in the dealer discount percentages. Updating Retail Sales and Use Tax, 23VAC10-210, for the rate change and the other legislative changes does not reflect any change in current tax policy and will have no impact on the administration of the retail sales and use tax.

Sourcing rules. As the additional 0.7% state retail sales and use tax is only imposed in certain localities, the retail sales and use tax rate may be different depending upon in which locality the sale or use is sourced. On June 13, 2013, the Department of Taxation published the "Guidelines for the Retail Sales and Use Tax Changes Enacted in the 2013 General Assembly Session" after working with affected dealers, providers of transient lodgings, and local governments. The guidelines set out rules based on long-standing policy pursuant to §§ 58.1-605 and 58.1-606 of the Code of Virginia regarding how to determine which Virginia locality is attributed the sale or use of tangible personal property for the purposes of the retail sales and use tax. The amendments are needed to set out these sourcing rules in a regulation.

Fuels for domestic consumption. The amendments are needed to update the list of cities and counties that the department is aware of having, as of 2014, adopted ordinances exempting fuels for domestic consumption from the local 1.0% sales and use tax. Updating the regulation does not reflect any change in current tax policy and will have no impact on the administration of the Retail Sales and Use Tax.

As the Commonwealth relies on tax revenues to fund core government activities, enforcement of its tax laws is essential to protect the health, safety, and welfare of citizens. Although administrative interpretations of the tax laws that are in the form of published rulings, tax bulletins, guidelines, and other published documents are accorded judicial notice, even published "rulings and policies themselves are not entitled to great weight, unless expressed in regulations" Chesapeake

Hospital Authority v. Commonwealth, 262 Va. 551 (2001). Therefore, to ensure enforcement, it is necessary to promulgate regulations containing the Tax Commissioner's interpretations of the tax laws. This action is necessary to conform the retail sales and use tax regulation to statutory changes.

Rationale for Using Fast-Track Process: Legislative changes. Amending Retail Sales and Use Tax, 23VAC10-210, to update the tax rate and reflect legislative changes regarding the absorption of the retail sales and use tax and the dealer discount percentages is expected to be noncontroversial and appropriate for the fast-track rulemaking process.

Sourcing rules. Amending 23VAC10-210-2070 to provide sourcing rules is expected to be noncontroversial and appropriate for the fast-track rulemaking process as it will set out rules based on long-standing policy that were published in guidelines issued in 2013. These rules are set out for purposes of the 1.0% local option sales and use tax in §§ 58.1-605 and 58.1-606 of the Code of Virginia. The department provided the draft guidelines on April 8, 2013, to Commissioners of the Revenue in the Northern Virginia and Hampton Roads Regions; industry organizations such as the Virginia Chamber of Commerce, Virginia Retail Merchants Association, and the Virginia Petroleum, Convenience, and Grocery Association; the Virginia Society of Certified Public Accountants; the Virginia Bar; and several retailers. After allowing the interested parties time to comment and review and receiving no opposition, the department published the final "Guidelines for the Retail Sales and Use Tax Changes Enacted in the 2013 General Assembly Session" on May 1, 2013. The guidelines were subsequently revised and reissued on June 13, 2013, pursuant to a legal decision regarding the localities that fall within the Hampton Roads Region. The department is not aware of anyone disagreeing with the revised guidelines.

Fuels for domestic consumption. Amending 23VAC10-210-630 to update the list of cities and counties that the department is aware of having, as of 2014, adopted ordinances exempting fuels for domestic consumption from the local 1.0% sales and use tax is expected to be noncontroversial and appropriate for the fast-track rulemaking process.

Substance: Legislative changes. This action amends Retail Sales and Use Tax, 23VAC10-210, to (i) update the retail sales and use tax rate to the rate provided in the statute, (ii) reflect the legislative change allowing dealers to absorb the sales and use tax during the sales tax holiday period, and (iii) reflect the legislative change in the dealer discount percentages. Updating the retail sales and use tax regulation for the rate change and the other legislative changes does not reflect any change in current tax policy and will have no impact on the administration of the retail sales and use tax.

Sourcing rules. This regulatory action amends 23VAC10-210-2070 to set out sourcing rules for the retail sales and use tax. Traditionally, determining the situs of a sale subject to the Virginia retail sales and use tax was necessary to determine which city or county received the 1.0% local option sales and use tax. Effective July 1, 2013, determining the situs of a sale became more important because an additional state retail sales and use tax was imposed in Northern Virginia and Hampton Roads at the rate of 0.7% pursuant to Chapter 766 of the 2013 Acts of Assembly. "Northern Virginia Region" includes the Counties of Arlington, Fairfax, Loudoun, and Prince William and the Cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park. "Hampton Roads Region" includes the Counties of Isle of Wight, James City, Southampton, and York and the Cities of Chesapeake, Franklin, Hampton, Newport News, Norfolk, Poquoson, Portsmouth, Suffolk, Virginia Beach, and Williamsburg.

On June 13, 2013, the Department of Taxation published the "Guidelines for the Retail Sales and Use Tax Changes Enacted in the 2013 General Assembly Session" after working with affected dealers, providers of transient lodgings, and local governments. The guidelines set out rules based on long-standing policy regarding how to determine which Virginia locality is attributed the sale or use of tangible personal property for the purposes of the retail sales and use tax. These rules are set out for purposes of the 1.0% local option sales and use tax in §§ 58.1-605 and 58.1-606 of the Code of Virginia.

Generally, intrastate sales are sourced to the city or county of the place of business of the dealer collecting the tax, without regard to the city or county of possible use by the purchaser. The use tax is generally sourced to the city or county where the goods are used or consumed by the purchaser, or stored for use or consumption. Out-of-state dealers who hold Certificates of Registration to collect the use tax from their customers must source sales into Virginia according to the city or county of destination.

Fuels for domestic consumption. This action amends 23VAC10-210-630 to update the list of cities and counties that notified the department prior to March 1983 that ordinances had been adopted exempting fuels for domestic consumption from the local 1.0% sales and use tax. The amendment will add to the list of cities and counties that the department is aware of having, as of 2014, adopted an ordinance exempting fuels for domestic consumption from the local 1.0% sales and use tax.

Issues: As the regulatory action will update Retail Sales and Use Tax, 23VAC10-210, to reflect current law and set out rules based on long-standing policy pursuant to §§ 58.1-605 and 58.1-606 of the Code of Virginia, there are no issues or disadvantages to the public or the Commonwealth associated with this regulatory action. The primary advantage to the public, the Department of Taxation, and the Commonwealth of this action is that it will conform the retail sales and use tax regulation to legislative changes in the statutory law and thereby assist taxpayers with voluntary compliance with the

tax, ease administration of the tax by the Department of Taxation, and help ensure the steady flow of tax revenues to the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Department of Taxation (Department) proposes several amendments to reflect statutory changes, in particular the increase in the state Retail Sales and Use Tax rate from 4 percent to 4.3 percent, and the additional 0.7 percent state Retail Sales and Use Tax in the Northern Virginia and Hampton Roads regions. Also, the Department proposes to update the list of cities and counties that have adopted an ordinance exempting fuels for domestic consumption from the local 1% sales and use tax.

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

Estimated Economic Impact. The current regulation does not reflect numerous statutory changes that have been made regarding the Retail Sales and Use Tax. Legislation enacted by the 2013 General Assembly (2013 Acts of Assembly, Chapter 766) increased the state Retail Sales and Use Tax rate from 4 percent to 4.3 percent and imposed an additional state Retail Sales and Use Tax in the Northern Virginia[1] and Hampton Roads[2] regions at the rate of 0.7 percent, effective July 1, 2013. The Department proposes several amendments to the regulation to reflect these changes.

As the additional 0.7% state Retail Sales and Use Tax is only imposed in certain localities, the total Retail Sales and Use Tax rate may be different depending on which locality the sale or use is sourced. On June 13, 2013, the Department published the "Guidelines for the Retail Sales and Use Tax Changes Enacted in the 2013 General Assembly Session" after working with affected dealers, providers of transient lodgings, and local governments. The Guidelines set out rules based on long-standing policy pursuant to Va. Code §§ 58.1-605 and 606 regarding how to determine which Virginia locality is attributed the sale or use of tangible personal property for the purposes of the Retail Sales and Use Tax. The Department proposes to include these rules in the regulation.

The regulation grants compensation to dealers for accounting for and paying the state tax in the form of discounts. The discount percentages listed in the current regulation are out of date due to explicit changes in several bills during the 2010, 2011, 2012, 2013, 2014, and 2015 General Assembly sessions.[3] Legislation enacted in 2006 (2006 Acts of Assembly, Chapter 593) allows dealers to absorb the sales and use tax during the sales tax holiday period. The Department proposes to amend the regulation to reflect the current statutory discount rates and the legislation on absorbing the sales and use tax during the sales tax holiday period.

The regulation (both current and proposed) state that "The local 1% sales and use tax will continue to apply to all purchases for domestic consumption of artificial or propane gas, firewood, coal and home heating oil unless the locality adopts an ordinance specifically exempting such fuels." The current regulation lists localities that as of 1983 had adopted such ordinances. The Department proposes to update the list of cities and counties with an ordinance exempting fuels for domestic consumption from the local 1% sales and use tax.

The proposed amendments will not affect the tax rates, rules and policies in effect, but will be beneficial by increasing clarity and reducing potential confusion for readers of the regulation.

Businesses and Entities Affected. The proposed amendments pertain to retailers, large and small, throughout the Commonwealth.

Localities Particularly Affected. Most of the proposed provisions apply to all localities. The additional 0.7 percent state Retail Sales and Use Tax applies to only the following: 1) the Counties of Arlington, Fairfax, Isle of Wight, James City, Loudoun, Prince William, Southampton, and York, and 2) the Cities of Alexandria, Chesapeake, Fairfax, Falls Church, Franklin, Hampton, Manassas, Manassas Park, Newport News, Norfolk, Poquoson, Portsmouth, Suffolk, Virginia Beach, and Williamsburg.

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

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

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

Small Businesses:

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

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

Alternative Method that Minimizes Adverse Impact. The proposed amendments do not create adverse impact for small businesses.

Adverse Impacts:

Businesses. The proposed amendments will not adversely affect businesses.

Localities. The proposed amendments will not adversely affect localities.

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

[1] The "Northern Virginia Region" is defined as the Counties of Arlington, Fairfax, Loudoun, and Prince William and the Cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park.

[2] The "Hampton Roads Region" is defined as the Counties of Isle of Wight, James City, Southampton, and York and the Cities of Chesapeake, Franklin, Hampton, Newport News, Norfolk, Poquoson, Portsmouth, Suffolk, Virginia Beach, and Williamsburg.

[3] House Bill 29 and House Bill 30 (2010 Acts of Assembly, Chapters 872 and 874); House Bill 1500 (2011 Acts of Assembly, Chapter 890); House Bill 1300 and House Bill 1301 (2012 Special Session I Acts of Assembly, Chapters 2 and 3); House Bill 1500 (2013 Acts of Assembly, Chapter 806); House Bill 5001, House Bill 5002, and House Bill 5010 (2014 Special Session I Acts of Assembly, Chapters 1, 2, and 3); and House Bill 1400 (2015 Acts of Assembly, Chapter 665).

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

Summary:

The amendments (i) reflect statutory increases in the state retail sales and use tax rate from 4.0% to 4.3%, and an additional 0.7% state retail sales and use tax in the Northern Virginia and Hampton Roads Regions, and (ii) update the list of cities and counties that have adopted an ordinance exempting fuels for domestic consumption from the local 1.0% sales and use tax. The amendments do not reflect any change in current tax policy.

23VAC10-210-160. Bad debts.

A. Generally. Any dealer may obtain a credit for the amount of any sales or use tax previously reported and paid on a return for accounts found to be worthless. Such credit must be claimed on the return filed for the period in which the account is determined to be worthless.

B. Limitations. No credit may exceed the amount of sales price which is actually uncollectible. Prior payments made to the dealer on a debt which is subsequently determined to be uncollectible must be allocated to the sales price, sales tax and other nontaxable charges based on the percentage that those charges represent to the total debt originally owed.

If any part of the sales price for which a credit was taken is subsequently reported to the dealer, it must be included in such dealer's next sales and use tax return.

The following example illustrates the operation of this section.

Example: Dealer A repairs an item of property for a customer. The total charge for such repair is ~~$77~~ $77.65, representing $50 in repair parts, $25 in separately stated, nontaxable repair labor, and ~~$2~~ $2.65 in tax. A reports the transaction and remits the tax thereon. After collecting $30, A determines that the remainder of the debt is uncollectible. A may claim a credit calculated as follows:

Allocation of Amount Previously Collected:

50 / ~~77~~ 77.65 x $30 = Amount to be Allocated to Repair Parts = ~~$19.48~~ $19.32

Amount of Sales Price for Computing Credit = $50.00 - ~~$19.48~~ $19.32 = ~~$30.52~~ $30.68

Amount of Credit which may be claimed = ~~$1.22 (4% x $30.52)~~ $1.63 (5.3% x $30.68)

Since only the charge for the repair parts was previously reported as a taxable sale, only the tax on that portion of the remaining outstanding debt attributable to the charge for such parts may be taken as a credit. If any portion of the ~~$30.52~~ $30.68 remaining sales price is subsequently collected, such amount must be reported on the dealer's return for the period in which collected.

C. Hampton Roads Region and Northern Virginia Region. The total rate of the state and local sales and use tax in localities that fall within these regions is 6.0% (4.3% state, 0.7% regional, and 1.0% local). The provisions of this section apply to transactions sourced to the Hampton Roads Region and the Northern Virginia Region, mutatis mutandis. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

23VAC10-210-220. Brackets for collection of the tax.

A. The rate of the sales and use tax is ~~5.0%~~ 5.3%, which is comprised of a ~~4.0%~~ 4.3% state tax and a 1.0% local tax applicable throughout Virginia. (See 23VAC10-210-6040 through 23VAC10-210-6043 for special tax rate and provisions applicable to sales through vending machines.) An additional state sales and use tax is imposed in the Northern Virginia and Hampton Roads Regions at the rate of 0.7%. The total rate of the state and local sales and use tax is 6.0% in localities that fall within these regions (4.3% state, 0.7% regional, and 1.0% local). For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

The bracket system is used to eliminate fractions of $.01 and must be used to compute the tax on transactions of $5.00 or less. On transactions over $5.00, the tax is computed at a straight ~~5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions), with one half cent or more treated as $.01. Any dealer who collects the tax in accordance with the bracket system set forth herein shall not be deemed to have over collected the tax. For over collection of the tax generally, see 23VAC10-210-340 D.

B. The bracket system does not relieve the dealer from the liability to pay an amount equal to ~~5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) of his gross taxable sales. However, if the dealer can prove to the department that more than 85% of the gross taxable sales for the period were from individual sales of $.10 or less (and that he was unable to adjust his prices in such manner as to prevent the economic incidence of the sales tax from falling on him), the department will determine the proper tax liability of the dealer based on the portion of gross taxable sales that came from sales of $.11 or more. Any dealer who may claim this exception must file with each return a separate statement

explaining his claim in detail for consideration by the department.

C. Below is the bracket system for the combined state and local tax of ~~5.0%~~ 5.3% on transactions of $5.00 or less:

~~Sales Price~~	~~Tax Due~~
~~0.01 to 0.09~~	~~0~~
~~0.10 to 0.29~~	~~0.01~~
~~0.30 to 0.49~~	~~0.02~~
~~0.50 to 0.69~~	~~0.03~~
~~0.70 to 0.89~~	~~0.04~~
~~0.90 to 1.09~~	~~0.05~~
~~1.10 to 1.29~~	~~0.06~~
~~1.30 to 1.49~~	~~0.07~~
~~1.50 to 1.69~~	~~0.08~~
~~1.70 to 1.89~~	~~0.09~~
~~1.90 to 2.09~~	~~0.1~~
~~2.10 to 2.29~~	~~0.11~~
~~2.30 to 2.49~~	~~0.12~~
~~2.50 to 2.69~~	~~0.13~~
~~2.70 to 2.89~~	~~0.14~~
~~2.90 to 3.09~~	~~0.15~~
~~3.10 to 3.29~~	~~0.16~~
~~3.30 to 3.49~~	~~0.17~~
~~3.50 to 3.69~~	~~0.18~~
~~3.70 to 3.89~~	~~0.19~~
~~3.90 to 4.09~~	~~0.2~~
~~4.10 to 4.29~~	~~0.21~~
~~4.30 to 4.49~~	~~0.22~~
~~4.50 to 4.69~~	~~0.23~~
~~4.70 to 4.89~~	~~0.24~~
~~4.90 to 5.00~~	~~0.25~~

Sales Price	Tax Due
0.01 to 0.09	0
0.10 to 0.28	0.01
0.29 to 0.47	0.02
0.48 to 0.66	0.03
0.67 to 0.84	0.04
0.85 to 1.03	0.05
1.04 to 1.22	0.06
1.23 to 1.41	0.07
1.42 to 1.60	0.08
1.61 to 1.79	0.09
1.80 to 1.98	0.10
1.99 to 2.16	0.11
2.17 to 2.35	0.12
2.36 to 2.54	0.13
2.55 to 2.73	0.14
2.74 to 2.92	0.15
2.93 to 3.11	0.16
3.12 to 3.30	0.17
3.31 to 3.49	0.18
3.50 to 3.67	0.19
3.68 to 3.86	0.20
3.87 to 4.05	0.21
4.06 to 4.24	0.22
4.25 to 4.43	0.23
4.44 to 4.62	0.24
4.63 to 4.81	0.25
4.82 to 4.99	0.26
5.00	0.27

For differential rate on fuels for domestic consumption, see 23VAC10-210-630.

D. This subsection contains the bracket system for the combined state, regional, and local tax of 6.0% in the Hampton Roads and Northern Virginia Regions on transactions of $5.00 or less:

Sales Price	Tax Due
0.00 to 0.08	0
0.09 to 0.24	0.01
0.25 to 0.41	0.02
0.42 to 0.58	0.03

0.59 to 0.74	0.04
0.75 to 0.91	0.05
0.92 to 1.08	0.06
1.09 to 1.24	0.07
1.25 to 1.41	0.08
1.42 to 1.58	0.09
1.59 to 1.74	0.10
1.75 to 1.91	0.11
1.92 to 2.08	0.12
2.09 to 2.24	0.13
2.25 to 2.41	0.14
2.42 to 2.58	0.15
2.59 to 2.74	0.16
2.75 to 2.91	0.17
2.92 to 3.08	0.18
3.09 to 3.24	0.19
3.25 to 3.41	0.20
3.42 to 3.58	0.21
3.59 to 3.74	0.22
3.75 to 3.91	0.23
3.92 to 4.08	0.24
4.09 to 4.24	0.25
4.25 to 4.41	0.26
4.42 to 4.58	0.27
4.59 to 4.74	0.28
4.75 to 4.91	0.29
4.92 to 5.00	0.30

23VAC10-210-250. Cash and trade discounts.

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

"Cash or trade discount" includes a discount for the early payment of the purchase price, a discount attributable to the value of an item taken in trade, or a discount based upon the method of payment.

B. Cash ~~and~~ or trade discounts taken on sales are not includible in the sales price for purposes of computing the tax. The amount of such discounts may be deducted from gross sales provided the discounts have been included in gross sales.

C. In computing the amount of a discount that may be subtracted from gross sales, the discount must be allocated between sales price and sales tax. The following examples illustrate the application of this concept.

Example 1: Dealer A sells an item to a customer for $100 and bills the customer $100 for the item and ~~$5.00~~ $5.30 for the tax. The terms of the sale provide for a 10% discount if the bill is paid within 30 days. The customer pays within 20 days and is therefore entitled to the discount, which is computed as follows:

Amount Billed	~~$105.00~~ $105.30
Sales Price	$100.00
Tax	~~$5.00~~ $5.30
Less	$10.00 discount
Sales price discount	100.00 x l0% = 10.00
Tax discount	~~5.0~~ 5.3 x 10% = ~~$0.50~~ $0.53

Therefore, the customer remits ~~$94.50~~ $94.77, which includes $90 in sales price and ~~$4.50~~ $4.77 in sales tax. Dealer A may deduct $10.00 from gross sales, and will accordingly remit only ~~$4.50~~ $4.77 in tax.

Example 2: Dealer B sells an item to a customer for $100 and bills the customer $100 for the item and ~~$5.00~~ $5.30 for the tax. The terms of the sale provide for a $10 discount if the bill is paid within 30 days. The customer pays within 20 days and is therefore entitled to the discount, which is computed as follows:

Amount Billed	~~$105.00~~ $105.30
Sales Price	$100.00
Tax	~~$5.00~~ $5.30
Less	$10.00 discount
	$10.00 / ~~$1.05~~ $1.053 = ~~$9.52~~ $9.50 sales price discount
	~~$0.48~~ $0.50 tax discount

Therefore, the customer remits ~~$95.00~~ $95.30, which includes ~~$90.48~~ $90.50 in sales price and ~~$4.52~~ $4.80 in sales tax. Dealer B may deduct ~~$9.52~~ $9.50 from gross sales, and will accordingly remit only ~~$4.52~~ $4.50 in tax.

Example 3: Dealer B repairs a piece of equipment for a customer and bills the customer $100 for parts, $50 for labor, and ~~$5.00~~ $5.30 for tax. The terms of the sale provide for a $10 discount if the bill is paid within 30 days. B pays within 20 days and earns the discount which is computed as follows:

Amount Billed	~~$155.00~~ $155.30
Sales Price of Parts	$100.00
Separately Stated Repair Labor (nontaxable)	$50.00
Sales tax	~~$5.00~~ $5.30

Less $10.00 discount attributed as follows:

Attributable to Parts: (100 / $150) x $10.00 = $6.67
$6.67 / ~~1.05~~ 1.053 = ~~$6.35~~ $6.33 sales price discount
~~$0.32~~ $0.34 sales tax reduction

$3.33 attributable to nontaxable labor

Therefore, the customer remits ~~$145.00~~ $145.30, which includes ~~$93.65~~ $93.67 in sales price for the parts, ~~$4.68~~ $4.96 in sales tax attributable to the parts, and $46.67 for nontaxable labor. Dealer B may deduct ~~$6.35~~ $6.33 from gross sales and will accordingly remit only ~~$4.68~~ $4.96 in tax.

Regardless of whether a cash or percentage discount is used, the discount must be allocated between the sales price and the tax to avoid overcollection of the tax.

D. Hampton Roads Region and Northern Virginia Region. The total rate of the state and local sales and use tax in localities that fall within these regions is 6.0% (4.3% state, 0.7% regional, and 1.0% local). The provisions of this section apply to transactions sourced to the Hampton Roads Region and the Northern Virginia Region, mutatis mutandis. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

23VAC10-210-340. Collection of tax by dealers.

A. Generally. The tax must be paid to the state by the dealer, but the dealer must separately state the amount of the tax and add the tax to the sales price or charge. Thereafter, the tax is a debt from the purchaser, consumer or lessee to the dealer until paid and is recoverable at law in the same manner as other debts.

Identification of the tax by a separate writing or symbol is not required provided the amount of the tax is shown as a separate item on the record of the transaction. For special rules relating to vending machines sales, see 23VAC10-210-6040 through 23VAC10-210-6043.

B. Advertising absorption of tax by dealers ~~is prohibited~~. It is a misdemeanor for a dealer to advertise or hold out to the public in any manner, directly or indirectly, that he will absorb all or any part of the sales or use tax, or that he will relieve the purchaser, consumer or lessee of the payment of all or any part of the tax, except as may be authorized under the bracket system or the special provisions relating to vending machine sales. This prohibition does not apply during the sales tax holiday provided under §§ 58.1-609.1, 58.1-611.2, and 58.1-611.3 of the Code of Virginia, nor for the 14 days immediately preceding the commencement of the sales tax holiday. During this 17-day period, dealers may advertise that they will absorb the tax on any or all nonqualifying items. The dealer may not absorb the tax prior to or following the sales tax holiday period and may not advertise that he will do so.

C. Erroneous collection of tax on nontaxable transactions. All sales and use tax collected by a dealer is held in trust for the state. Therefore, any dealer collecting the sales or use tax on nontaxable transactions must remit to the Department of Taxation such erroneously or illegally collected tax unless he can show that the tax has been refunded to the purchaser or credited to the purchaser's account.

D. Overcollection of the tax. Any dealer who collects tax in excess of a ~~4%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) rate or who otherwise overcollects the tax, except as may be authorized under the bracket system or the special provisions relating to vending machine sales, must remit any amount overcollected to the state on a timely basis. Failure to do so will result in a penalty of 25% of the amount of the overcollection. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

23VAC10-210-450. Credit for taxes paid to other states or their political subdivisions.

A. Generally. Any person who purchases tangible personal property in another state and who has paid a sales or use tax to such state or its political subdivision or both on the property, is granted a credit against the use tax imposed by Virginia on its use within this state for the amount of tax paid in the state of purchase. This credit does not require that the state of purchase grant a similar credit for tax paid to Virginia. This credit does not apply to tax erroneously charged or incorrectly paid to another state. For example, if a person purchases and takes delivery in Virginia of tangible personal property purchased from an out-of-state dealer who incorrectly charges out-of-state tax, no credit is available. The purchaser must apply to the out-of-state seller for refund.

B. Amount of credit. The credit provided in this section is equal to the tax paid to the state or political subdivision or both in which the property was purchased, but cannot exceed the Virginia use tax imposed on the property. For example, if property is purchased in a state which imposes a 6.0% sales and use tax, the credit is limited to the ~~4.5%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) use tax imposed by Virginia. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

C. Claiming the credit. To obtain a credit for tax paid to another state or its political subdivision, a person must apply, by letter, to the department and include a copy of the appropriate invoice stating the amount of tax billed and the

state or political subdivision or both to which it was paid. A person requesting credit may be required by the department to furnish an affidavit stating that the tax has been paid and has not been refunded.

23VAC10-210-485. Dealer's compensation or discount.

A. Generally. As compensation for accounting for and paying the state tax, a dealer is allowed a discount of ~~2.0%, 3.0%, or 4.0%~~ 0.8%, 1.2%, or 1.6%, depending on the volume of monthly taxable sales, of the first 3.0% of the state tax due in the form of a deduction, provided the amount due was not delinquent at the time of payment. No compensation is allowed on the remainder of the state sales tax or on the local tax. Dealers must compute the discount without regard to the number of certificates of registration that they hold (see subsection C ~~below)~~ of this section).

To compute the dealer's discount, a dealer (other than a vending machine dealer) would multiply the ~~4.0%~~ 4.3% state tax listed on his return by:

1. ~~3.0% (or .03)~~ 0.01116 if monthly taxable sales are less than $62,501; or

2. ~~2.25% (or .0225)~~ 0.00837 if monthly sales are at least $62,501 but are less than $208,001; or

3. ~~1.5% (or .015)~~ 0.00558 if monthly taxable sales equal or exceed $208,001.

Any dealer whose average monthly sales tax liability exceeds $20,000 is not eligible for the discount. No dealer discount is allowed on the 0.7% regional tax imposed in the Hampton Roads and Northern Virginia Regions. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

Examples:

Dealer A who makes taxable sales of $10,000 during the month would report state and local tax of ~~$500 ($400~~ $530 ($430 state tax and $100 local tax), from which he would retain a dealer's discount of ~~$12~~ $4.80, provided that his return is timely filed and the state and local tax is timely paid. The ~~$12~~ $4.80 discount is computed by multiplying the ~~4.0%~~ 4.3% state tax ~~($400)~~ ($430) by ~~3.0%~~ 0.01116 since the dealer's monthly taxable sales volume is less than $62,501.

Dealer B who makes taxable sales of $250,000 during the month would report state and local tax of ~~$12,500 ($10,000~~ $13,250 ($10,750 state tax and $2,500 local tax), from which he would retain a dealer's discount of ~~$150~~ $55.99 provided that his return is timely filed and the state and local tax is timely paid. The ~~$150~~ $55.99 discount is computed by multiplying the ~~4.0%~~ 4.3% state tax ~~($10,000)~~ ($10,750) by ~~1.5%~~ 0.00558 since the dealer's monthly taxable sales volume is greater than $208,001.

B. Vending machine sales. In the case of a vending machine dealer who pays combined state and local tax at the rate of ~~6.0%~~ 6.3% on his wholesale purchases for resale, the dealer's discount would be computed by multiplying the ~~5.0%~~ 5.3% state tax listed on his return by:

1. ~~3.2% (or .032)~~ 0.01208 if monthly taxable sales are less than $62,501; or

2. ~~2.4% (or .024)~~ 0.00906 if monthly taxable sales are at least $62,501 but are less than $208,001; or

3. ~~1.6% (or .016)~~ 0.00604 if monthly taxable sales equal or exceed $208,001.

Examples:

Vending machine dealer A with $15,000 in wholesale purchases for resale during the month would report state and local tax of ~~$900 ($750~~ $945 ($795 state tax and $150 local tax), from which he would retain a dealer's discount of ~~$24~~ $9.60, provided that his return is timely filed and the state and local tax is timely paid. The ~~$24~~ $9.60 discount is computed by multiplying the ~~5.0%~~ 5.3% state tax ~~($750)~~ ($795) by ~~3.2%~~ 0.01208 since the dealer's monthly taxable sales volume is less than $62,501.

Vending machine dealer B with $200,000 in wholesale purchases for resale during the month would report state and local tax of ~~$12,000 ($10,000~~ $12,600 ($10,600 state tax and $2,000 local tax), from which he would retain a dealer's discount of ~~$240~~ $96.04, provided that his return is timely filed and the state and local tax is timely paid. The ~~$240~~ $96.04 discount is computed by multiplying the ~~5.0%~~ 5.3% state tax ($10,000) by ~~2.4%~~ 0.00906 since the dealer's monthly taxable sales volume is at least $62,501 but is less than $208,001.

C. Multiple registrations. Dealers holding two or more certificates of registration must compute the dealer's discount based upon taxable sales from all business locations. This requirement applies to dealers filing consolidated returns and those filing separate returns for each business location.

Example:

Dealer C holds separate certificates of registration for five business locations. Each location has monthly taxable sales of less than $62,501, but total taxable sales for all five locations are $300,000 for the month. Because total taxable sales exceed $208,001, the dealer's discount is computed using the ~~1.5%~~ 0.00558 discount rate.

Dealers with multistate business locations must compute the discount based upon taxable sales from all business locations in Virginia and on Virginia taxable sales from out-of-state business locations.

Example:

Dealer A, with business locations in Virginia, also has business locations in other states, all of which are registered for collection and remittance of the tax. The out-of-state business locations sell goods to Virginia customers located in Virginia. The total monthly taxable sales for all Dealer A's Virginia business locations are $200,000, and the total Virginia taxable sales from Dealer A's out-of-state

business locations are $100,000. Because total taxable sales exceed $208,001, the dealer's discount is computed using the ~~1.5%~~ 0.00558 discount rate.

The department will perform a reconciliation, on an annual basis or more frequently, of dealers holding multiple certificates of registration in order to ensure that the dealer's discount is computed properly by those dealers.

D. Quarterly filers. Dealers filing quarterly returns may determine the appropriate dealer's discount rate by dividing their quarterly taxable sales by 3.

Example:

Dealer D has quarterly taxable sales of $100,000. His average monthly taxable sales for the quarter ($100,000 ÷ 3) are $33,333.33. Because his average monthly taxable sales are less than $62,501, Dealer D would compute the dealer's discount using the ~~3.0%~~ 0.01116 rate.

E. Refund requests. Any amount of tax refunded by the department to a dealer will be reduced by any dealer's discount claimed on the transaction to which the refund relates. For example, if a dealer sells an item for $1,000, timely files a return reporting the ~~$50~~ $53 tax on the transaction and claims the discount, the amount refunded would be ~~$48.80 ($50~~ $52.52 ($53 less ~~3.0%~~ 0.01116 of the ~~$40~~ $43 state tax = $50 - ~~1.20~~ 0.48 = ~~$48.80)~~ $52.52) (assuming the dealer's taxable sales during the month of the sale were less than $62,501).

For extensions, see 23VAC10-210-550; for penalties and interest, see 23VAC10-210-2030 through ~~23VAC10-210-2034~~ 23VAC10-210-2032.

23VAC10-210-630. Fuels for domestic consumption.

A. Generally. The state sales and use tax does not apply to purchases of artificial or propane gas, firewood, coal or heating oil for domestic consumption.

B. Domestic consumption defined. "Domestic consumption" is the use of artificial or propane gas, firewood, coal, or home heating oil by an individual for other than business, commercial, or industrial purposes. The renting or leasing of residential units is considered commercial usage.

Domestic consumption is restricted to fuels used by individuals; purchases of fuel by groups or organizations will be subject to the tax unless the fuel purchased is for domestic consumption by an individual. For example, an organization may purchase firewood to be given away to indigent persons for use in heating their own homes; this transaction would be deemed a purchase for domestic consumption. Purchases by groups or organizations for use in their own facilities are not purchases for domestic consumption.

Domestic consumption usage is not restricted to heating purposes, but may also include cooking or heating water.

The term "domestic consumption" includes purchases of fuel by: ~~(1)~~ (i) an owner or lessee for use in a single-family dwelling in which he resides; ~~(2)~~ (ii) individual residents for use in apartments, townhouses, trailer courts, condominiums or other multi-family dwellings in which they reside; and ~~(3)~~ (iii) a condominium or similar owner cooperative association provided such association is comprised solely of the owners of the dwelling and more than 50% of the fuel purchased is for use in owner-occupied units.

The term "domestic consumption" does not include purchases by: ~~(1)~~ (i) nonprofit churches, civic or other charitable groups, except as set forth above; ~~(2)~~ (ii) businesses operated by nonprofit groups; ~~(3)~~ (iii) profit hospitals, nursing homes or homes for adults; ~~(4)~~ (iv) profit schools or institutions of learning; ~~(5)~~ (v) lessors of apartments, trailer courts, condominiums, rooming houses or other multi-family dwellings; fraternities or sororities; ~~(6)~~ (vi) hotels, motels, inns, cabins or lodges; and ~~(7)~~ (vii) any commercial, business or industrial operations.

Purchases of heating fuels for their own use or consumption by persons or entities who are entitled to a general sales tax exemption (for example: ~~(1)~~ (i) nonprofit schools and institutions of learning; ~~(2)~~ (ii) licensed nonprofit hospitals, nursing homes, and homes for adults; ~~(3)~~ (iii) nonprofit volunteer fire and rescue squads; and ~~(4)~~ (iv) federal, state, or local governments) are not subject to sales and use tax (state or local).

C. 1. Classifying purchases as domestic or nondomestic. In determining when tax is to be collected by the dealer on a purchase used for both domestic and nondomestic purposes, a principal usage test shall apply. A purchase shall be classified as exempt if more than 50% of the fuel purchased is for domestic consumption. However, if 50% or less of the fuel purchased is for domestic consumption, the entire purchase shall be taxable and the tax shall be collected by the dealer at the time of the sale.

~~The preceding paragraph~~ 2. Subdivision 1 of this subsection establishes when a fuel dealer must collect tax at the time of sale, and it does not establish any rule of exemption for consumers. The ultimate taxability of a fuel purchase depends on its actual usage. The purchaser will be liable for payment to the department of use tax on any portion of a domestic purchase (i.e., a purchase on which no sales tax was paid to the dealer) subsequently used for nondomestic purposes. A purchaser who has paid tax under the ~~above~~ rules in subdivision 1 of this subsection, however, may apply to the department for a refund of tax paid on that portion which is actually used for domestic consumption. Refund claims must be filed on forms prescribed by the department between January 1 and April 15 of the year following the year of purchase. Refund applications pursuant to this exemption will be denied if post-marked after April 15 of the year following the year of purchase.

D. Exemption certificates. Sales and Use Tax Certificate of Exemption, Form ST-15, is available for use by dealers to substantiate sales of heating fuel for domestic consumption.

A purchaser need file only one such certificate with a dealer to qualify for exemption. However, the certificate will be valid only for purchases of fuel made by the person named on the certificate and for use at his residence, the address of which is also listed on the certificate. Any change of address of purchaser will require completion of a new certificate of exemption.

A dealer is not required to obtain a certificate of exemption for each transaction if the record of the sale is clearly identifiable as a sale of fuel for domestic consumption. However, this should not be construed as altering the fact that the burden of proof is on the dealer to demonstrate that each untaxed transaction is legitimately exempt from the tax.

Dealers will not be required to obtain a certificate of exemption on sales of small quantities of kerosene, firewood, or other fuels, provided sales receipts or daily sales records are available which clearly indicate the number of gallons (or other measure) of the specific type of fuel sold and the number of purchasers.

E. Local sales and use tax. The local ~~1%~~ 1.0% sales and use tax will continue to apply to all purchases for domestic consumption of artificial or propane gas, firewood, coal and home heating oil unless the locality adopts an ordinance specifically exempting such fuels.

1. Sales tax. The local ~~1%~~ 1.0% sales tax will be allocated to the locality in which the place of business from which the sale is made is located. Place of business is defined as an established business location at which orders are regularly received. Therefore the situs of sale shall be the business location that first takes the purchaser's order, either in person, by purchase order, or by letter or telephone, regardless of the location of the merchandise or the point of acceptance of the order or shipment.

2. Use tax. The local use tax on sales made to Virginia residents by out-of-state dealers and the local use tax remitted by consumers on any portion of a domestic purchase used for nondomestic consumption will be allocated to the locality in which the fuel is delivered. The following examples will clarify this.

Example 1: A resident of a city or county which imposes the ~~1%~~ 1.0% local sales and use tax on fuels for domestic consumption purchases fuel from an out-of-state dealer who delivers it to the purchaser's residence in Virginia. The ~~1%~~ 1.0% local tax will apply to the transaction.

Example 2: A resident of a ~~city/county~~ city or county which imposes the ~~1%~~ 1.0% local tax purchases fuel for domestic consumption from a dealer located in a ~~city/county~~ city or county which does not impose the ~~1%~~ 1.0% local tax. The purchaser uses a portion of the fuel for nondomestic purposes and is therefore liable for payment of the use tax on that portion. The purchaser will therefore be required to remit the ~~4%~~ 5.3% use tax ~~(3%~~ (4.3% state; ~~1%~~ 1.0% local) or 6.0% use tax in the Hampton Roads and Northern Virginia Regions (4.3% state, 0.7% regional, and 1.0% local). For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

Example 3: A resident purchases fuel for domestic consumption from a dealer located in a locality which imposes the ~~1%~~ 1.0% local tax and therefore pays the ~~1%~~ 1.0% on the purchase of the fuel. The purchaser uses a portion of the fuel for nondomestic purposes and is consequently liable for payment of the use tax on that portion. The purchaser will be required to remit only ~~3%~~ 4.3% (5.0% in the Hampton Roads and Northern Virginia Regions) state tax; the ~~1%~~ 1.0% local tax was paid on the original fuel purchase. This applies regardless of whether the purchaser's city or county of residence does or does not impose the ~~1%~~ 1.0% local tax on fuels.

3. Local exemption. ~~Following is a list of those cities and counties which, as of December 1, 1982, have notified the department that ordinances have been~~ As of 2014, the department is aware that the following cities and counties have adopted ordinances exempting fuel for domestic consumption from the local ~~1%~~ 1.0% sales and use tax. Additional localities may adopt ordinances at any time and localities having exemption ordinances in effect may rescind such ordinances at any time.

~~Cities~~

~~Alexandria~~	~~Norfolk~~
~~Bedford~~	~~Norton~~
~~Chesapeake~~	~~Poquoson~~
~~Covington~~	~~Roanoke~~
~~Danville~~	~~Salem~~
~~Fairfax~~	~~Staunton~~
~~Fredericksburg~~	~~Virginia Beach~~
~~Lexington~~	~~Waynesboro~~
~~Manassas~~	~~Winchester~~
~~Martinsville~~	

~~Counties~~

~~Alleghany~~	~~Lee~~
~~Arlington~~	~~Louisa~~
~~Augusta~~	~~Mathews~~
~~Bath~~	~~Middlesex~~
~~Bedford~~	~~Page~~
~~Caroline~~	~~Patrick~~
~~Clarke~~	~~Pittsylvania~~
~~Fairfax~~	~~Prince William~~

~~Fauquier~~ ~~Pulaski~~

~~Floyd~~ ~~Roanoke~~

~~Frederick~~ ~~Shenandoah~~

~~Giles~~ ~~Smyth~~

~~Goochland~~ ~~Spotsylvania~~

~~Hanover~~ ~~Stafford~~

~~Henry~~ ~~Warren~~

~~James City~~ ~~Washington~~

~~King William~~

~~NOTE: The following cities and counties have notified the department since December 1, 1982 that ordinances have been adopted exempting fuel for domestic consumption from the 1% local sales and use tax:~~

~~Cities~~

~~Hampton~~ ~~Newport News~~

~~Counties~~

~~Franklin~~ ~~Wise~~

~~Gloucester~~

Cities

Alexandria	Chesapeake	Covington
Danville	Fairfax	Fredericksburg
Hampton	Harrisonburg	Lexington
Manassas	Martinsville	Newport News
Norfolk	Norton	Poquoson
Portsmouth	Roanoke	Salem
Staunton	Virginia Beach	Waynesboro
Winchester		

Counties

Alleghany	Arlington	Augusta
Bath	Bedford	Campbell
Caroline	Clarke	Fairfax
Fauquier	Floyd	Franklin
Frederick	Giles	Gloucester
Goochland	Hanover	Henry
James City	King William	Lee
Louisa	Madison	Mathews
Middlesex	Page	Patrick
Pittsylvania	Prince George	Prince William
Pulaski	Roanoke	Shenandoah
Smyth	Spotsylvania	Stafford
Warren	Washington	Wise

23VAC10-210-680. Gifts purchased in Virginia.

If a resident or nonresident buys a gift in Virginia and requests the seller to ship or mail such gift to another person, the purchaser is deemed to receive title to the gift at the time of purchase and the transaction is therefore taxable in Virginia. The location of the recipient of the gift has no bearing upon the taxability of the transaction; therefore, even if the recipient is located outside Virginia the sale is not a sale in interstate commerce. The following example illustrates this concept.

Example: A purchases a watch for $200 from a Virginia merchant, M, and tells M to send the watch to B who lives in Maryland. A must pay the sales tax of ~~$8~~ $10.60 to M at the time of purchase.

The recipient of the gift ultimately receives title to the gift from the purchaser and not the merchant and there is no relationship between the merchant and the recipient.

The total rate of the state and local sales and use tax in localities that fall within the Hampton Roads and Northern Virginia Regions is 6.0% (4.3% state, 0.7% regional, and 1.0% local). The provisions of this section apply to transactions sourced to the Hampton Roads Region and the Northern Virginia Region, mutatis mutandis. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

23VAC10-210-2070. ~~Place of business in Virginia; situs~~ Situs of sale.

~~A. Generally. For determining the place of business in Virginia from which a sale is made, "place of business" means the business location in Virginia that first takes the purchaser's order, either in person, by purchase order or by letter or telephone, regardless of the location of the merchandise or the point of acceptance of the order or shipment. For example, an order placed for merchandise in a store in County A, forwarded by the store in County A to a sales office in City B and shipped to the purchaser from a warehouse or branch store in County C is a sale made in County A.~~

~~B. Place of business defined. The term "place of business in Virginia" includes, but is not limited to, a store, a sales or other office or any warehouse.~~

~~C. Out-of-state dealers. An out-of-state dealer who has a place of business in Virginia is required to register as a dealer at that place. If the same dealer, at a place of business outside~~

~~this state, receives orders from Virginia customers directly and not through a place of business in Virginia, he must also register as an out-of-state dealer.~~

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

"Hampton Roads Region" means the Counties of Isle of Wight, James City, Southampton, and York and the Cities of Chesapeake, Franklin, Hampton, Newport News, Norfolk, Poquoson, Portsmouth, Suffolk, Virginia Beach, and Williamsburg.

"Local sales and use tax" means the local retail sales and use tax imposed by ordinance in all Virginia cities and counties at the rate of 1.0%.

"Northern Virginia Region" means the Counties of Arlington, Fairfax, Loudoun, and Prince William and the Cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park.

"Place of business" means the business location in Virginia that first takes the purchaser's order, whether in person, by purchase order, or by letter or telephone, regardless of the location of the merchandise or the point of acceptance of the order or shipment. "Place of business" includes a store, a sales or other office, or any warehouse.

"Regional sales and use tax" means the additional state retail sales and use tax imposed in the Hampton Roads Region and the Northern Virginia Region at the rate of 0.7%.

B. Sourcing.

1. Sales tax. Sales by dealers located in Virginia are generally subject to the sales tax and sourced to the city or county of the place of business of the dealer collecting the tax, without regard to the city or county of possible use by the purchaser. The sale of tangible personal property at the place of business of the seller is sourced to that place of business, even if the goods are ultimately delivered to the purchaser at another location. The remote sale (by telephone, Internet, or mail order) of tangible personal property from an in-state dealer with a place of business in Virginia is sourced to the location in which the order was first taken, even if the goods are ultimately delivered to the purchaser at another location. Accordingly, an order placed for merchandise in a store in County A, forwarded by the store in County A to a sales office in City B and shipped to the purchaser from a warehouse or branch store in County C is a sale made in County A.

Example 1: Dealer A makes a sale to a customer at his place of business in the City of Fairfax in the Northern Virginia Region. Dealer A has the goods delivered to the customer in Loudoun County in the Northern Virginia Region. The sale is sourced to the City of Fairfax. Dealer A should collect 6.0% (4.3% state, 0.7% Regional, and 1.0% local) sales tax on the purchase. The 1.0% local tax should be sourced to the City of Fairfax.

Example 2: Dealer B makes a sale to a customer at his place of business in Loudoun County in the Northern Virginia Region, but the goods are delivered to the customer in Roanoke County, which is not in the Northern Virginia or Hampton Roads Region. The sale is sourced to Loudoun County, in the Northern Virginia Region. Dealer B should collect 6.0% sales tax on the purchase. The 1.0% local tax should be sourced to Loudoun County.

Example 3: Customer C orders merchandise from Dealer D by placing a call to Dealer D's store, located in the City of Newport News in the Hampton Roads Region. The goods will be shipped to Customer C's residence that is neither in the Hampton Roads nor the Northern Virginia Region. The sale is sourced to the City of Newport News in the Hampton Roads Region. Dealer D should collect 6.0% (4.3% state, 0.7% Regional, and 1.0% local) sales tax on the purchase. The 1.0% local tax should be sourced to the City of Newport News.

Example 4: Customer E orders merchandise from Dealer F's website, which has a place of business and warehouse in North Carolina. Dealer F is registered to collect the Virginia retail sales and use tax. The invoice indicates that the merchandise will be shipped to Customer E's residence in the City of Richmond, which is outside the Northern Virginia and Hampton Roads Regions. Because Dealer F's place of business and warehouse are located outside of Virginia, the sale is sourced to the location in which the merchandise is delivered, the City of Richmond, which is outside the Northern Virginia and Hampton Roads Regions. Dealer F should collect 5.3% (4.3% state and 1.0% local) sales tax on the purchase. The 1.0% local tax should be sourced to the City of Richmond.

2. Use tax collected by dealers. The use tax is generally sourced to the city or county where the goods are used or consumed by the purchaser, or stored for use or consumption. An out-of-state dealer who has a place of business in Virginia is required to register as a dealer at that place. If the same dealer, at a place of business outside this state, receives orders from Virginia customers directly and not through a place of business in Virginia, he must also register as an out-of-state dealer. Out-of-state dealers who hold Certificates of Registration to collect the use tax from their customers must source sales into Virginia according to the city or county of destination.

Example 1: Dealer A makes Internet sales from his place of business in North Carolina. Dealer A holds a Certificate of Registration to collect the use tax from Virginia customers. Dealer A makes a sale and ships the goods to the City of Fairfax. Dealer A would collect 6.0% (4.3% state, 0.7% Regional, and 1.0% local) use tax on the sale. The 1.0% local tax should be sourced to the City of Fairfax.

3. Consumer use tax. Generally, Virginia residents and others purchasing goods from a business that does not

collect the Virginia retail sales and use tax or purchasing goods tax-free while outside Virginia and bringing them into Virginia are subject to the consumer use tax. The use tax is sourced to the city or county where the goods are used or consumed by the purchaser, or stored for use or consumption. For more information on use tax, see 23VAC10-210-6030.

Any person purchasing tangible personal property in other areas of the Commonwealth for use in either the Hampton Roads Region or the Northern Virginia Region is not responsible for the regional consumer use tax if the retail sales and use tax has been paid on the purchase.

Example 1: Customer A, who is located in the City of Fairfax, makes an Internet purchase of tangible personal property from a West Virginia dealer who does not hold a Virginia Certificate of Registration and does not collect the use tax from Virginia customers. Customer A must remit 6.0% (4.3% state, 0.7% regional, and 1.0% local) use tax on the purchase.

Example 2: Customer B is located in the City of Charlottesville. Customer B buys equipment in Charlottesville that is intended for use performing a construction contract in Fairfax County and pays 5.3% sales tax. Customer B subsequently moves the equipment into Fairfax County. Customer B does not owe the 0.7% regional use tax on the equipment as the sales tax has been paid.

23VAC10-210-3080. Returned goods.

A. Generally. A dealer may deduct from gross sales any portion of the sales price of tangible personal property returned by a customer provided that such amount has been refunded to or credited to the account of the purchaser. Adequate records must be kept to disclose the essential facts.

B. Returns before tax paid by dealer. If a dealer refunds or credits to a customer's account all or any portion of the sales price of returned goods and has not yet paid the sales tax to the department, such portion of the sales price may be deducted from gross sales by the dealer in the appropriate place on his return for the period.

Example 1. Customer A purchases a sweater from Dealer B for ~~$20.00~~ $20 and pays to B the appropriate ~~$1.00~~ $1.06 sales tax. A returns the sweater the same day and B refunds ~~$21.00~~ $21.06. If the sale was included in gross sales for the month, B may deduct the ~~$20.00~~ $20 sales price of the sweater.

C. Returns after tax paid by dealer. If a dealer refunds or credits to a customer's account all or any portion of the sales price of returned goods after the dealer has paid the tax on the goods to the department, such portion may be deducted from gross sales on the dealer's return for the period in which the refund was made or credit given.

Example ~~2.~~ 1. In December Customer C purchases a bed from Dealer D for $700 and pays the ~~$35~~ $37.10 tax. C returns the bed to D in January and D credits C's account for ~~$735~~ $737.10. In reporting gross sales for January, D may deduct the $700 sales price of the bed reported in a previous month.

D. Refund or credit for returned goods. If a dealer as described in subsection C of this section has insufficient gross sales during the period in which goods are returned or a ~~refund/credit~~ refund or credit issued to absorb the amount of the sales price of the returned goods, the dealer may carry the deduction forward as a credit against gross sales until used. If any portion of such credit has not been used by the time a dealer ceases business or if a dealer is no longer engaged in making retail sales, he may request a refund for any portion of the unused credit for returned goods. The amount of refund will be the net amount of tax remitted, therefore, if a dealer deducted dealer's discount in filing his original return, such discount shall similarly be deducted from the amount to be refunded. The following example illustrates this concept.

Example 1. Customer E purchases equipment from Dealer G in January for $10,000 and pays the ~~$500~~ $530 sales tax. The transaction is reported on G's January sales tax return which is filed timely. E returns the equipment in April and G refunds to E $8,000 of the sales price and the applicable tax of ~~$400~~ $424. G's gross sales for April are only $5,000, therefore, only $5,000 of the amount refunded may be used as a credit. G goes out of business on April 30 and applies for refund of the tax attributable to the remaining $3,000 of sales price which was refunded. G will be issued a refund of ~~$146.40~~ $155.40 computed as follows:

(Sales Price X ~~5.0%~~ 5.3% tax) - dealer's discount = Refund ($3,000 X ~~5.0%~~ 5.3% tax) - ~~(4.0%~~ (1.6% X $90) = ~~$146.40~~ $157.56

E. Sales of returned goods. When any returned tangible personal property is resold, the sale is subject to the sales tax.

F. Hampton Roads Region and Northern Virginia Region. The total rate of the state and local sales and use tax in localities that fall within these regions is 6.0% (4.3% state, 0.7% regional, and 1.0% local). The provisions of this section apply to transactions sourced to the Hampton Roads Region and the Northern Virginia Region, mutatis mutandis. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

23VAC10-210-6041. Vending machine sales; dealers engaged in the business of placing vending machines.

A. Registration requirements. Except as otherwise authorized by the Tax Commissioner, every person engaged in the business of placing vending machines and selling tangible personal property through such machines shall apply for a Certificate of Registration for each county and city in which machines are placed. A separate registration is required for each place of business from which nonvending machine sales are made. Dealers holding or applying for multiple vending or nonvending registrations may request permission

at the time of application to file consolidated vending or nonvending returns.

B. Computation of tax. All items of tangible personal property sold through vending machines by those vending machines dealers engaged in placing vending machines and selling tangible personal property through such machines are taxable at the rate of ~~6.0% (5.0%~~ 6.3% (5.3% state and 1.0% local) and 7.0% (5.3% state, 0.7% regional, and 1.0% local) in the Hampton Roads and Northern Virginia Regions. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

Any dealers, all of whose machines are under contract to nonprofit organizations, should refer to 23VAC10-210-6042. Dealers acquiring items from other suppliers and selling them in the same condition which they were acquired shall compute the ~~6.0%~~ 6.3% (7.0% in the Hampton Roads and Northern Virginia Regions) tax on the cost price of the purchased tangible personal property. Dealers who manufacture the tangible personal property to be sold through vending machines shall compute the ~~6.0%~~ tax on the cost of the manufactured tangible personal property (cost of goods manufactured). The cost of manufactured personal property includes raw material cost plus labor and overhead attributable to the manufacture of the item being sold.

Example:

Dealer A purchases (or manufactures) items, with a total cost price of $1,000, during the month for sale through vending machines. Dealer A would compute the tax as follows:

Total cost price ($1,000) X State tax rate ~~(.05)~~ (.053) = State tax ~~($50)~~ ($53)

Total cost price ($1,000) X Local tax rate (.01) = Local tax ($10)

TOTAL TAX = ~~$60~~ $63

The method of accounting used for federal income tax purposes shall be the accounting method used in determining the cost price of purchased tangible personal property and the cost of manufactured tangible personal property. For example, if the first-in, first-out method of accounting is used for federal income tax purposes, this accounting method shall be used each month for computing the cost price of purchased tangible personal property or the cost of manufactured tangible personal property.

As an alternative method of computing the tax, any dealer unable to maintain satisfactory records to determine the cost price of purchased tangible personal property and the cost of manufactured tangible personal property may request in writing to the Tax Commissioner authority to remit an amount based on a percentage of gross receipts which takes into account the inclusion of the ~~5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) sales tax.

Example:

Dealer B, who has been authorized by the Tax Commissioner to compute the tax based on gross receipts, had gross receipts from vending machine sales during the month of $3,000. Dealer B would compute the tax as follows:

Gross receipts ($3,000) X State tax rate ~~(.04)~~ (.043) = State tax ~~($120)~~ ($129)

Gross receipts ($3,000) X Local tax rate (.01) = Local tax ($30)

TOTAL TAX = ~~$150~~ $159

Upon receiving such authorization from the Tax Commissioner, a return shall be filed to report the ~~4 5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) sales tax beginning with the period set out in the authorization letter. All subsequent returns shall be filed using this method unless the dealer applies in writing to the Tax Commissioner and is given authorization in writing to change his filing status. Authorization to compute the tax using this alternative method will not eliminate the requirement to maintain records which show the location of each vending machine, purchases and inventories of merchandise bought for sale through vending machines, and total gross receipts for each vending machine.

C. Filing of returns. Except as otherwise authorized by the Tax Commissioner, dealers engaging in the business of placing vending machines and selling tangible personal property through such machines must file a return to report the tax on the items sold through vending machines.

Returns are due by the 20th day of the month following the period in which tangible personal property is sold through vending machines, with the tax to be computed in the manner set out in subsection B ~~above~~ of this section. A return is required to be filed for each locality where vending machines are located unless a dealer has requested and been granted authority to file a consolidated return.

D. Purchases. Tangible personal property purchased for resale through vending machines may be purchased under Certificate of Exemption, Form ST-10. All tangible property purchased for use or consumption by the dealer and not for resale, including vending machines and repair parts for such machines, and withdrawals of tangible personal property from a tax exempt manufacturing or resale inventory for use or consumption by the dealer are subject to the tax at the rate of ~~5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) of the cost price of the property. If the supplier does not charge the tax on purchases for use or consumption, the vending machine dealer shall pay the tax directly to the Department of Taxation on the Retail Sales and Use Tax Return (if he is registered for nonvending sales) or on the Consumer's Use Tax Return. Dealers who manufacture or process tangible personal property for sale may be entitled to the industrial exemption for tangible personal property

used directly in manufacturing or processing as set forth in subdivision 2 of § 58.1-609.3~~(2)~~ of the Code of Virginia and 23VAC10-210-920.

E. Records. Records shall be kept for a period of three years and shall show the location of each machine; purchases and inventories of merchandise bought for sales through vending machines; and the cost price of purchased tangible personal property or the cost of manufactured tangible personal property for each machine.

23VAC10-210-6042. Vending machine sales; dealers under contract with nonprofit organizations.

A. Registration requirements. A separate Certificate of Registration is required for each county and city in which vending machines are placed. Dealers holding multiple registrations may request permission to file a consolidated return at the time of application.

B. Computation of tax. Dealers engaged in the business of placing vending machines all of which are under contract to nonprofit organizations may deduct sales of $.10 or less from gross receipts and divide the remaining balance by ~~1.05~~ 1.053 (1.06 in the Hampton Roads and Northern Virginia Regions) to determine the amount of taxable sales upon which the ~~5.0%~~ tax is due and payable. To qualify for this method of computing the tax, all machines of the vending machine dealer must be under contract to nonprofit organizations. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

C. Filing of returns. The Retail Sales and Use Tax Return, is required to be filed for each locality in which vending machines are placed by the 20th day of the month to report the ~~5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) tax on (i) sales made in the previous period and (ii) untaxed purchases for use or consumption by the dealer or withdrawals from tax exempt inventory for use or consumption by the dealer.

D. Records. A contract shall be kept for each vending machine under contract to nonprofit organizations. Additionally, records shall be kept for a period of four years to show the location of each vending machine, purchases and inventories of merchandise bought for sale, and total gross receipts for each vending machine separating items sold for $.10 or less from items sold for more than $.10.

23VAC10-210-6043. Vending machine sales; other dealers selling tangible personal property through vending machines.

Dealers not engaged in the business of placing vending machines but who use vending machines at their places of business to sell merchandise~~,~~ (e.g., service station operators~~,~~) must report the tax at the rate of ~~5.0%~~ 5.3% (6.0% in the Hampton Roads and Northern Virginia Regions) of gross taxable sales on the same return on which nonvending machine sales are reported. For definitions of the "Hampton Roads Region" and the "Northern Virginia Region" see 23VAC10-210-2070.

VA.R. Doc. No. R16-4601; Filed June 6, 2016, 1:34 p.m.

DEPARTMENT FOR AGING AND REHABILITATIVE SERVICES

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department for Aging and Rehabilitative Services is conducting a periodic review and small business impact review of **22VAC30-11, Public Participation Guidelines**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins July 11, 2016, and ends August 1, 2016.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Vanessa S. Rakestraw, Policy Analyst, 8004 Franklin Farms Drive, Richmond, VA 23229, FAX (804) 662-7663, or email vanessa.rakestraw@dars.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

AIR POLLUTION CONTROL BOARD

Proposed State Implementation Plan Revision - 9VAC5-20, Revisions D97 and B16; 9VAC5-40, Revisions C09, D09, and E09

Notice of action: The Department of Environmental Quality (DEQ) is announcing an opportunity for public comment on a proposed revision to the Commonwealth of Virginia State Implementation Plan (SIP). The SIP is a plan developed by the Commonwealth in order to fulfill its responsibilities under the federal Clean Air Act to attain and maintain the ambient air quality standards promulgated by the U.S. Environmental Protection Agency (EPA) under the federal Clean Air Act. The Commonwealth intends to submit portions of the regulations to the EPA as a revision to the SIP in accordance with the requirements of § 110(a) of the federal Clean Air Act.

Regulations affected: The regulations of the board affected by this action are General Provisions, Malfunctions (9VAC5-20, Revisions D97 and B16) and Existing Stationary Sources (9VAC5-40, Revisions C09, D09, and E09).

Purpose of notice: DEQ is seeking comment on the issue of whether the regulation amendments should be submitted as a revision to the SIP.

Public comment period: June 27, 2016, to July 27, 2016.

Public hearing: A public hearing may be conducted if a request is made in writing to the contact listed at the end of this notice. In order to be considered, the request must include the full name, address, and telephone number of the person requesting the hearing and be received by DEQ by the last day of the comment period. Notice of the date, time, and location of any requested public hearing will be announced in a separate notice, and another 30-day comment period will be conducted.

Public comment stage: Because the regulation amendments have already been adopted, DEQ is accepting comment only on the issue cited under "purpose of notice" and not on the content of the regulation amendments.

Description of proposal: Three sets of regulatory amendments are being considered for this proposal. Revision D97 originally amended 9VAC5-20-180 but was not submitted as a SIP revision; portions of it are now being submitted in order to provide a correct baseline for the provisions of Revision B16. As discussed below, sections relevant to 9VAC5-20-180 are also be submitted for the purpose of several volatile organic compound (VOC) regulations.

Revision D97: Under this revision, 9VAC5-20-180 was amended as follows: (i) provisions were added to clarify that 9VAC5-20-180 applies to only facility and control equipment maintenance or malfunction; (ii) provisions were added to specify an affirmative defense does not apply to excess emissions due to malfunction or maintenance for sources subject to new source performance standards, national emission standards for hazardous air pollutants, maximum achievable control technology, or acid rain provisions of the federal Clean Air Act or that cause an exceedance of an ambient air quality standard or prevention of significant deterioration (PSD) ambient air quality increment; (iii) provisions were changed to be consistent with recommendations made pursuant to the review of existing regulations mandated by Executive Order 15(94); (iv) provisions pertaining to malfunctions for hazardous air pollution sources were revised because they were not consistent with requirements pertaining to sources that meet

federal standards for hazardous air pollutants; (v) provisions that provide legal relief if a violation has taken place due to excess emissions as a result of facility and control equipment maintenance or malfunction were changed in order to entitle the owner of a facility to use an affirmative defense for relief from penalties; (vi) provisions pertaining to facility and control equipment maintenance or malfunction were changed to incorporate the limitations and the criteria for an affirmative defense; and (vii) provisions that authorize the board to reduce the level of operation or shut down a facility if it is necessary to prevent a violation of any primary ambient air quality standard were expanded to include any ambient air increment identified in the PSD program.

Revision B16: On June 12, 2015 (80 FR 33840), EPA issued a final SIP call concerning treatment of excess emissions in state rules by sources during periods of startup, shutdown, or malfunction (SSM), including Virginia's SSM rules at 9VAC5-20-180 G. The U.S. Court of Appeals for the District of Columbia Circuit has held that such provisions are illegal, and state plans must be amended accordingly. Essentially, EPA finds that 9VAC5-20-180 G creates an impermissible affirmative defense for violations of emission limits, and therefore 9VAC5-20-180 G must be amended. 9VAC5-20-180 C must also be amended for 9VAC5-20-180 G to operate properly and to make several minor administrative changes.

Revisions C09, D09, and E09: At the time these regulations were promulgated, there was uncertainty as to the status of Virginia's malfunction regulations; therefore, those provisions were not submitted as SIP revisions when the rest of the rules were submitted to EPA on February 1, 2016. Now that the issue of malfunctions has been resolved and 9VAC5-20-180 has been amended to EPA's satisfaction, reference to 9VAC5-20-180 may now be submitted for the purpose of these rules.

Federal information: This notice is being given to satisfy the public participation requirements of federal regulations (40 CFR 51.102) and not any provision of state law. Except as noted below, the proposal will be submitted as a revision to the Commonwealth of Virginia SIP under § 110(a) of the federal Clean Air Act in accordance with 40 CFR 51.104. Only the directly amended provisions of the proposal will be submitted as a revision to the Commonwealth of Virginia SIP, and no provisions relevant to hazardous air pollutants will be submitted. In addition, the D97 version of 9VAC5-20-180 G will not be submitted as it is superseded by the B16 version.

How to comment: DEQ accepts written comments by email, fax, and postal mail. In order to be considered, comments must include the full name, address, and telephone number of the person commenting and be received by DEQ by the last day of the comment period. All comments, exhibits, and documents received are part of the public record.

To review documents: The proposal and any supporting documents are available on the DEQ Air Public Notices for Plans website (http://www.deq.state.va.us/Programs/Air/PublicNotices/airplansandprograms.aspx). The documents may also be obtained by contacting the DEQ representative named at the end of this notice. The public may review the documents between 8:30 a.m. and 4:30 p.m. of each business day until the close of the public comment period at the following DEQ locations:

1) Main Street Office, 8th Floor, 629 East Main Street, Richmond, VA, telephone (804) 698-4070,

2) Southwest Regional Office, 355 Deadmore Street, Abingdon, VA, telephone (276) 676-4800,

3) Blue Ridge Regional Office, Roanoke Location, 3019 Peters Creek Road, Roanoke, VA, telephone (540) 562-6700,

4) Blue Ridge Regional Office, Lynchburg Location, 7705 Timberlake Road, Lynchburg, VA, telephone (434) 582-5120,

5) Valley Regional Office, 4411 Early Road, Harrisonburg, VA, telephone (540) 574-7800,

6) Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA, telephone (804) 527-5020,

7) Northern Regional Office, 13901 Crown Court, Woodbridge, VA, telephone (703) 583-3800, and

8) Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA, telephone (757) 518-2000.

Contact Information: Karen Sabasteanski, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4426, FAX (804) 698-4510, or email karen.sabasteanski@deq.virginia.gov.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Correctional Solar LLC Notice of Intent - Small Renewable Energy Project (Solar) Permit by Rule

Correctional Solar LLC has notified the Department of Environmental Quality of its intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in New Kent County, pursuant to 9VAC15-60. The project will be located on 429 acres across multiple parcels, on land south east of the intersection of New Kent Highway and Mount Nebo Road as well as along the west side of Barham Road just south of the New Kent Highway Mount Nebo Road intersection. The solar project conceptually consists of 88,209 320-watt panels plus nine 2.5-megawatt inverters, which together will provide a maximum 20 megawatts of nameplate capacity.

Contact Information: Mary E. Major, 629 East Main Street, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

STATE BOARD OF HEALTH

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Health is conducting a periodic review and small business impact review of **12VAC5-31, Virginia Emergency Medical Services Regulations**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins June 27, 2016, and ends July 18, 2016.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Michael Berg, Regulatory and Compliance Manager, Virginia Department of Health, Office of Emergency Medical Services, 1001 Technology Park Drive, Glen Allen, VA 23059, telephone (804) 888-9131, FAX (804) 371-3108, or email michael.berg@vdh.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

DEPARTMENT OF HEALTH

Drinking Water State Revolving Fund Program Intended Use Plan for FY 2017

Dear Waterworks Owner and Other Interested Parties:

Under the Safe Drinking Water Act, Congress authorizes capitalization grants to the states through the Drinking Water State Revolving Loan Fund Program (DWSRF). As part of the annual DWSRF grant application process Virginia seeks meaningful public involvement through input, review, and comments. The Virginia Department of Health (VDH), Office of Drinking Water (ODW) has prepared a draft intended use plan (IUP) that explains the goals of the program, funding priorities, how VDH intends to use the grant funds, and other important information submitted from the funding requests and set-aside suggestions.

VDH received numerous funding requests and set-aside suggestions following the January DWSRF funding solicitation announcement. The draft 2017 IUP and draft project lists are open for review and comment by the public for a period of 30 days. The document entitled "Virginia Drinking Water State Revolving Fund Program Design Manual" (dated January 2016) is a part of the intended use plan and was mailed to eligible waterworks in January 2016, announced in the Virginia Register, and placed on the agency website. The Program Design Manual provides information on VDH's project prioritization criteria and methodologies.

VDH will hold a public meeting to solicit comments and recommendations regarding the IUP on Thursday, July 21, 2016, 9 a.m. to 11 a.m. at the Department of Environmental Quality, Piedmont Office, 4949-A Cox Road, Henrico, VA 23060. Individuals planning to attend the public meeting should contact Theresa Hewlett at (804) 864-7501 by the close of business on July 15, 2016.

Written comments from the public need to be submitted by July 27, 2016, the close of the public comment period. VDH will consider all meaningful public input and comments and make revisions to the IUP and project priority list if necessary. Please direct requests for information and forward written comments to Steven Pellei, PE, Virginia Department of Health, Office of Drinking Water, James Madison Building, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7500 or FAX (804) 864-7521. The following information is provided on VDH's website at http://www.vdh.virginia.gov/drinking-water/office-of-drinking-water/financial-construction/drinking-water-state-revolving-fund-program.

VDH's 2017 Draft Intended Use Plan (IUP)

VDH's 2017 Preliminary Project Priority List/2017 Comprehensive Project List

The IUP is subject to change depending on EPA's award allocations.

BOARD OF HOUSING AND COMMUNITY DEVELOPMENT PUBLIC HEARING

Public Hearing on the Virginia Uniform Statewide Building Code

Pursuant to subdivision A 12 of § 2.2-4006 and § 36-100 of the Code of Virginia, the Board of Housing and Community Development will hold a public hearing on the Virginia Uniform Statewide Building Code (13VAC5-63), Virginia Statewide Fire Prevention Code (13VAC5-51), Virginia Amusement Device Regulations (13VAC5-31), and the

Virginia Industrialized Building Safety Regulations (13VAC5-91).

The purpose of this public hearing is to consider updating the codes to the newest editions of the model codes and standards and to consider related proposals prior to the publication of proposed regulations.

The public hearing will be held at the Virginia Housing Center, 4224 Cox Road, Glen Allen, VA 23060, 12:30 p.m., July 18, 2016. For more information, contact the State Building Code Office.

Contact Information: State Building Code Office, 600 East Main Street, Suite 300, Richmond, VA 23219, telephone (804) 371-7150, FAX (804) 371-7092, or email sbco@dhcd.virginia.gov.

BOARD OF LONG-TERM CARE ADMINISTRATORS

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Board of Long-Term Care Administrators is currently reviewing each of the regulations listed below to determine whether the regulation should be repealed, amended, or retained in its current form. The review of each regulation will be guided by the principles in Executive Order 17 (2014). Public comment is sought on the review of any issue relating to each regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

18VAC95-20, Regulations Governing the Practice of Nursing Home Administrators

18VAC95-30, Regulations Governing the Practice of Assisted Living Facility Administrators

Agency Contact: Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, FAX (804) 527-4434, or email elaine.yeatts@dhp.virginia.gov.

The comment period begins June 27, 2016, and ends July 27, 2016.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Virginia Regulatory Town Hall, and a report of the small business impact review will be published in the Virginia Register of Regulations.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

2016 Notice of Intent to Amend Virginia State Plan for Medical Assistance (pursuant to § 1902(a)(13) of the Social Security Act (USC § 1396a(a)(13)))

The Virginia Department of Medical Assistance Services (DMAS) hereby affords the public notice of its intention to amend the Virginia State Plan for Medical Assistance to provide for changes to the Amount, Duration, and Scope of Medical and Remedial Care Services (12VAC30-50); Methods and Standards for Establishing Payment Rates - Inpatient Hospital Services (12VAC30-70); Methods and Standards for Establishing Payment Rates; Other Types of Care (12VAC30-80); and Methods and Standards for Establishing Payment Rates for Long Term Care (12VAC30-90).

DMAS is making these changes in its methods and standards for setting payment rates for services in order to comply with the legislative mandates set forth in Chapter 780 of the 2016 Acts of Assembly, Item 306.

Reimbursement Changes Affecting Hospitals (12VAC30-70)

12VAC30-70-351 is being amended to reduce fiscal year (FY) 2017 inflation by 50% for inpatient and outpatient hospital operating (including freestanding psychiatric and long-stay hospitals), graduate medical education (GME) and indirect medical education (IME) payments, disproportionate share hospital (DSH) payments, and outpatient hospital rates with the exception of 100% of inflation for inpatient and outpatient hospital operating, GME, and IME payments for Children's Hospital of King's Daughters.

The expected decrease in annual aggregate expenditures is $13,895,790.

12VAC30-70-221 and 12VAC30-70-381 are being amended to change the methodology for costing claims used to rebase weights from a fee-for-service global cost-to-charge methodology to a methodology that uses per-diems and cost-to-charge ratios by cost center for the fee-for-service and managed care claims, effective July 1, 2016. In a similar fashion, each hospital's total costs by claim using this methodology will be divided by the total charges for the hospital cost-to-charge ratio.

The expected increase in annual aggregate expenditures is $0.

12VAC30-70-281 is being amended to create GME supplemental payments for new primary care and high-need specialty residencies, effective July 1, 2017.

The expected increase in annual aggregate expenditures is $2,500,000.

Reimbursement Changes Affecting Other Providers (12VAC30-80)

12VAC30-80-32 is being amended to increase rates for existing substance use disorder services and add rates for new substance use disorder services, effective April 1, 2017, and peer support services, effective January 1, 2017.

The expected annual increase in expenditures for the rate increase is $1,460,647, and the expected annual increase for expenditures for new services is $2,871,908. Administrative expenses of the program are expected to be $872,269 for a total annual aggregate increase of $5,204,824.

12VAC30-80-30 is being amended to implement a supplemental payment for Children's National Health System physicians, effective July 1, 2016. The total supplemental Medicaid payment shall be based on the upper payment limit approved by the Centers for Medicare and Medicaid Services (CMS) and all other Virginia Medicaid fee-for-service payments but not to exceed $551,000.

The expected increase in annual aggregate expenditures is $551,000.

Reimbursement Changes Affecting Nursing Facilities (12VAC30-90)

12VAC30-90-264 is being amended to convert the specialized care rate methodology to a fully prospective state fiscal year rate, effective July 1, 2016. This would be accomplished consistent with the existing cost-based methodology by adding inflation to the per diem costs subject to existing ceilings for direct, indirect, and ancillary costs from the most recent settled cost report prior to the state fiscal year for which the rates are being established. The same inflation adjustment shall apply to plant costs for specialized care facilities that do not have prospective capital rates that are based on fair rental value. The department shall use the state fiscal year inflation rate recently adopted for regular nursing facilities. Partial year inflation shall be applied to per diem costs if the provider fiscal year end is different than the state fiscal year. Ceilings shall also be maintained by state fiscal year.

The expected increase in annual aggregate expenditures is $0.

This notice is intended to satisfy the requirements of 42 CFR 447.205 and of § 1902(a)(13) of the Social Security Act, 42 USC § 1396a(a)(13). A copy of this notice is available for public review from William Lessard, Provider Reimbursement Division, Department of Medical Assistance Services, 600 Broad Street, Suite 1300, Richmond, VA 23219, and this notice is available for public review on the Regulatory Town Hall (www.townhall.virginia.gov). Comments or inquiries may be submitted, in writing, within 30 days of this notice publication to Mr. Lessard and such comments are available for review at the same address.

Contact Information: Emily McClellan, Regulatory Manager, Division of Policy and Research, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-4300, FAX (804) 786-1680, TDD (800) 343-0634, or email emily.mcclellan@dmas.virginia.gov.

DEPARTMENT OF TAXATION

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Taxation is conducting a periodic review and small business impact review of **23VAC10-390, Virginia Soft Drink Excise Tax Regulations**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins June 27, 2016, and ends July 18, 2016.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Joe Mayer, Lead Policy Analyst, P.O. Box 27185, Richmond, VA 23261-7185, telephone (804) 371-2299, FAX (804) 371-2355, or email joseph.mayer@tax.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

STATE WATER CONTROL BOARD

Proposed Consent Special Order for Mr. Billy E. Chumbley and Virginia Pride Contractors

An enforcement action has been proposed for Mr. Billy E. Chumbley and Virginia Pride Contractors for violations in Botetourt County, Virginia. The special order by consent addresses and resolves violations of environmental law and regulations. A description of the proposed action is available

at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Jerry Ford, Jr. will accept comments by email at jerry.ford@deq.virginia.gov or postal mail at Department of Environmental Quality, Blue Ridge Regional Office, 3019 Peters Creek Road, Roanoke, VA 24019, from June 27, 2016, to July 27, 2016.

Proposed Consent Special Order for Hilex Poly Co. LLC

An enforcement action has been proposed for Hilex Poly Co. LLC, for alleged violations that occurred at the Hilex Poly Co. LLC Facility in Richmond, Virginia. The State Water Control Board proposes to issue a consent special order to Hilex Poly Co. LLC to address noncompliance with State Water Control Law. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Cynthia Akers will accept comments by email at cynthia.akers@deq.virginia.gov, FAX at (804) 527-5106, or postal mail at Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060, from June 27, 2016, to July 27, 2016.

Proposed Consent Order for Asim Khan

An enforcement action has been proposed for Asim Khan for violations at Browns In and Out Market in Esmont, Virginia. The State Water Control Board proposes to issue a consent order to Asim Khan to address noncompliance with State Water Control Law. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Karen Hensley will accept comments by email at karen.hensley@deq.virginia.gov, FAX at (540) 574-7878, or postal mail at Department of Environmental Quality, Valley Regional Office, P.O. Box 3000, Harrisonburg, VA 22801, from June 27, 2016, to July 27, 2016.

Proposed Enforcement Action for Kinder Morgan Liquids Terminals, LLC

An enforcement action has been proposed for Kinder Morgan Liquids Terminals, LLC for alleged violations of the State Water Control Law in Chesapeake, Virginia. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. John Brandt will accept comments by email at john.brandt@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from June 27, 2016, to July 27, 2016.

Proposed Consent Order for New River Resource Authority

An enforcement action has been proposed with the New River Resource Authority for violations in Pulaski County, Virginia. The State Water Control Board proposes to issue a consent order to New River Resource Authority to address and resolve violations of environmental law and regulations. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Jeffrey Hurst will accept comments by email at jeffrey.hurst@deq.virginia.gov, FAX at (540) 562-6725, or by postal mail at Department of Environmental Quality, Blue Ridge Regional office, 3019 Peters Creek Road, Roanoke, VA 24019, from June 27, 2016, to July 27, 2016.

Proposed Consent Order for Round Hill Investors, LLC

An enforcement action has been proposed for Round Hill Investors, LLC in Loudoun County, Virginia. The consent order describes a settlement to resolve violations of State Water Control Law and the applicable regulations associated with the development of the Round Hill Subdivision Project. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Daniel Burstein will accept comments by email at daniel.burstein@deq.virginia.gov, FAX at (703) 583-3821, or postal mail at Department of Environmental Quality, Northern Regional Office, 13901 Crown Court, Woodbridge, VA 22193, from June 28, 2016, through July 28, 2016

Total Maximum Daily Load Implementation Plan for the West Run, Stephens Run, Crooked Run, and Willow Brook Watersheds

The Department of Environmental Quality (DEQ) seeks written and oral comments from interested persons on the development of a total maximum daily load (TMDL) implementation plan (IP) for the West Run, Stephens Run, Crooked Run, and Willow Brook watersheds in Frederick, Warren, and Clarke Counties. West and Stephens Runs were first listed as impaired on the Virginia's § 303(d) TMDL Priority List and Report due to violations of the state's water quality standard for bacteria in 2010, while Willow Brook and Crooked Run were listed in 2006 and 2002, respectively. The creeks have remained on the § 303(d) list for these impairments since then.

The impaired segment of West Run extends 6.12 miles from its headwaters downstream to its confluence with Crooked Run. The impaired segment of Stephens Run extends 0.95 miles from its confluence with an unnamed tributary to its confluence with Crooked Run. The impaired segment of Crooked Run extends 8.87 miles from the Lake Frederick dam to its confluence with the Shenandoah River. Willow Brook is impaired from its headwaters to its confluence with the Shenandoah River (3.95 miles).

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the Code of Virginia require DEQ to develop TMDLs for

pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL Priority List and Report. In addition, § 62.1- 44.19:7 C of the Code of Virginia requires expeditious implementation of total maximum daily loads when appropriate. The IP should provide measurable goals and the date of expected achievement of water quality objectives. The IP should also include the corrective actions needed and the associated costs, benefits, and environmental impacts. DEQ completed bacteria TMDLs for the Crooked, Stephens, and West Runs in September 2014. The TMDLs were approved by the U.S. Environmental Protection Agency December 22, 2015. The final TMDL report is available on the DEQ website at http://www.deq.virginia.gov/Portals/0/DEQ/Water/TMDL/apptmdls/shenrvr/ShenTribs_Bacteria_Benthic_Final.pdf, Development of the Crooked, Stephens, and West Runs and Willow Brook TMDL Implementation Plan began in January 2016.

The Virginia Department of Environmental Quality will host a public meeting to present a draft TMDL implementation plan for Crooked, Stephens, and West Runs and Willow Brook. The meeting will be held on Wednesday, June 29, 2016, at 7 p.m. at the North Warren Volunteer Fire Hall's Celebration Hall (266 Rockland Court, 2nd Floor, Front Royal, Virginia).

A 30-day public comment period for the meeting will begin June 30, 2016, and end July 29, 2016. Written comments should include the name, address, and telephone number of the person submitting the comments and should be sent to Nesha McRae, Department of Environmental Quality, P.O. Box 3000, Harrisonburg, VA 22801, telephone (540) 574-7850, or email nesha.mcrae@deq.virginia.gov.

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, General Assembly Building, 201 North 9th Street, 2nd Floor, Richmond, VA 23219; *Telephone:* Voice (804) 786-3591; *Email:* varegs@dls.virginia.gov.

Meeting Notices: Section 2.2-3707 C of the Code of Virginia requires state agencies to post meeting notices on their websites and on the Commonwealth Calendar at http://www.virginia.gov/connect/commonwealth-calendar.

Cumulative Table of Virginia Administrative Code Sections Adopted, Amended, or Repealed: A table listing regulation sections that have been amended, added, or repealed in the *Virginia Register of Regulations* since the regulations were originally published or last supplemented in the print version of the Virginia Administrative Code is available at http://register.dls.virginia.gov/documents/cumultab.pdf.

Filing Material for Publication in the *Virginia Register of Regulations*: Agencies use the Regulation Information System (RIS) to file regulations and related items for publication in the *Virginia Register of Regulations*. The Registrar's office works closely with the Department of Planning and Budget (DPB) to coordinate the system with the Virginia Regulatory Town Hall. RIS and Town Hall complement and enhance one another by sharing pertinent regulatory information.