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TABLE OF CONTENTS

Register Information Page	1945
Publication Schedule and Deadlines	1946
Petitions for Rulemaking	1947
Regulations	1948
4VAC50-20. Impounding Structure Regulations (Final)	1948
9VAC25-110. Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Domestic Sewage Discharges of Less Than or Equal to 1,000 Gallons per Day (Final)	1950
12VAC5-421. Food Regulations (Proposed)	1965
12VAC5-481. Virginia Radiation Protection Regulations (Final)	2025
12VAC5-640. Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings (Forms)	2051
15VAC5-10. Regulations Governing Virginia Legal Aid Societies (Final)	2051
24VAC30-290. Guide for Additions, Abandonments and Discontinuances (Final)	2053
Governor	2055
General Notices/Errata	2056

VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

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

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

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

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

A regulation becomes effective at the conclusion of the 30-day final adoption period, or at any other later date specified by the promulgating agency, unless (i) a legislative objection has been filed, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 21-day objection period; (ii) the Governor exercises his authority to require the agency to provide for additional public comment, in which event the regulation,

unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the period for which the Governor has provided for additional public comment; (iii) the Governor and the General Assembly exercise their authority to suspend the effective date of a regulation until the end of the next regular legislative session; or (iv) the agency suspends the regulatory process, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 30-day public comment period and no earlier than 15 days from publication of the readopted action.

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

FAST-TRACK RULEMAKING PROCESS

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

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency, upon consultation with the Attorney General, and at the discretion of the Governor, may adopt emergency regulations that are necessitated by an emergency situation. An agency may also adopt an emergency regulation when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment. The emergency regulation becomes operative upon its adoption and filing with the Registrar of Regulations, unless a later date is specified. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under certain circumstances as provided for in § 2.2-4011 D. Emergency regulations are published as soon as possible in the *Register*. During the time the emergency status is in effect, the agency may proceed with the adoption of permanent regulations through the usual procedures. To begin promulgating the replacement regulation, the agency must (i) file the Notice of Intended Regulatory Action with the Registrar within 60 days of the effective date of the emergency regulation and (ii) file the proposed regulation with the Registrar within 180 days of the effective date of the emergency regulation. If the agency chooses not to adopt the regulations, the emergency status ends when the prescribed time limit expires.

STATEMENT

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

CITATION TO THE VIRGINIA REGISTER

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

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

Members of the Virginia Code Commission: **John S. Edwards**, Chair; **James M. LeMunyon**, Vice Chair; **Gregory D. Habeeb**; **Ryan T. McDougle**; **Pamela S. Baskerville**; **Robert L. Calhoun**; **Carlos L. Hopkins**; **E.M. Miller, Jr.**; **Thomas M. Moncure, Jr.**; **Christopher R. Nolen**; **Timothy Oksman**; **Charles S. Sharp**; **Mark J. Vucci**.

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

PUBLICATION SCHEDULE AND DEADLINES

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

February 2016 through April 2017

<u>Volume: Issue</u>	<u>Material Submitted By Noon*</u>	<u>Will Be Published On</u>
32:13	February 3, 2016	February 22, 2016
32:14	February 17, 2016	March 7, 2016
32:15	March 2, 2016	March 21, 2016
32:16	March 16, 2016	April 4, 2016
32:17	March 30, 2016	April 18, 2016
32:18	April 13, 2016	May 2, 2016
32:19	April 27, 2016	May 16, 2016
32:20	May 11, 2016	May 30, 2016
32:21	May 25, 2016	June 13, 2016
32:22	June 8, 2016	June 27, 2016
32:23	June 22, 2016	July 11, 2016
32:24	July 6, 2016	July 25, 2016
32:25	July 20, 2016	August 8, 2016
32:26	August 3, 2016	August 22, 2016
33:1	August 17, 2016	September 5, 2016
33:2	August 31, 2016	September 19, 2016
33:3	September 14, 2016	October 3, 2016
33:4	September 28, 2016	October 17, 2016
33:5	October 12, 2016	October 31, 2016
33:6	October 26, 2016	November 14, 2016
33:7	November 9, 2016	November 28, 2016
33:8	November 22, 2016 (Tuesday)	December 12, 2016
33:9	December 7, 2016	December 26, 2016
33:10	December 19, 2016 (Monday)	January 9, 2017
33:11	January 4, 2017	January 23, 2017
33:12	January 18, 2017	February 6, 2017
33:13	February 1, 2017	February 20, 2017
33:14	February 15, 2017	March 6, 2017
33:15	March 1, 2017	March 20, 2017
33:16	March 15, 2017	April 3, 2017

*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF COUNSELING

Initial Agency Notice

Title of Regulation: **18VAC115-60. Regulations Governing the Practice of Licensed Substance Abuse Treatment Practitioners.**

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

Name of Petitioner: Denise Knox.

Nature of Petitioner's Request: Amend 18VAC115-60-55 which provided a time-limited waiver for acceptance of credentials that did not meet educational and examination requirements for licensure set forth in 18VAC115-60-40 (Licensure by examination) and 18VAC115-60-50 (Licensure by endorsement). The time-limited waiver expired February 16, 2004.

Agency Plan for Disposition of Request: In accordance with Virginia law, the petition will be filed with the Registrar of Regulations and published on February 22, 2016, with comment requested until March 25, 2016. It will also be placed on the Virginia Regulatory Town Hall and available for comments to be posted electronically. At its first meeting following the close of comment, scheduled for May 20, 2016, the board will consider the request to amend regulations and all comment received in support or opposition.

Public Comment Deadline: March 25, 2016.

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

V.A.R. Doc. No. R16-16; Filed January 30, 2016, 12:41 p.m.

REGULATIONS

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

Symbol Key

Roman type indicates existing text of regulations. Underscored language indicates proposed new text. Language that has been stricken indicates proposed text for deletion. Brackets are used in final regulations to indicate changes from the proposed regulation.

TITLE 4. CONSERVATION AND NATURAL RESOURCES

VIRGINIA SOIL AND WATER CONSERVATION BOARD

Final Regulation

REGISTRAR'S NOTICE: The Virginia Soil and Water Conservation Board is claiming an exclusion from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 a of the Code of Virginia, which excludes regulations that are necessary to conform to changes in Virginia statutory law where no agency discretion is involved. The Virginia Soil and Water Conservation Board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 4VAC50-20. Impounding Structure Regulations (amending 4VAC50-20-50).

Statutory Authority: § 10.1-605 of the Code of Virginia.

Effective Date: March 23, 2016.

Agency Contact: David C. Dowling, Policy and Planning Director, Department of Conservation and Recreation, 600 East Main Street, 24th Floor, Richmond, VA 23219, telephone (804) 786-2291, FAX (804) 786-6141, or email david.dowling@dcr.virginia.gov.

Background:

Chapters 475 and 489 of the 2014 Acts of Assembly directed the Department of Conservation and Recreation, on behalf of the Virginia Soil and Water Conservation Board, to conduct a study that would result in a set of new probable maximum precipitation or PMP values for Virginia. The legislation further states "[s]uch PMP revisions shall be adopted by the Board if it finds that the analysis is valid and reliable and will result in cost savings to owners for impounding structure spillway construction or rehabilitation efforts." The PMP values incorporated into the Impounding Structure Regulations currently are based on U.S. Army Corps of Engineers hydrometeorological studies from as early as the 1970s.

The study entitled "Probable Maximum Precipitation Study for Virginia (November 2015)" was completed on December 1, 2015. The board adopted the study, the PMP values, and authorized this regulatory action on December 9, 2015. The study and related information may be found on the department's website at <http://www.dcr.virginia.gov/dam-safety-andfloodplains/>.

Summary:

This action amends 4VAC50-20-50 (Performance standards required for impounding structures) and incorporates by reference the Probable Maximum Study for Virginia (and associated PMP Evaluation Tool and Database) (November 2015).

The amendments (i) remove references to the National Weather Service, NOAA, PMP values and insert references to PMP values "derived from the Probable Maximum Study for Virginia (and associated PMP Evaluation Tool and Database) (November 2015)"; (ii) remove the reference to "flat terrain" from the description of PMP as this set of PMP values does bring orographic variables into the analysis; (iii) update the citation for the Department of Environmental Quality's Virginia Stormwater Management Program (VSMP) Regulation; and (iv) incorporate by reference the PMP study and evaluation tool.

4VAC50-20-50. Performance standards required for impounding structures.

A. In accordance with the definitions provided by § 10.1-604 of the Code of Virginia and 4VAC50-20-30, an impounding structure shall be regulated if the impounding structure is 25 feet or greater in height and creates a maximum impounding capacity of 15 acre-feet or greater, or the impounding structure is six feet or greater in height and creates a maximum impounding capacity of 50 acre-feet or greater and is not otherwise exempt from regulation by the Code of Virginia. Impounding structures exempted from this chapter are those that are:

1. Licensed by the State Corporation Commission that are subject to a safety inspection program;
2. Owned or licensed by the United States government;
3. Operated primarily for agricultural purposes that are less than 25 feet in height or that create a maximum impoundment capacity smaller than 100 acre-feet;
4. Water or silt-retaining dams approved pursuant to § 45.1-222 or 45.1-225.1 of the Code of Virginia; or
5. Obstructions in a canal used to raise or lower water.

Impounding structures of regulated size and not exempted shall be constructed, operated and maintained such that they perform in accordance with their design and purpose throughout the life of the project. For impounding structures, the ~~spillway(s)~~ spillway capacity shall perform at a minimum to safely pass the appropriate spillway design flood as determined in Table 1. For the purposes of utilizing Table 1,

Hazard Potential Classification shall be determined in accordance with 4VAC50-20-40.

TABLE 1 Impounding Structure Regulations			
Applicable to all impounding structures that are 25 feet or greater in height and that create a maximum impounding capacity of 15 acre-feet or greater, and to all impounding structures that are six feet or greater in height and that create a maximum impounding capacity of 50 acre-feet or greater and is not otherwise exempt from regulation by the Code of Virginia.			
Hazard Potential Class of Dam	Spillway Design Flood (SDF) ^B for New Construction ^F	Spillway Design Flood (SDF) ^B for Existing Impounding Structures ^{F, G}	Minimum Threshold for Incremental Damage Analysis
High	PMF ^C	0.9 PMP ^H	100-YR ^D
Significant	.50 PMF	.50 PMF	100-YR ^D
Low	100-YR ^D	100-YR ^D	50-YR ^E

B. The spillway design flood (SDF) represents the largest flood that need be considered in the evaluation of the performance for a given project. The impounding structure shall perform so as to safely pass the appropriate SDF. Reductions in the established SDF may be evaluated through the use of incremental damage analysis pursuant to 4VAC50-20-52. The SDF established for an impounding structure shall not be less than those standards established elsewhere by state law or regulations, including but not limited to the Virginia Stormwater Management Program (VSMP) ~~Permit Regulations (4VAC50-60) Regulation (9VAC25-870)~~. Due to potential for future development in the dam break inundation zone that would necessitate higher spillway design flood standards or other considerations, owners may find it advisable to consider a higher spillway design flood standard than is required.

C. PMF: Probable Maximum Flood is the flood that might be expected from the most severe combination of critical meteorologic and hydrologic conditions that are reasonably possible in the region. ~~The PMF is derived from the current probable maximum precipitation (PMP) available from the National Weather Service, NOAA derived from the Probable Maximum Precipitation Study for Virginia (and associated PMP Evaluation Tool and Database) (November 2015). In some cases, a modified PMF may be calculated utilizing local topography, meteorological conditions, hydrological conditions, or PMP values supplied by NOAA. Any deviation in the application of established developmental procedures must be explained and justified by the owner's engineer.~~ The owner's engineer must develop PMF hydrographs for 6-, 12-, and 24-hour durations. The hydrograph that creates the largest peak outflow is to be used to determine capacity for nonfailure and failure analysis.

Present and planned land-use conditions shall be considered in determining the runoff characteristics of the drainage area.

D. 100-Yr: 100-year flood represents the flood magnitude expected to be equaled or exceeded on the average of once in 100 years. It may also be expressed as an exceedence probability with a 1.0% chance of being equaled or exceeded in any given year. Present and planned land-use conditions shall be considered in determining the runoff characteristics of the drainage area.

E. 50-Yr: 50-year flood represents the flood magnitude expected to be equaled or exceeded on the average of once in 50 years. It may also be expressed as an exceedence probability with a 2.0% chance of being equaled or exceeded in any given year. Present and planned land-use conditions shall be considered in determining the runoff characteristics of the drainage area.

F. For the purposes of Table 1 "Existing impounding structure" and "New construction" are defined in 4VAC50-20-30.

G. An existing impounding structure as defined in 4VAC50-20-30, that is currently classified as high hazard, or is subsequently found to be high hazard through reclassification, shall only be required to pass the flood resulting from 0.6 PMP instead of the flood resulting from the 0.9 PMP SDF if the dam owner meets the requirements set out in 4VAC50-20-53.

H. PMP: Probable maximum precipitation means the theoretically greatest depth of precipitation for a given duration that is meteorologically possible over a given size storm area at a particular geographical location at a particular time of year with no allowance made for future long-term climatic trends. In practice, this is derived ~~over flat terrain~~ by storm transposition and moisture adjustment to observed storm patterns. In Virginia, the 0.9 PMP is meant to characterize the maximum recorded rainfall event within the Commonwealth.

DOCUMENTS INCORPORATED BY REFERENCE (4VAC50-20)

[ACER Technical Memorandum No. 11, Downstream Hazard Classification Guidelines, December 1988, U.S. Department of the Interior, Bureau of Reclamation](#)

[Probable Maximum Precipitation Study for Virginia \(and associated PMP Evaluation Tool and Database\), Prepared for the Virginia Department of Conservation and Recreation by Applied Weather Associates, LLC, November 2015](#)

[Trip Generation, 8th Ed., 2008, Institute of Transportation Engineers, 1627 Eye Street, NW, Suite 600, Washington, DC 20006](#)

VA.R. Doc. No. R16-4564; Filed February 3, 2016, 10:24 a.m.



TITLE 9. ENVIRONMENT

STATE WATER CONTROL BOARD

Final Regulation

REGISTRAR'S NOTICE: The State Water Control Board is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 8 of the Code of Virginia, which exempts general permits issued by the State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), Chapter 24 (§ 62.1-242 et seq.) and Chapter 25 (§ 62.1-254 et seq.) of Title 62.1 of the Code of Virginia if the board (i) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01; (ii) following the passage of 30 days from the publication of the Notice of Intended Regulatory Action forms a technical advisory committee composed of relevant stakeholders, including potentially affected citizens groups, to assist in the development of the general permit; (iii) provides notice and receives oral and written comment as provided in § 2.2-4007.03; and (iv) conducts at least one public hearing on the proposed general permit.

Title of Regulation: **9VAC25-110. Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Domestic Sewage Discharges of Less Than or Equal to 1,000 Gallons per Day (amending 9VAC25-110-10 through 9VAC25-110-80; adding 9VAC25-110-15).**

Statutory Authority: § 62.1-44.15 of the Code of Virginia; § 402 of the Clean Water Act; 40 CFR Parts 122, 123, and 124.

Effective Date: August 2, 2016.

Agency Contact: Allan Brockenbrough, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4147, FAX (804) 698-4032, or email allan.brockenbrough@deq.virginia.gov.

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.

Summary:

The amendments reissue the existing Virginia Pollutant Discharge Elimination System general permit for domestic sewage discharges of less than or equal to 1,000 gallons per day (VAG40) that will expire on August 1, 2016. The general permit contains effluent limitations, permit conditions, and monitoring requirements for domestic sewage discharges to surface waters from treatment works with a design discharge flow of less than or equal to 1,000 gallons per day on a monthly average. The permit requirements are designed to protect the quality of the waters receiving the treated wastewater discharges. Amendments update and clarify definitions, effective dates, authorization to discharge, registration statement

requirements, general permit limits pages, special conditions, and conditions applicable to all permits. The amendments include (i) adding a limit set for discharges to receiving waters subject to the Policy for the Potomac River Embayments (9VAC25-415); (ii) requiring owners of treatment works serving buildings or dwellings other than individual single family dwellings to submit the monitoring results to the Department of Environmental Quality on a Discharge Monitoring Report (DMR) after each monitoring period; and (iii) requiring owners of treatment works serving buildings or dwellings other than individual single family dwellings to maintain a log of all maintenance performed on the treatment works and submit the log to the department along with the facilities monitoring results.

9VAC25-110-10. Definitions.

The words and terms used in this chapter shall have the same meanings as given in the State Water Control Law, Chapter 3.1 (§ 62.1-44.2 et seq.) of Title 62.1 of the Code of Virginia and the VPDES Permit Regulation (9VAC25-31), unless the context clearly indicates otherwise, except that for the purposes of this chapter:

"7Q10" means the lowest flow averaged over a period of seven consecutive days that can be statistically expected to occur once every 10 climatic years.

"Board" or "State Water Control Board" means the Virginia State Water Control Board.

~~"Climatic year" means a year beginning on April 1 and ending on March 31.~~

"Combined application" means the Virginia Department of Health Discharging System Application for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons per Day and State Water Control Board Virginia Pollutant Discharge Elimination System General Permit Registration Statement for Domestic Sewage Discharges Less Than or Equal to 1,000 Gallons per Day. This application combines the VDH Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings (12VAC5-640) requirements with the board's registration statement requirements.

"Department" or "DEQ" means the Virginia Department of Environmental Quality ~~or the department.~~

"Domestic sewage" means the water-carried human wastes from residences, buildings, industrial establishments or other places.

"Individual single family dwelling" means a residence housing one family or household or one that is designed for one family only.

"Receiving water" means a creek, stream, river, lake, estuary, groundwater formation, or other body of water into which treated waste or untreated waste is discharged.

"Total maximum daily load" or "TMDL" means a calculation of the maximum amount of a pollutant that a

waterbody can receive and still meet water quality standards, and an allocation of that amount to the pollutant's sources. A TMDL includes wasteload allocations (WLAs) for point source discharges, and load allocations (LAs) for nonpoint sources or natural background or both, and must include a margin of safety (MOS) and account for seasonal variations.

"VDH" means the Virginia Department of Health.

9VAC25-110-15. Applicability of incorporated references based on the dates that they became effective.

Except as noted, when a regulation of the U.S. Environmental Protection Agency set forth in Title 40 of the Code of Federal Regulations (CFR) is referenced and incorporated herein, that regulation shall be as it exists and has been published as of July 1, [2014 2015].

9VAC25-110-20. Purpose; delegation of authority; effective date of permit.

A. This general permit regulation governs domestic sewage discharges to surface waters from treatment works with a design discharge flow of less than or equal to 1,000 gallons per day on a monthly average.

B. The Director of the Department of Environmental Quality, or his designee, may perform any act of the board provided under this chapter, except as limited by § 62.1-44.14 of the Code of Virginia.

C. This general VPDES permit will become effective on August 2, ~~2014~~ 2016, and it expires on August 1, ~~2016~~ 2021. With respect to a particular ~~facility dwelling, building, or site served~~, this general permit shall become effective upon the ~~facility dwelling, building, or site served~~ owner's compliance with the provisions of 9VAC25-110-60.

9VAC25-110-60. Authorization to discharge.

A. Any owner of a treatment works governed by this general permit is hereby authorized to discharge treated domestic sewage to surface waters of the Commonwealth of Virginia provided that:

1. The owner submits a registration statement, if required to do so, in accordance with 9VAC25-110-70, and that registration statement is accepted by the board. For an individual single family dwelling, the owner may submit a combined application in place of a registration statement;
2. The owner complies with the effluent limitations and other requirements of 9VAC25-110-80; and
3. The board has not notified the owner, in accordance with subsection B of this section, that the discharge is not eligible for coverage under this permit.

B. The board will notify an owner that the discharge is not eligible for coverage under this permit in the event of any of the following:

1. The owner is required to obtain an individual VPDES permit in accordance with 9VAC25-31-170 B 3 of the VPDES Permit Regulation;

2. The owner is proposing to discharge to surface waters specifically named in other board regulations that prohibit such discharges;

3. The owner is proposing to discharge to surface waters in an area where there are central sewage facilities reasonably available, as determined by the board;

4. The owner of any proposed treatment works or any treatment works that has not previously been issued a VPDES permit has applied to the Virginia Department of Health for an onsite sewage disposal system permit, and the Virginia Department of Health has determined that an onsite system is available to serve that parcel of land;

5. The discharge would violate the antidegradation policy stated in 9VAC25-260-30 of the Virginia Water Quality Standards; or

6. ~~A TMDL (board adopted, EPA approved, or EPA imposed) contains an individual WLA for the facility, unless this general permit specifically addresses the TMDL pollutant of concern and the permit limits are at least as stringent as those required by the TMDL WLA. The discharge is not consistent with the assumptions and requirements of an approved TMDL.~~

C. Compliance with this general permit constitutes compliance, for purposes of enforcement, with the federal Clean Water Act §§ 301, 302, 306, 307, 318, 403, and 405 (a) through (b), and the State Water Control Law, ~~and applicable regulations under either,~~ with the exceptions stated in 9VAC25-31-60 of the VPDES Permit Regulation. Approval for coverage under this general VPDES permit does not relieve any owner of the responsibility to comply with any other applicable federal, state or local statute, ordinance or regulation, including, for owners of sewage treatment works that serve individual single family dwellings, the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings (12VAC5-640) of the Virginia Department of Health adopted pursuant to §§ 32.1-12, 32.1-163, and 32.1-164 of the Code of Virginia and, for owners of sewage treatment works that serve ~~nonsingle buildings or dwellings other than individual single~~ family dwellings, the Sewage Collection and Treatment Regulations (9VAC25-790) adopted by the State Water Control Board pursuant to § ~~62.1-44.18~~ 62.1-44.19 of the Code of Virginia.

D. Continuation of permit coverage.

1. Any owner that was authorized to discharge under the domestic sewage discharges general permit issued in ~~2006,~~ 2011 and who is required to and submits a complete registration statement, or for an individual single family dwelling a combined application, on or before August 1, ~~2014~~ 2016, is authorized to continue to discharge treated domestic sewage under the terms of the ~~2006~~ 2011 general permit until such time as the board either:

- a. Issues coverage to the owner under this general permit; or

Regulations

b. Notifies the owner that the discharge is not eligible for coverage under this general permit is denied.

2. When the owner that was covered under the expiring or expired general permit has violated or is violating the conditions of that permit, the board may choose to do any or all of the following:

a. Initiate enforcement action based upon the 2011 general permit which has been continued;

b. Issue a notice of intent to deny coverage under the new reissued general permit. If the general permit coverage is denied, the owner would then be required to cease the activities discharges authorized by the administratively continued coverage under the terms of the 2011 general permit or be subject to enforcement action for operating without a permit;

c. Issue an individual permit with appropriate conditions; or

d. Take other actions authorized by the VPDES Permit Regulation (9VAC25-31).

9VAC25-110-70. Registration statement.

A. Deadlines for submitting registration statement. Any owner seeking coverage under this general permit, and who is required to submit a registration statement, shall submit a complete General general VPDES Permit Registration Statement permit registration statement in accordance with this chapter section, which shall serve as a notice of intent to be covered for coverage under the general General VPDES permit Permit for domestic sewage discharges Domestic Sewage Discharges of less than Less Than or equal Equal to 1,000 gallons per day Gallons per Day. For an individual single family dwelling, the owner may submit a combined application in place of the registration statement.

1. New facilities treatment works. Any owner proposing a new discharge shall submit a complete registration statement, or for an individual single family dwelling a combined application, to the department at least 60 days prior to the date planned for commencing operation of the treatment works.

2. Existing facilities treatment works.

a. Any owner of an existing treatment works covered by an individual VPDES permit who is proposing to be covered by this general permit shall notify the department and submit a complete registration statement, or for an individual single family dwelling a combined application, at least 240 days prior to the expiration date of the individual VPDES permit.

b. Any owner of a treatment works that was authorized to discharge under the general permit issued in 2006 2011, and who intends to continue coverage under this general permit, is automatically covered by this general permit and is not required to submit a registration statement, or for an individual single family dwelling a combined application, if:

(1) The ownership of the treatment works has not changed since the registration statement or combined application for coverage under the 2006 2011 general permit was submitted, or, if the ownership has changed, (i) a new registration statement or combined application or (ii) VPDES Change of Ownership form was submitted to the department by the new owner at the time of the title transfer;

(2) There has been no change in the design or operation, or both, of the treatment works since the registration statement or combined application for coverage under the 2006 2011 general permit was submitted;

(3) For treatment works serving individual single family dwellings, the Virginia Department of Health VDH has no objection to the automatic permit coverage renewal for this treatment works based on system performance issues, enforcement issues, or other issues sufficient to the board. If the Virginia Department of Health VDH objects to the automatic renewal for this treatment works, the owner will be notified by the board in writing; and

(4) For treatment works serving nonsingle buildings or dwellings other than individual single family dwellings, the board has no objection to the automatic permit coverage renewal for this treatment works based on system performance issues, or enforcement issues, or other issues sufficient to the board. If the board objects to the automatic renewal for this treatment works, the owner will be notified by the board in writing.

c. Any owner that of a treatment works that was authorized to discharge under the general permit issued in 2011 that does not qualify for automatic permit coverage renewal shall submit a complete registration statement, or for an individual single family dwelling a combined application, to the department on or before June 2, 2011 2016.

3. Late notifications registration statements. Late registration Registration statements will be accepted by the board, or for individual single family dwellings combined applications, for existing treatment works covered under subdivision 2 b of this subsection will be accepted after August 1, 2016, but authorization to discharge will not be retroactive. Owners described in subdivision 2 b of this subsection that submit registration statements or combined applications after June 2, 2016, are authorized to discharge under the provisions of 9VAC25-110-60 D if a complete registration statement, or combined application, is submitted before August 2, 2016.

B. Registration statement. The registration statement shall contain the following information:

1. a. Indicate if the facility building served by the treatment works is a an individual single family dwelling. If the facility building is not a an individual single family dwelling, describe the facility's use of the building or site served.

- b. Name and street address of the facility building or site served by the treatment works.
2. a. Name, mailing address, email address (where available), and ~~work and home telephone numbers~~ number of the facility owner of the treatment works. ~~For a dwelling, indicate~~ Indicate if the owner is or will be the occupant of the dwelling or building served by the treatment works.
- b. ~~If the owner is not or will not be the occupant of the dwelling or building, provide an alternate contact name, mailing address, email address (where available), and telephone number of the dwelling or building, if available.~~
3. Name of the water body receiving the discharge. Indicate if the discharge point is on a stream that usually flows during dry weather.
4. The amount of discharge from the treatment works, in gallons per day, on a monthly average, and the design flow of the treatment works, in gallons per day.
5. A description of any pollutants, other than domestic sewage, to be discharged.
6. For a proposed treatment works, indicate if there are central sewage facilities available to serve the facility building or site.
7. If the facility treatment works currently has a VPDES permit, provide the permit number. Indicate if the facility treatment works has been built and begun discharging.
8. For the owner of any proposed treatment works or any treatment works that has not previously been issued a VPDES permit:
- a. A 7.5 minute ~~USGS~~ U.S. Geological Survey (USGS) topographic map or equivalent (e.g., a computer generated map) that indicates the discharge point, the location of the property to be served by the treatment works, and the location of any wells, springs, other water bodies, and any residences within 1/2 mile downstream from the discharge point;
- b. A site diagram of the existing or proposed ~~sewage~~ treatment works; to include the property boundaries, the location of the ~~facility or dwelling to be~~ building, or site served, the individual sewage treatment units, the receiving water body, and the discharge line location; and
- c. A copy of the notification from the Virginia Department of Health that an onsite sewage disposal system permit has been applied for and that the Virginia Department of Health has determined that there is no onsite system available to serve that parcel of land.
9. ~~Maintenance contract~~ Operation and maintenance.
- a. For the owner of a treatment works serving an individual single family dwelling, ~~indicate if a valid operation and maintenance contract has been obtained in~~

~~accordance with the requirements are specified in VDH regulations at 12VAC5-640-500, or if an variance to the maintenance contract requirement has been requested and granted by the Virginia Department of Health. Provide the name of the individual or company contracted to perform the treatment works maintenance and the expiration date of the current contract, if applicable. If the treatment works has not been constructed yet, provide the name after construction is complete and prior to starting the treatment plant operation.~~

~~Indicate if a monitoring contract has been obtained in accordance with the requirements in 12VAC5-640-490 F, or if the monitoring contract requirement has been waived by the Virginia Department of Health, or if the monitoring requirements are included as part of the maintenance contract. Provide the name of the individual or company contracted to perform the treatment works monitoring and the expiration date of the current contract, if applicable. If the treatment works has not been constructed yet, provide the name after construction is complete and prior to starting the treatment plant operation;~~

b. For the owner of a treatment works serving a ~~nonsingle~~ building or dwelling other than an individual single family dwelling, indicate if a valid maintenance contract has been obtained, or if an exception to the maintenance contract requirement has been requested and granted in accordance with subdivision 10 of this subsection. Provide the name of the individual or company contracted to perform the treatment works maintenance and the expiration date of the current contract, if applicable. If the treatment works has not been constructed yet, provide the name after the certificate to construct (CTC) is issued, and prior to requesting a certificate to operate (CTO). ~~A valid maintenance contract shall provide for the following:~~

~~(1) Performance of all testing required in accordance with either 9VAC25-110-80 Part I A or Part I B, as appropriate, and periodic (at least annual) inspections of the treatment works. Note: The treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The owner or maintenance provider should not force a discharge in order to collect a sample;~~

~~(2) A written notification to the owner within 24 hours whenever the contract provider becomes aware that maintenance or repair of the owner's treatment works is necessary. The owner is responsible for prompt maintenance and repair of the treatment works including all costs associated with the maintenance or repair. Immediately upon receipt of notice that repair or maintenance is required, the owner shall begin emergency pump and haul of all sewage generated from~~

Regulations

the facility or dwelling if full and complete repairs cannot be accomplished within 48 hours.

~~(3) A log of the following items shall be maintained by the contract provider for as long as the contract is in force:~~

~~(a) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts, and document and explain why no sample was taken or possible;~~

~~(b) Alarm activation incidents;~~

~~(c) Maintenance, corrective, or repair activities performed;~~

~~(d) Recommended repair or replacement items; and~~

~~(e) Copies of all reports prepared by the contract provider.~~

~~(4) An inspection shall be conducted by the contract provider within 48 hours after notification by the owner that a problem may be occurring; and~~

~~(5) The maintenance contract shall be kept in force during the entire permit term, and shall be valid for a minimum of 24 months of consecutive coverage.~~

10. The owner of a treatment works serving a nonsingle building or dwelling other than an individual single family dwelling may request an exception to the maintenance contract requirement by submitting an operation and maintenance plan to the board for review and approval. If an operation and maintenance plan has been approved by the board previously and remains current and complete, then it does not need to be resubmitted. In such cases, the owner shall provide the date of approval of the operation and maintenance plan; and identify any changes that have been made to the approved plan. At a minimum, the operation and maintenance plan shall contain the following information:

~~a. An up-to-date operation and maintenance manual for the treatment works;~~

~~b. A log of all maintenance performed on the treatment works including, but not limited to, the following:~~

~~(1) The date and amount of disinfection chemicals added to the chlorinator.~~

~~(2) If dechlorination is used, the date and amount of any dechlorination chemicals that are added.~~

~~(3) The date and time of equipment failure(s) and the date and time the equipment was restored to service.~~

~~(4) The date and approximate volume of sludge removed.~~

~~(5) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts, and document and explain why no sample was taken or possible;~~

~~e. Dated receipts for chemicals purchased, equipment purchased, and maintenance performed; and~~

~~d. An effluent monitoring plan to conform with the requirements of 9VAC25-110-80 Part I A or Part I B, as appropriate, including all sample collection, preservation, and analysis procedures. Note: The treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The owner or maintenance provider should not force a discharge in order to collect a sample.~~

11. The following certification: "I hereby grant to duly authorized agents of the Department of Environmental Quality, upon presentation of credentials, permission to enter the property where the treatment works is located for the purpose of determining compliance with or the suitability of coverage under the General Permit. I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system or those persons directly responsible for gathering the information, the information submitted is to the best of my knowledge and belief true, accurate, and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment for knowing violations."

C. The registration statement shall be signed in accordance with the requirements of 9VAC25-31-110 A of the VPDES Permit Regulation.

D. The registration statement may be delivered to the department by either postal or electronic mail and shall be submitted to the DEQ regional office serving the area where the treatment works is located.

9VAC25-110-80. General permit.

Any owner whose registration statement is accepted by the board, or whose permit coverage is automatically renewed, shall comply with the requirements contained herein and be subject to all requirements of 9VAC25-31-170.

General Permit No.: VAG40

Effective Date: August 2, ~~2014~~ 2016

Expiration Date: August 1, ~~2016~~ 2021

GENERAL PERMIT FOR DOMESTIC SEWAGE
DISCHARGES OF LESS THAN OR EQUAL TO 1,000
GALLONS PER DAY

AUTHORIZATION TO DISCHARGE UNDER THE
VIRGINIA POLLUTANT DISCHARGE ELIMINATION
SYSTEM AND THE VIRGINIA STATE WATER
CONTROL LAW

In compliance with the provisions of the Clean Water Act (33 USC § 1251 et seq.), as amended, and pursuant to the State Water Control Law and regulations adopted pursuant thereto, owners of treatment works with domestic sewage

discharges of a design flow of less than or equal to 1,000 gallons per day on a monthly average are authorized to discharge to surface waters within the boundaries of the Commonwealth of Virginia, except those waters specifically named in board regulations that prohibit such discharges.

The authorized discharge shall be in accordance with [the information submitted with the registration statement,] this cover page, Part I-Effluent Limitations, Monitoring Requirements and Special Conditions, and Part II-Conditions Applicable to All VPDES Permits, as set forth herein.

Part I Effluent Limitations, Monitoring Requirements and Special Conditions

A. Effluent limitations and monitoring requirements - receiving waters where the 7Q10 flows are less than 0.2 MGD.

1. During the period beginning with the permit's effective date and lasting until the permit's expiration date, the permittee is authorized to discharge from outfall number 001 to receiving waters where the 7Q10 flows are less than 0.2 MGD.

The discharge shall be limited and monitored by the permittee as specified below:

EFFLUENT CHARACTERISTICS	DISCHARGE LIMITATIONS		MONITORING REQUIREMENTS	
	Instantaneous Minimum	Instantaneous Maximum	Frequency	Sample Type
Flow (MGD) ⁽¹⁾	NA	NL	1/year	Estimate
BOD ₅	NA	30 mg/l	1/year	Grab
Total Suspended Solids	NA	30 mg/l	1/year	Grab
Total Residual Chlorine ⁽²⁾				
After contact tank	1.0 mg/l	NA	1/year	Grab
Final effluent	NA	0.016 mg/l ⁽⁶⁾	1/year	Grab
E. coli ⁽³⁾	NA	235/100 <u>235</u> CFU/100 ml	1/year	Grab
enterococci ⁽⁴⁾	NA	104/100 <u>104</u> CFU/100 ml	1/year	Grab
Fecal Coliform Bacteria ⁽⁵⁾	NA	200/100 <u>200</u> CFU/100 ml	1/year	Grab
pH (standard units)	6.0	9.0	1/year	Grab
Dissolved Oxygen	5.0 mg/l ⁽⁶⁾	NA	1/year	Grab

NL = No Limitation, monitoring required

NA = Not Applicable

⁽¹⁾The design flow of this treatment ~~facility~~ works is less than or equal to 1,000 gallons per day.

⁽²⁾Applies only when chlorine is used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations).

⁽³⁾Applies only when methods other than chlorine are used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the ~~facility~~ treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁴⁾Applies only when the discharge is into saltwater or the transition zone (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the ~~facility~~ treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁵⁾Applies only when the discharge is into shellfish waters (see 9VAC25-260-160 for the description of what are shellfish waters). When the ~~facility~~ treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

Regulations

⁽⁶⁾Does not apply when the receiving stream is an ephemeral stream. "Ephemeral streams" are drainage ways, ditches, hollows, or swales that contain only (i) flowing water during or immediately following periods of rainfall or (ii) water supplied by the discharger. These waterways would normally have no active aquatic community.

2. All monitoring data required by Part I A 1 shall be maintained on site in accordance with Part II B. ~~Reporting of results to DEQ is not required; however, the monitoring~~ Monitoring results for treatment works serving buildings or dwellings other than individual single family dwellings shall be ~~made available to DEQ personnel upon request~~ submitted to the department on a Discharge Monitoring Report (DMR) no later than the 10th of [~~January~~ September] following the monitoring period. The monitoring period is [~~January~~ September] 1 through [~~December~~ August] 31. A copy of the maintenance log required by Part I D 2 b (4) shall also be submitted with the DMR. Monitoring results for treatment works serving individual single family dwellings shall be ~~are~~ submitted to the Virginia Department of Health in accordance with 12VAC5-640.

3. The 30-day average percent removal for BOD₅ and total suspended solids shall not be less than 85%.

B. Effluent limitations and monitoring requirements - receiving waters where the 7Q10 flows are equal to or greater than 0.2 MGD.

1. During the period beginning with the permit's effective date and lasting until the permit's expiration date, the permittee is authorized to discharge from outfall number 001 to receiving waters where the 7Q10 flows are equal to or greater than 0.2 MGD.

The discharge shall be limited and monitored by the permittee as specified below:

EFFLUENT CHARACTERISTICS	DISCHARGE LIMITATIONS		MONITORING REQUIREMENTS	
	Instantaneous Minimum	Instantaneous Maximum	Frequency	Sample Type
Flow (MGD) ⁽¹⁾	NA	NL	1/year	Estimate
BOD ₅	NA	30 mg/l	1/year	Grab
Total Suspended Solids	NA	30 mg/l	1/year	Grab
Total Residual Chlorine ⁽²⁾				
<u>After contact tank</u>	<u>1.0 mg/l</u>	<u>NA</u>	<u>1/year</u>	<u>Grab</u>
Final effluent	1.0 mg/l <u>NA</u>	2.0 mg/l	1/year	Grab
E. coli ⁽³⁾	NA	235/400 <u>235</u> CFU/100 ml	1/year	Grab
enterococci ⁽⁴⁾	NA	104/400 <u>104</u> CFU/100 ml	1/year	Grab
Fecal Coliform Bacteria ⁽⁵⁾	NA	200/400 <u>200</u> CFU/100 ml	1/year	Grab
pH (standard units)	6.0	9.0	1/year	Grab

NL = No Limitation, monitoring required

NA = Not Applicable

⁽¹⁾The design flow of this treatment ~~facility~~ treatment works is less than or equal to 1,000 gallons per day.

⁽²⁾Applies only when chlorine is used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations).

⁽³⁾Applies only when methods other than chlorine are used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the ~~facility~~ treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁴⁾Applies only when the discharge is into saltwater or the transition zone (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the ~~facility~~ treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁵⁾Applies only when the discharge is into shellfish waters (see 9VAC25-260-160 for the description of what are shellfish waters). When the facility treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

2. All monitoring data required by Part I B 1 shall be maintained on site in accordance with Part II B. ~~Reporting of results to DEQ is not required; however, the monitoring~~ Monitoring results for treatment works serving buildings or dwellings other than individual single family dwellings shall be made available to DEQ personnel upon request submitted to the department on a Discharge Monitoring Report (DMR) no later than the 10th of [~~January~~ September] following the monitoring period. The monitoring period is [~~January~~ September] 1 through [~~December~~ August] 31. A copy of the maintenance log required by Part I D 2 b (4) shall also be submitted with the DMR. Monitoring results for treatment works serving individual single family dwellings shall be are submitted to the Virginia Department of Health in accordance with 12VAC5-640.

3. The 30-day average percent removal for BOD₅ and total suspended solids shall not be less than 85%.

C. Effluent limitations and monitoring requirements - discharges to receiving waters subject to the Policy for the Potomac River Embayments (9VAC25-415).

1. During the period beginning with the permit's effective date and lasting until the permit's expiration date, the permittee is authorized to discharge from outfall number 001 to receiving waters subject to the Policy for the Potomac River Embayments (9VAC25-415).

The discharge shall be limited and monitored by the permittee as specified below:

<u>EFFLUENT CHARACTERISTICS</u>	<u>DISCHARGE LIMITATIONS</u>		<u>MONITORING REQUIREMENTS</u>	
	<u>Instantaneous Minimum</u>	<u>Instantaneous Maximum</u>	<u>Frequency</u>	<u>Sample Type</u>
<u>Flow (MGD)⁽¹⁾</u>	<u>NA</u>	<u>NL</u>	<u>1/3 months</u>	<u>Estimate</u>
<u>pH (standard units)</u>	<u>6.0</u>	<u>9.0</u>	<u>1/3 months</u>	<u>Grab</u>
<u>cBOD₅</u>	<u>NA</u>	<u>5 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Total Suspended Solids</u>	<u>NA</u>	<u>6.0 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Ammonia as N (Apr 1 – Oct 31)</u>	<u>NA</u>	<u>1.0 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Ammonia as N (Nov 1 – Mar 31)</u>	<u>NA</u>	<u>3.1 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Dissolved Oxygen</u>	<u>6.0 mg/l</u>	<u>NA</u>	<u>1/3 months</u>	<u>Grab</u>
<u>E. coli⁽³⁾</u>	<u>NA</u>	<u>235 CFU/100 ml</u>	<u>1/3 months</u>	<u>Grab</u>
<u>enterococci⁽⁴⁾</u>	<u>NA</u>	<u>104 CFU/100 ml</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Total Phosphorus</u>	<u>NA</u>	<u>0.18 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Total Residual Chlorine⁽²⁾</u>				
<u>After contact tank</u>	<u>1.0 mg/l</u>	<u>NA</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Final effluent</u>	<u>NA</u>	<u>0.016 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>

NL = No Limitation, monitoring required

NA = Not Applicable

⁽¹⁾The design flow of this treatment works is less than or equal to 1,000 gallons per day.

⁽²⁾Applies only when chlorine is used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations).

Regulations

⁽³⁾ Applies only when methods other than chlorine are used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁴⁾ Applies only when the discharge is into saltwater or the transition zone (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

2. All monitoring data required by Part I C 1 shall be maintained on site in accordance with Part II B. Monitoring results shall be submitted to the department on a Discharge Monitoring Report (DMR) no later than the 10th day of the month following the monitoring period. The quarterly monitoring periods shall be January through March, April through June, July through September, and October through December. A copy of the maintenance log required by Part I D 2 b (4) shall also be submitted with the DMR. Monitoring results for treatment works serving individual single family dwellings shall also be submitted to the Virginia Department of Health in accordance with 12VAC5-640.

3. The 30-day average percent removal for BOD₅ and total suspended solids shall not be less than 85%.

D. Special conditions.

1. There shall be no discharge of floating solids or visible foam in other than trace amounts.

2. Maintenance contract Operation and maintenance.

a. Treatment works serving individual single family dwellings. The Operation and maintenance requirements for treatment works serving individual single family dwellings are specified in the Virginia Department of Health regulations at 12VAC5-640-500 require maintenance contracts for treatment works serving individual single family dwellings.

~~(1) For existing treatment works, the permittee shall keep a maintenance contract in force during the permit term, unless the permittee has been granted a variance from the maintenance contract requirement by the Virginia Department of Health. A copy of the maintenance contract, if applicable, shall be kept at the site of the treatment works and shall be made available to DEQ or to the Virginia Department of Health for examination upon request. The permittee is also responsible for ensuring that the local health department has a current copy of a valid maintenance agreement in accordance with 12VAC5-640-500 B.~~

~~(2) For proposed treatment works, the permittee shall submit a copy of a valid maintenance contract to both DEQ and the Virginia Department of Health prior to operation of the treatment works unless the permittee has been granted a variance from the maintenance contract requirement by the Virginia Department of Health. The maintenance contract shall be kept in force during the permit term. A copy of the maintenance contract, if applicable, shall be kept at the site of treatment works,~~

~~and made available to DEQ or the Virginia Department of Health for examination upon request. The permittee is also responsible for ensuring that the local health department has a current copy of a valid maintenance agreement in accordance with 12VAC5-640-500 B.~~

~~(3) At a minimum, the maintenance contract shall provide for the following:~~

~~(a) Performance of all testing required in either Part I A or Part I B of this permit, as appropriate, and in the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings, 12VAC5-640-490 B, unless the owner maintains a separate monitoring contract in accordance with 12VAC5-640-490 F. Note: The treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The owner or maintenance provider should not force a discharge in order to collect a sample;~~

~~(b) A written notification to the owner within 24 hours whenever the contract provider becomes aware that maintenance or repair of the owner's treatment works is necessary. The owner is responsible for prompt maintenance and repair of the treatment works including all costs associated with the maintenance or repair. Immediately upon receipt of notice that repair or maintenance is required, the owner shall begin emergency pump and haul of all sewage generated in the dwelling if full and complete repairs cannot be accomplished within 48 hours; and~~

~~(c) The maintenance contract shall be valid for a minimum of 24 months of consecutive coverage.~~

b. Treatment works serving nonsingle buildings or dwellings other than individual single family dwellings.

(1) For existing treatment works, the permittee shall keep a maintenance contract in force during the permit term, unless an exception to the maintenance contract requirement has been requested and granted in accordance with Part I C D 3. A copy of the maintenance contract, if applicable, shall be kept at the site of the treatment works and made available to DEQ for examination upon request.

(2) For proposed treatment works, the permittee shall submit a copy of certification that the permittee has a valid maintenance contract to DEQ prior to operation of the treatment works, unless an exception to the maintenance contract requirement has been requested and granted in accordance with Part I C D 3. The A

maintenance contract shall be kept in force during the permit term. A copy of the maintenance contract shall be kept at the site of the treatment works, and shall be made available to DEQ for examination upon request.

(3) At a minimum, the maintenance contract shall provide for the following:

(a) Performance of all testing required in accordance with either Part I A, Part I B, or Part I ~~B~~ C, as appropriate, and periodic (at least annual) inspections of the treatment works. Note: ~~The Discharges from the~~ treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that ~~facility~~) treatment works). The owner or maintenance provider should not force a discharge in order to collect a sample;

(b) A written notification to the owner within 24 hours whenever the contract provider becomes aware that maintenance or repair of the owner's treatment works is necessary. The owner is responsible for prompt maintenance and repair of the treatment works including all costs associated with the maintenance or repair. Immediately upon receipt of notice that repair or maintenance is required, the owner shall begin emergency pump and haul of all sewage generated from the ~~facility~~ building or dwelling or otherwise ensure that no discharge occurs if full and complete repairs cannot be accomplished within 48 hours;

(c) A log of the following items shall be maintained at the treatment works by the contract provider:

(i) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts; and document and explain why no sample was taken or possible;

(ii) Alarm activation incidents;

(iii) Maintenance, corrective, or repair activities performed;

(iv) Recommended repair or replacement items; and

(v) Copies of all reports prepared by the contract provider; and

(d) An inspection shall be conducted by the contract provider within 48 hours after notification by the owner that a problem may be occurring; ~~and~~.

~~(e) The maintenance contract shall be valid for a minimum of 24 months of consecutive coverage.~~

(4) The permittee shall keep a log of all maintenance performed on the treatment works including, but not limited to, the following:

(a) The date and amount of disinfection chemicals added to the chlorinator.

(b) If dechlorination is used, the date and amount of any dechlorination chemicals that are added.

(c) The date and time of equipment failure and the date and time the equipment was restored to service.

(d) The date and approximate volume of sludge removed.

(e) Dated receipts for chemicals purchased, equipment purchased, and maintenance performed.

3. Operation and maintenance plan. The owner of any treatment works serving a ~~non~~single building or dwelling other than an individual single family dwelling may request an exception to the maintenance contract requirement by submitting an operation and maintenance plan to the board for review and approval. At a minimum, the operation and maintenance plan shall contain the following information:

a. An up-to-date operation and maintenance manual for the treatment works;

b. A log of all maintenance performed on the treatment works including, but not limited to, the following:

(1) The date and amount of disinfection chemicals added to the chlorinator (if applicable).

(2) If dechlorination is used, the date and amount of any dechlorination chemicals that are added.

(3) The date and time of equipment ~~failure(s)~~ failure and the date and time the equipment was restored to service.

(4) The date and approximate volume of sludge removed.

(5) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts; and document and explain why no sample was taken or possible;

c. Dated receipts for chemicals purchased, equipment purchased, and maintenance performed; and

d. An effluent monitoring plan to conform with the requirements of Part I A, Part I B, or Part I ~~B~~ C, as appropriate, including all sample collection, preservation, and analysis procedures. Note: ~~The Discharges from the~~ treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that ~~facility~~) treatment works). The owner or maintenance provider should not force a discharge in order to collect a sample.

Should the permittee fail to implement the approved operation and maintenance plan, or if there are violations of effluent limitations, the board reserves the right to require the permittee to obtain a maintenance contract.

4. Compliance recordkeeping under Part I A, Part I B, and Part I ~~B~~ C.

a. The quantification levels (QL) shall be less than or equal to the following concentrations:

Effluent Parameter	Quantification Level
BOD ₅	2.0 mg/l
<u>cBOD₅</u>	<u>2 mg/l</u>

Regulations

<u>Ammonia as N</u>	<u>0.20 mg/l</u>
<u>Total Phosphorus</u>	<u>0.10 mg/l</u>
TSS	1.0 mg/l
Chlorine	0.10 mg/l

The QL is defined as the lowest concentration used to calibrate a measurement system in accordance with the procedures published for the test method.

b. Recording results. Any concentration data below the QL used in the analysis shall be recorded as "<QL" if it is less than the QL in subdivision 4 a of this subsection. Otherwise the numerical value shall be recorded.

c. Monitoring results shall be recorded using the same number of significant digits as listed in the permit. Regardless of the rounding convention used by the permittee (e.g., 5 always rounding up or to the nearest even number), the permittee shall use the convention consistently, and shall ensure that consulting laboratories employed by the permittee use the same convention.

5. The discharges authorized by this permit shall be controlled as necessary to meet water quality standards.

Part II

Conditions Applicable to ~~a#~~ All VPDES Permits

A. Monitoring.

1. Samples and measurements taken as required by this permit shall be representative of the monitored activity.

2. Monitoring shall be conducted according to procedures approved under 40 CFR Part 136 or alternative methods approved by the U.S. Environmental Protection Agency, unless other procedures have been specified in this permit.

3. The permittee shall periodically calibrate and perform maintenance procedures on all monitoring and analytical instrumentation at intervals that will ensure accuracy of measurements.

4. Samples taken as required by this permit shall be analyzed in accordance with 1VAC30-45 (Certification for Noncommercial Environmental Laboratories) or 1VAC30-46 (Accreditation for Commercial Environmental Laboratories).

B. Records.

1. Records of monitoring information shall include:

- The date, exact place, and time of sampling or measurements;
- The individual(s) who performed the sampling or measurements;
- The date(s) and time(s) analyses were performed;
- The individual(s) who performed the analyses;
- The analytical techniques or methods used; and
- The results of such analyses.

2. Except for records of monitoring information required by this permit related to the permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years, the permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the registration statement for this permit, for a period of at least three years from the date of the sample, measurement, report or request for coverage. This period of retention shall be extended automatically during the course of any unresolved litigation regarding the regulated activity or regarding control standards applicable to the permittee, or as requested by the board.

C. Reporting monitoring results. Monitoring results under this permit are not required to be submitted to the department. However, should the board request that the permittee submit monitoring results, the following subsections would apply.

1. The permittee shall submit the results of the monitoring required by this permit not later than the 10th day of the month after monitoring takes place, unless another reporting schedule is specified elsewhere in this permit. Monitoring results shall be submitted to the department's regional office.

2. Monitoring results shall be reported on a Discharge Monitoring Report (DMR) or on forms provided, approved or specified by the department.

3. If the permittee monitors any pollutant specifically addressed by this permit more frequently than required by this permit using test procedures approved under 40 CFR Part 136 or using other test procedures approved by the U.S. Environmental Protection Agency or using procedures specified in this permit, the results of this monitoring shall be included in the calculation and reporting of the data submitted on the DMR or reporting form specified by the department.

4. Calculations for all limitations that require averaging of measurements shall utilize an arithmetic mean unless otherwise specified in this permit.

D. Duty to provide information. The permittee shall furnish to the department, within a reasonable time, any information that the board may request to determine whether cause exists for modifying, revoking and reissuing, or terminating coverage under this permit or to determine compliance with this permit. The board may require the permittee to furnish, upon request, such plans, specifications, and other pertinent information as may be necessary to determine the effect of the wastes from ~~his~~ the discharge on the quality of state waters, or such other information as may be necessary to accomplish the purposes of the State Water Control Law. The permittee shall also furnish to the department, upon request, copies of records required to be kept by this permit.

E. Compliance schedule reports. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.

F. Unauthorized discharges. Except in compliance with this permit, or another permit issued by the board, it shall be unlawful for any person to:

1. Discharge into state waters sewage, industrial wastes, other wastes, or any noxious or deleterious substances; or
2. Otherwise alter the physical, chemical or biological properties of such state waters and make them detrimental to the public health, to animal or aquatic life, to the use of such waters for domestic or industrial consumption, for recreation, or for other uses.

G. Reports of unauthorized discharges. Any permittee who discharges or causes or allows a discharge of sewage, industrial waste, other wastes or any noxious or deleterious substance into or upon state waters in violation of Part II F, or who discharges or causes or allows a discharge that may reasonably be expected to enter state waters in violation of Part II F, shall notify the department of the discharge immediately upon discovery of the discharge, but in no case later than 24 hours after said discovery. A written report of the unauthorized discharge shall be submitted to the department within five days of discovery of the discharge. The written report shall contain:

1. A description of the nature and location of the discharge;
2. The cause of the discharge;
3. The date on which the discharge occurred;
4. The length of time that the discharge continued;
5. The volume of the discharge;
6. If the discharge is continuing, how long it is expected to continue;
7. If the discharge is continuing, what the expected total volume of the discharge will be; and
8. Any steps planned or taken to reduce, eliminate and prevent a recurrence of the present discharge or any future discharges not authorized by this permit.

Discharges reportable to the department under the immediate reporting requirements of other regulations are exempted from this requirement.

H. Reports of unusual or extraordinary discharges. If any unusual or extraordinary discharge including a bypass or upset should occur from a treatment works and the discharge enters or could be expected to enter state waters, the permittee shall promptly notify, in no case later than 24 hours, the department by telephone after the discovery of the discharge. This notification shall provide all available details of the incident, including any adverse ~~affects~~ effects on aquatic life and the known number of fish killed. The permittee shall reduce the report to writing and shall submit it to the

department within five days of discovery of the discharge in accordance with Part II I 2. Unusual and extraordinary discharges include, but are not limited to, any discharge resulting from:

1. Unusual spillage of materials resulting directly or indirectly from processing operations;
2. Breakdown of processing or accessory equipment;
3. Failure or taking out of service some or all of the treatment works; and
4. Flooding or other acts of nature.

I. Reports of noncompliance. The permittee shall report any noncompliance that may adversely affect state waters or may endanger public health.

1. An oral report shall be provided within 24 hours from the time the permittee becomes aware of the circumstances. The following shall be included as information that shall be reported within 24 hours under this paragraph:

- a. Any unanticipated bypass; and
- b. Any upset that causes a discharge to surface waters.

2. A written report shall be submitted within five days and shall contain:

- a. A description of the noncompliance and its cause;
- b. The period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and
- c. Steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance.

The board may waive the written report on a case-by-case basis for reports of noncompliance under Part II I if the oral report has been received within 24 hours and no adverse impact on state waters has been reported.

3. The permittee shall report all instances of noncompliance not reported under Part II I 1 or 2, in writing, at the time the next monitoring reports are submitted. The reports shall contain the information listed in Part II I 2.

NOTE: The immediate (within 24 hours) reports required in Parts II G, H, and I may be made to the department's regional office. Reports may be made by telephone ~~or by fax, FAX, or~~ online at <http://www.deq.virginia.gov/Programs/PollutionResponsePreparedness/MakingaReport.aspx>. For reports outside normal working hours, ~~leave a message~~ may be left and this shall fulfill the immediate reporting requirement. For emergencies, the Virginia Department of Emergency Management maintains a 24-hour telephone service at 1-800-468-8892.

J. Notice of planned changes.

1. The permittee shall give notice to the department as soon as possible of any planned physical alterations or

Regulations

additions to the permitted facility. Notice is required only when:

a. The permittee plans alteration or addition to any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced:

(1) After promulgation of standards of performance under ~~Section §~~ 306 of the Clean Water Act (33 USC § 1251 et seq.) that are applicable to such source; or

(2) After proposal of standards of performance in accordance with ~~Section §~~ [306] of the Clean Water Act that are applicable to such source, but only if the standards are promulgated in accordance with ~~Section §~~ 306 within 120 days of their proposal;

b. The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants that are subject neither to effluent limitations nor to notification requirements specified elsewhere in this permit; or

c. The alteration or addition results in a significant change in the permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or of disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan.

2. The permittee shall give advance notice to the department of any planned changes in the permitted facility or activity that may result in noncompliance with permit requirements.

K. Signatory requirements.

1. Registration statement. All registration statements shall be signed as follows:

a. For a corporation: by a responsible corporate officer. For the purpose of this section, a responsible corporate officer means: (i) a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy-making or decision-making functions for the corporation, or (ii) the manager of one or more manufacturing, production, or operating facilities, provided the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiating and directing other comprehensive measures to assure long term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or other actions taken to gather complete and accurate information for permit ~~application~~ registration requirements; and where authority to sign documents has

been assigned or delegated to the manager in accordance with corporate procedures;

b. For a partnership or sole proprietorship: by a general partner or the proprietor, respectively; or

c. For a municipality, state, federal, or other public agency: by either a principal executive officer or ranking elected official. For purposes of this section, a principal executive officer of a public agency includes: (i) the chief executive officer of the agency or (ii) a senior executive officer having responsibility for the overall operations of a principal geographic unit of the agency.

2. Reports, etc. All reports required by permits [7] and other information requested by the board shall be signed by a person described in Part II K 1 or by a duly authorized representative of that person. A person is a duly authorized representative only if:

a. The authorization is made in writing by a person described in Part II K 1;

b. The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity such as the position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company. A duly authorized representative may thus be either a named individual or any individual occupying a named position; and

c. The written authorization is submitted to the department.

3. Changes to authorization. If an authorization under Part II K 2 is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of Part II K 2 shall be submitted to the department prior to or together with any reports, or information to be signed by an authorized representative.

4. Certification. Any person signing a document under Part II K 1 or 2 shall make the following certification:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

L. Duty to comply. The permittee shall comply with all conditions of this permit. Any permit noncompliance

constitutes a violation of the State Water Control Law and the Clean Water Act, except that noncompliance with certain provisions of this permit may constitute a violation of the State Water Control Law but not the Clean Water Act. Permit noncompliance is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or denial of a permit coverage renewal application.

The permittee shall comply with effluent standards or prohibitions established under ~~Section~~ § 307(a) of the Clean Water Act for toxic pollutants and with standards for sewage sludge use or disposal established under ~~Section~~ § 405(d) of the Clean Water Act within the time provided in the regulations that establish these standards or prohibitions or standards for sewage sludge use or disposal, even if this permit has not yet been modified to incorporate the requirement.

M. Duty to reapply.

1. If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, and the permittee does not qualify for automatic permit coverage renewal, the permittee shall submit a new registration statement, or for an individual single family dwelling a combined application, at least 60 days before the expiration date of the existing permit, unless permission for a later date has been granted by the board. The board shall not grant permission for registration statements or combined applications to be submitted later than the expiration date of the existing permit.

2. A permittee qualifies for automatic permit coverage renewal and is not required to submit a registration statement, or for an individual single family dwelling a combined application, if:

a. The ownership of the treatment works has not changed since this general permit went into effect on August 2, ~~2011~~ 2016, or, if the ownership has changed, (i) a new registration statement or for an individual single family dwelling a combined application or (ii) a VPDES Change of Ownership form was submitted to the department by the new owner at the time of the title transfer;

b. There has been no change in the design or operation, or both, of the treatment works since this general permit went into effect on August 2, ~~2011~~ 2016;

c. For treatment works serving individual single family dwellings, the Virginia Department of Health does not object to the automatic permit coverage renewal for this treatment works based on system performance issues, enforcement issues, or other issues sufficient to the board. If the Virginia Department of Health objects to the automatic renewal for this treatment works, the permittee will be notified by the board in writing; and

d. For treatment works serving ~~nonsingle~~ buildings or dwellings other than single family dwellings, the board has no objection to the automatic permit coverage

renewal for this treatment works based on system performance issues, ~~or~~ enforcement issues, or other issues sufficient to the board. If the board objects to the automatic renewal for this treatment works, the permittee will be notified by the board in writing.

3. Any permittee that does not qualify for automatic permit coverage renewal shall submit a new registration statement, or for an individual single family dwelling a combined application, in accordance with Part II M 1.

N. Effect of a permit. This permit does not convey any property rights in either real or personal property or any exclusive privileges, nor does it authorize any injury to private property or invasion of personal rights, or any infringement of federal, state or local law or regulations.

O. State law. Nothing in this permit shall be construed to preclude the institution of any legal action under, or relieve the permittee from any responsibilities, liabilities, or penalties established pursuant to, any other state law or regulation or under authority preserved by ~~Section~~ § 510 of the Clean Water Act. Except as provided in permit conditions on "bypassing" (Part II U); and "upset" (Part II V) nothing in this permit shall be construed to relieve the permittee from civil and criminal penalties for noncompliance.

P. Oil and hazardous substance liability. Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties to which the permittee is or may be subject under §§ 62.1-44.34:14 through 62.1-44.34:23 of the State Water Control Law.

Q. Proper operation and maintenance. The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also include effective plant performance, adequate funding, adequate staffing, and adequate laboratory and process controls, including appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems that are installed by the permittee only when the operation is necessary to achieve compliance with the conditions of this permit.

R. Disposal of solids or sludges. Solids, sludges or other pollutants removed in the course of treatment or management of pollutants shall be disposed of in a manner so as to prevent any pollutant from such materials from entering state waters.

S. Duty to mitigate. The permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit that has a reasonable likelihood of adversely affecting human health or the environment.

T. Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it

Regulations

would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

U. Bypass.

1. "Bypass" means the intentional diversion of waste streams from any portion of a treatment facility. The permittee may allow any bypass to occur that does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to ensure efficient operation. These bypasses are not subject to the provisions of Parts II U 2 and 3.

2. Notice.

a. Anticipated bypass. If the permittee knows in advance of the need for a bypass, prior notice shall be submitted, if possible, at least 10 days before the date of the bypass.

b. Unanticipated bypass. The permittee shall submit notice of an unanticipated bypass as required in Part II I.

3. Prohibition of bypass.

a. Bypass is prohibited, and the board may take enforcement action against a permittee for bypass, unless:

(1) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(2) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass that occurred during normal periods of equipment downtime or preventive maintenance; and

(3) The permittee submitted notices as required under Part II U 2.

b. The board may approve an anticipated bypass after considering its adverse effects if the board determines that it will meet the three conditions listed ~~above~~ in Part II U 3 a.

V. Upset.

1. An upset, defined in 9VAC25-31-10, constitutes an affirmative defense to an action brought for noncompliance with technology-based permit effluent limitations if the requirements of Part II V 2 are met. A determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is not a final administrative action subject to judicial review.

2. A permittee who wishes to establish the affirmative defense of upset shall demonstrate through properly signed, contemporaneous operating logs, or other relevant evidence that:

a. An upset occurred and that the permittee can identify the cause(s) of the upset;

b. The permitted facility was at the time being properly operated;

c. The permittee submitted notice of the upset as required in Part II I; and

d. The permittee complied with any remedial measures required under Part II S.

3. In any enforcement proceeding the permittee seeking to establish the occurrence of an upset has the burden of proof.

W. Inspection and entry. The permittee shall allow the director, or an authorized representative, upon presentation of credentials and other documents as may be required by law, to:

1. Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

3. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

4. Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act and the State Water Control Law, any substances or parameters at any location.

For purposes of this section, the time for inspection shall be deemed reasonable during regular business hours, and whenever the facility is discharging. Nothing contained herein shall make an inspection unreasonable during an emergency.

X. Permit actions. Permits may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, termination, or notification of planned changes or anticipated noncompliance does not stay any permit condition.

Y. Transfer of permits. ~~4-~~ Permits are not transferable to any person except after notice to the department. ~~Except as provided in Part II Y 2, a permit may be transferred by the permittee to a new owner or operator only if the permit has been modified or revoked and reissued, or a minor modification made, to identify the new permittee and incorporate such other requirements as may be necessary under the State Water Control Law and the Clean Water Act.~~ 2- As an alternative to transfers under Part II Y 1, Coverage under this permit may be automatically transferred to a new permittee if:

a- 1- The current permittee notifies the department within 30 days of the transfer of the title to the facility or

property, unless permission for a later date has been granted by the board;

~~b. 2.~~ The notice includes a written agreement between the existing and new permittees containing a specific date for transfer of permit responsibility, coverage, and liability between them; and

~~e. 3.~~ The board does not notify the existing permittee and the proposed new permittee of its intent to ~~modify or revoke and reissue~~ deny the new permittee coverage under the permit. If this notice is not received, the transfer is effective on the date specified in the agreement mentioned in Part II Y 2 ~~b.~~

Z. Severability. The provisions of this permit are severable, and if any provision of this permit or the application of any provision of this permit to any circumstance is held invalid, the application of such provision to other circumstances, and the remainder of this permit, shall not be affected thereby.

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 (9VAC25-110)

[VPDES Change of Ownership Agreement Form \(eff. 7/10\)- Combined Application - Virginia Department of Health Discharging System Application for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons per Day and State Water Control Board Virginia Pollutant Discharge Elimination System General Permit Registration Statement for Domestic Sewage Discharges Less Than or Equal to 1,000 Gallons per Day \(eff. 9/2011\)](#)

VA.R. Doc. No. R15-4177; Filed January 28, 2016, 8:21 a.m.



TITLE 12. HEALTH

STATE BOARD OF HEALTH

Proposed 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, 12VAC5-421-250, through 12VAC5-421-410, 12VAC5-421-430 through 12VAC5-421-520, 12VAC5-421-540, 12VAC5-421-550, 12VAC5-421-570, 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, 12VAC5-421-3630, 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, 12VAC5-421-1435, 12VAC5-421-1535, 12VAC5-421-1880, 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.

Public Hearing Information:

March 29, 2016 - 9 a.m. - Department of Health, James Madison Building, Mezzanine Conference Room, 109 Governor Street, Richmond, VA 23219

Public Comment Deadline: April 23, 2016.

Regulations

Agency Contact: Julie Henderson, Director of Food and General Environmental Services, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7455, FAX (804) 864-7475, TTY (800) 828-1120, or email julie.henderson@vdh.virginia.gov.

Basis: Sections 35.1-11 and 35.1-14 of the Code of Virginia authorize and require the State Board of Health to promulgate and enforce regulations governing restaurants in accordance with the provisions of Title 35.1 of the Code of Virginia.

Section 35.1-14 C provides the legal basis for the promulgation and modification of 12VAC5-421. Specifically, subsections C and E of § 35.1-14 identify the authority and certain requirements for the expedited adoption of the federal Food and Drug Administration (FDA) Food Code. The authority to adopt the FDA Food Code is discretionary; the authority to regulate restaurants is not.

Purpose: The purpose of 12VAC5-421 is to prevent foodborne illness by ensuring that foods prepared and served by food establishments in Virginia are safe, unadulterated, and prepared under sanitary conditions, which is accomplished by providing minimum sanitary standards for food establishments to protect the dining public. These standards include approved sources for foods used in food establishments, specifications for safe handling, storage, preparation and serving of food, personal hygiene of employees, precautions to prevent the transmission of diseases communicable through food, and the general sanitation of the facility. When followed, these minimum standards will protect the public's health, safety, and welfare. Additionally, 12VAC5-421-30 states the following, "The chapter has been promulgated by the State Board of Health to specify the following requirements to protect public health."

The first goal of the regulation and the proposed modifications is to maintain a scientifically-sound basis for regulation of the food industry. The modifications proposed to the existing regulation are necessary to ensure appropriate measures are put in place that address emerging and ongoing food safety concerns that exist within an evolving food industry.

The second goal is to facilitate the shared responsibility of the food industry and the government in ensuring that food provided to the consumer is safe and does not become a vehicle for a disease outbreak or for the transmission of communicable disease. Foodborne disease in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. The U.S. Centers for Disease Control and Prevention estimate that foodborne diseases cause approximately 48 million people to become ill, 128,000 hospitalizations, and 3,000 deaths in the United States each year. Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness. Those risk factors include (i) improper holding temperatures; (ii) inadequate

cooking, such as undercooking raw eggs; (iii) contaminated equipment; (iv) food from unsafe sources; and (v) poor personal hygiene. This regulation and the proposed modifications address controls for these risk factors. The regulation also provides the necessary guidance to the food industry relative to controlling risk factors and implementing appropriate intervention strategies.

The third goal of the proposed regulation is to ensure a regulatory approach that is uniform throughout Virginia's food industry by administering standards that are equivalent to those administered by VDACS in the retail food industry. This regulatory uniformity also extends throughout the nation as most states have adopted versions of these regulations.

Substance: Substantive changes are as follows:

Part I

- Added "catering" definition and included exclusions from the term "caterer"
- Added "core item" definition
- Added "cut leafy greens" definition (used in TCS food definition)
- Amended "drinking water" to comply with Office of Drinking Water definitions
- Deleted "Enterohemorrhagic Escherichia coli (EHEC)" definition
- Included further explanation of "food establishment" and amended the bed and breakfast operations exemption to reflect 12VAC5-431 (Hotel Regulations) definition.
- Added "continental breakfast" definition
- Added "mechanically tenderized" definition as it relates to meat products
- Added "noncontinuous cooking" definition
- Deleted the term "potentially hazardous food (time/temperature control for safety food)" and made a universal change throughout the regulation to replace it with the term "time/temperature control for safety food" (TCS food)
- Added "potable water" definition
- Added "priority item" definition
- Added "priority foundation item" definition
- Added "private well" definition
- Amended "sewage" definition to reflect 12VAC5-610 definition
- Added "temporary food event" definition
- Added "waterworks" definition to comply with Office of Drinking Water standards

Part II

- Sections have been added that require at least one employee who supervises or has authority over food establishment operations to be a certified food protection manager (CFPM). Food establishments that pose minimal risk to contributing to

foodborne illness may be exempt from the requirement to have a CFPM. Specifically exempt from the CFPM requirement are food establishments that only serve non-TCS foods and whose extent of food handling does not exceed reheating, cold holding, and hot holding of commercially prepared ready-to-eat foods.

- The revisions specify that CFPM certification must be obtained through one of the following programs approved by the Conference for Food Protection: National Restaurant Association Solutions, National Registry of Food Safety Professionals, Prometric, or 360 Training.
- Employee training must now include food allergy awareness, in addition to food safety.
- Amended to add Salmonella (nontyphoidal) as one of the reportable illnesses for action by the person in charge. Added language to address employee health controls for the exclusion and restriction of Salmonella (nontyphoidal), as well as the removal of exclusion and restriction from Salmonella (nontyphoidal) once clearance has been received.
- Language has been added that requires food establishments be able to verify that all food employees have been informed of their responsibility to report certain information about their health status as it relates to diseases that are transmitted by food. The person in charge must be able to provide the regulatory authority access to the documentation.
- Language has been added to include the washing of prosthetic hand devices for the cleaning procedures of hands and arms
- A new section was added that requires a food establishment to have procedures in place for employees to follow when responding to vomitus or fecal matter discharge on surfaces in the establishment.

Part III

- Removed existing language that requires a mushroom identification expert to identify all wild mushrooms sold in retail establishments. New language was added that recognized a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment.
- Updated 12VAC5-421-330 addressing game animals to require either voluntary inspection by the state regulatory agency that has animal health jurisdiction or voluntary inspection by USDA.
- Removed existing language that allows for exceptions to shellfish tags and identification in food establishments.
- Amended regulation to allow bare hand contact with ready-to-eat food if the ingredient is added to a food that will be cooked to temperatures that comply with 12VAC5-421-700 A and B or 12VAC5-421-710 or is cooked to a minimum temperature of 145°F.
- Added "mechanically tenderized" meats to the list of foods that should be cooked to heat all parts of the food to 155°F (68°C) for 15 seconds.

- Amended 12VAC5-421-700 to add a new subdivision D 2 to not allow the sale of undercooked, comminuted meat from a children's menu.

- Added new section, 12VAC5-421-725, entitled "Noncontinuous cooking of raw animal foods." This section allows food establishments to partially cook raw animal foods with prior approval from the regulatory authority. Written procedures must be maintained at the food establishment.

Part IV

- Amended 12VAC5-421-1520 to add new subsection B that requires food establishments with a mechanical warewasher that sanitizes with hot water to provide an irreversible registering temperature indicator.
- Added language to include specifications on the use of chemical sanitizer devices generated on site.

Part V

- Amended the reporting procedures for private wells.
- Amended to allow for dogs in outdoor dining areas of retail food establishments if certain conditions are met:

The outdoor dining area is not fully enclosed with floor to ceiling walls and is not considered a part of the interior physical facility.

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.

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.

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.

Dogs are not allowed on chairs, seats, benches or tables.

Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.

Establishments provide effective means for cleaning up dog vomitus and fecal matter.

A sign, clearly observable to the public and within the outdoor dining area, states the requirements as specified in proposed subdivisions B 6 d, e, and f of 12VAC5-3310.

Part VII

- Amended language to add further clarification of chemicals allowed for use to wash or assist in the peeling process of fruits and vegetables if done so in accordance with 21 CFR 173 and within the manufacturer's instructions.
- Added requirement for applicants seeking to operate a temporary food establishment to submit an application for a permit at least 10 days before the date planned for opening the temporary food establishment.

Regulations

- Added language that will require the correction of a priority item within 72 hours and a priority foundation item or HACCP plan deviation within 10 days.

- Amended all terms referencing "hearing" as "informal fact-finding conference" in accordance with § 2.2-4019 of the Code of Virginia.

- Removed language pertaining to the appeals process to align procedure with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

The following items have been added to the regulation in relevant areas to designate the criticality of certain regulatory requirements:

- The term "critical item" has been changed to "priority item." "Priority item" means a provision whose application contributes directly to the elimination, prevention, or reduction to an acceptable level, hazards associated with foodborne illness or injury and for which 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, handwashing and is denoted using a superscript P: ^(P).

- "Priority foundation item" has been added. "Priority foundation item" means a provision 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).

- The term "core item" has been added. "Core item" means a provision 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. Any item that is not designated as a "priority" or "priority foundation" item is a "core item."

Issues: The primary advantage of the regulations to the public is that they establish modern science-based standards that support the prevention of foodborne illness risk factors and ensure the safety of food service within the Commonwealth. The revisions will also make the regulations more understandable. The primary advantage to the agency is that the regulations will be based on current food science. The primary advantage to the regulated community, particularly chains and franchises that operate in other states as well as in multiple jurisdictions across the Commonwealth that have adopted the current version of the FDA Food Code, will be better consistency in regulatory application. There will be no disadvantages to the public or the Commonwealth with the adoption of these regulations.

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.

The Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Health proposes to update the Food Regulations to be consistent with the Food and Drug Administration's (FDA's) most recent, 2013, Food Code.

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

Estimated Economic Impact. This regulation establishes minimum sanitary standards for restaurants or restaurant like food establishments such as convenience stores with 15 or more seats. The current regulation is based on the FDA's 2005 Food Code and the 2007 Food Code Supplement. The existing regulation is being amended to be consistent with the most recent, 2013, FDA Food Code.

The proposed changes include 1) the addition of cut leafy greens to the list of foods that retail food establishments need to refrigerate in order to ensure that the product is safe to consume; 2) food establishments must have employees who are fully informed regarding food allergens and their dangers; 3) retail food establishment employees must be aware of their responsibility to inform management of any health or illness issues that might affect the safety of food products; 4) the food establishment must have procedures in place for addressing vomitus or fecal matter discharge on surfaces in the food establishment; 5) wild mushrooms cannot be sold unless the establishment has been approved to do so by the regulatory authority; 6) bare hand contact with ready-to-eat food ingredients is allowed in certain instances; 7) game animals that are sold must be raised, slaughtered, and processed under a voluntary inspection program that is conducted by the United States Department of Agriculture or the state agency that has jurisdiction over animal health; 8) the food establishment must discontinue operations and notify the Virginia Department of Health (VDH) if an imminent health hazard exists at the establishment; 9) the food establishment must immediately contact the agency to report the illness of a food employee if the illness is of a nature that can be transmitted through food; and 10) the food establishments with some exceptions depending on risk must have at least one supervisor who is a Certified Food Protection Manager.¹

Many of the proposed changes simply refine and provide further clarity to existing regulation and are not expected to create a significant economic impact. The change that will have some economic impact is the requirement for certain food establishments to have at least one supervisor who is a certified food protection manager. The proposed language specifies that certification must be obtained through one of the programs approved by the Conference for Food

Protection. The certification classes are offered online as well as at physical locations and take a few days to complete. Once all the classes are taken, the candidate takes the certification exam in a physical location. VDH estimates the cost of the certification ranges from \$100 to \$200 per individual every five years. In addition, there would be time and travel costs involved to take the classes and the certification exam. It is also estimated that a large majority of the affected industry already meet this requirement. Thus, this proposed change will require additional time, expense and effort from some of the food establishments.

On the other hand, this change will help ensure that an individual is in place at the establishment who fully understands food safety risk factors, practices, and principles. As a result, a reduction in food borne illnesses and a greater degree of public confidence in the safety of the food supply may be expected. According to VDH, food borne disease in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. The U.S. Centers for Disease Control and Prevention estimates that food borne diseases cause approximately 48 million people to become ill, 128,000 hospitalizations, and 3,000 deaths in the United States each year.

Businesses and Entities Affected. The proposed amendments apply to approximately 36,000 restaurants or restaurant like food establishments. Approximately 12,000 establishments operate under local ordinances that already require a certified food manager. Of the remaining 24,000 establishments, a large majority are national or regional restaurant chains or franchises that already have a certified food manager on staff.

Localities Particularly Affected. The regulations apply throughout the Commonwealth.

Projected Impact on Employment. The proposed changes will require food establishment managers to take food safety classes and obtain certification from approved providers. Thus, an increase in the demand for services of food safety instructors may be expected. In addition, food establishments may have to schedule additional hours for other supervisors to fill in when the food safety supervisor is working toward the certification.

Effects on the Use and Value of Private Property. Food safety certification will impose costs on food establishments. Consequently, their asset values may be negatively affected by a very small amount.

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. Of the 36,000 affected food establishments, 95 percent are estimated to be small businesses. The majority of affected entities are believed to already have a certified food manager on staff. The costs and other effects discussed above apply to those that do not already have a food manager on staff.

Alternative Method that Minimizes Adverse Impact. There is no known alternative that minimizes the adverse impact on small businesses while accomplishing the same goals.

Adverse Impacts:

Businesses: Of the 36,000 affected food establishments, five percent are estimated to be non-small businesses. The majority of affected entities are believed to already have a certified food manager on staff. The costs and other effects discussed above apply to those that do not already have a food manager on staff.

Localities: No adverse impact on localities is expected.

Other Entities: No adverse impact on other entities is expected.

¹ These changes are also being proposed concurrently with the Virginia Department of Agriculture and Consumer Services (VDACS) adoption of the current 2013 FDA Food Code. Pursuant to § 3.2-5121(C) of the Code of Virginia, this action is exempt from portions of the Administrative Process Act, provided VDH and VDACS adopts the same version and both agencies' regulations have the same effective date.

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

Summary:

The Food Regulations (2VAC5-421) 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 to operate a food establishment from the Virginia Department of Health (VDH).

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.

Regulations

Many of the proposed changes simply refine and provide further clarity to existing regulations.

Proposed 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 the 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.

The amendments are proposed concurrently with the Virginia Department of Agriculture and Consumer Services proposed action to adopt certain changes based on the 2013 FDA Food Code and Supplement, which was published in [31:4 VA.R. 199-261 October 20, 2014](#).

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.

"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:

- To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or
- 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 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

Regulations

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 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 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 ~~(+)~~, 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~~

Regulations

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 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.

"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 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.

Regulations

"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 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-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 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-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;~~

~~e. 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 Pf^{Pf}.

"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;

Regulations

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: 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, 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:

Regulations

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 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}

Regulations

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 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.~~ 7. Employees are properly cooking ~~potentially hazardous food~~ TCS 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.~~ 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 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);^P or
 - f. Salmonella (nontyphoidal).^P

3. Had ~~a previous illness~~ 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) 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. ~~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) 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:

Regulations

1. Jaundiced;^{Pf} or
2. Diagnosed with an illness due to a pathogen as specified under subdivision 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 fever, or reports ~~a previous infection with Salmonella Typhi~~ having had 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 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

Regulations

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 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 nontyphoidal Salmonella 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. Reinstates 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. Reinstates 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~~ Shigella spp. or Enterohemorrhagic or 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) 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

Regulations

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 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 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;~~^{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) 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;^{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.

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 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:

Regulations

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 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 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~~

Regulations

~~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}~~

~~e. 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}~~

~~4. 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 12VAC5-421-700 or 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.

Regulations

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 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 sauce, mayonnaise, meringue, 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 B₁;^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 12VAC5-421-1890 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.

12VAC5-421-570. 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.

Regulations

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. A take-home food container returned to a food establishment shall not be refilled at a food establishment with a ~~potentially hazardous~~ time/temperature control for safety food.

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 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.

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, 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 4 <u>one</u> 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 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.

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}

Regulations

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 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 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;^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, 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}

12VAC5-421-760. 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.^E

C. Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact package from 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) for hot holding.^E

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.^E

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;^E 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, "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~~ 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 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 control 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),^E and
2. Within a total of six hours from 135°F (57°C) to 41°F (5°C) or less.^E

~~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.^E

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.^E

Regulations

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, ~~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 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 marked with a date or day that 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 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. 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. 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;^P

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}

Regulations

4. The food shall be:

a. Discarded if the temperature of the foods exceeds 70°F (21°C);^{Pf} 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;^{Pf} and

5. The food in unmarked containers or packages, or marked with a time that exceeds the six-hour limit shall be discarded.^{Pf}

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 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.^{Pf}

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~~ 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 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;^{Pf}

5. Includes operational procedures that:

a. Prohibit contacting food with bare hands,^{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.

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~~ 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 12VAC5-421-700; subsections A, B, and C of this section;^P
- c. Protected from contamination after cooking as specified in 12VAC5-421-450 through 12VAC5-421-690;^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 or the original manufacturer's "sell by" or "use by" date, whichever comes 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 food that is always:

Regulations

1. Labeled with the production time and date.
2. Held at 41 °F or less during refrigerated storage.
3. Removed from its package 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 131-168 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 in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food;
3. An accurate declaration of the 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 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.

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 of animal products 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 6, 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~~ 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. 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. 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

Regulations

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.

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.

Multiuse food-contact surfaces shall be:

1. Smooth;^{Pf}
2. Free of breaks, open seams, cracks, chips, 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 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}

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

Regulations

under Part III (12VAC5-421-260 et seq.) of this chapter;^{Pf} 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.^{Pf}

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;^{Pf} 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.^{Pf}

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 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 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 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

Regulations

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.^{Pf}

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 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	
	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 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 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.

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

Regulations

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 such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, 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

12VAC5-421-1890. 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.^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 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) 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

Regulations

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~~
 - ~~e. 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.^E

B. A water filter shall be made of safe materials.^E

12VAC5-421-2180. Approved system and cleanable fixtures.

A. A plumbing system shall be designed, constructed, and installed according to law.^E

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 \pm one inch (25 mm).^E

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 Statewide Uniform Building Code (13VAC5-63) for construction, installation, maintenance, inspection, and testing for that specific application and type of device.^E

12VAC5-421-2230. Handwashing sinks, numbers, and capacities.

A. Except as specified in subsection B 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, automatic handwashing facilities may be substituted for handwashing sinks in a food establishment with 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

Regulations

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.

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. 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. Dogs are not allowed on chairs, seats, benches, or tables.

f. Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.

g. 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
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.

Regulations

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
 - e. ~~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~~
 - f. ~~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~~
 - g. ~~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 e 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 shall meet the requirements specified in 40 CFR 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 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.~~

Regulations

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 ~~€~~ if the regulatory authority determines that plans and specifications are necessary to ensure compliance with ~~this regulation~~ this chapter.^{Pf}

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~~ 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; 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.

Regulations

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 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 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.²

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.^{3f}

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 ~~40 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~~ 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:

Regulations

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)

[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 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~~

[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, \[www.nsf.org\]\(http://www.nsf.org\)](#)

[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 February 2, 2016, 5:10 p.m.

Final Regulation

REGISTRAR'S NOTICE: The following regulatory action is exempt from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 c of the Code of Virginia, which excludes regulations that are necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation. The State Board of Health will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-10).**

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

Effective Date: March 23, 2016.

Agency Contact: Steve Harrison, Director, Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8151, FAX (804) 864-8155, or email steve.harrison@vdh.virginia.gov.

Summary:

This action amends 12VAC5-481-10, Definitions, to be compatible with 10 CFR Part 37. The U.S. Nuclear Regulatory Commission (NRC) promulgated 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, on March 19, 2013. Agreement states are required to implement compatible regulations within three years of this date or the program will be deemed noncompatible by the NRC, which may result in the revocation of Virginia's agreement state status. The definitions are associated with 12VAC5-481-451, which was amended to become effective on March 9, 2016 (see 32:12 VA.R. 1906-1924 February 8, 2016).

Part I General Provisions

12VAC5-481-10. Definitions.

As ~~The~~ following words and terms as used in ~~these~~ regulations, ~~these terms~~ this chapter shall have the definitions

Regulations

~~set forth below.~~ following meanings unless the context clearly indicates otherwise:

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

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

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

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

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

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

"Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

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

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

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

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

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

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

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

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

"Aggregated" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material as listed in 12VAC5-481-451.

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

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

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

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

"Air kerma" or "K" means kerma in air (see definition of "kerma").

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

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

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

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

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

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

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

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

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

"ANSI" means the American National Standards Institute.

"Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 12VAC5-481-451 and has completed the training required in 12VAC5-481-451.

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

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

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

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

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is

subsequently used to provide professional or commercial services.

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

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

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

"Authorized medical physicist" means an individual who:

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

"Authorized nuclear pharmacist" means a pharmacist who:

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

Regulations

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

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

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

"Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

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

"Barrier" (See "Protective barrier").

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

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

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

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

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

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

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

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

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in-vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Board" means the State Board of Health.

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

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

"Byproduct material" means:

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;
2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;
3. a. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or
b. Any material that:
 - (1) Has been made radioactive by use of a particle accelerator; and
 - (2) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

- a. The NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
- b. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"C-arm fluoroscope" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

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

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

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

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

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

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

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

"Category 1 quantities of radioactive material" or "Category 1" means a quantity of radioactive material meeting or exceeding the Category 1 threshold in Table 1 of 12VAC5-481-451. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Category 2 quantities of radioactive material" or "Category 2" means a quantity of radioactive material meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of 12VAC5-481-451. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

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

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

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

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

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

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

"CFR" means Code of Federal Regulations.

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

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

Regulations

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

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

"cm" means centimeters.

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

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

where:

s = Standard deviation of the observed values;

\bar{x} = Mean value of observations in sample;

x_i = i_{th} observation in sample;

n = Number of observations in sample.

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

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

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

"Committed dose equivalent" or " $H_{T,50}$ " means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" or " $H_{E,50}$ " is the sum of the products of the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum (w_T H_{T,50})$).

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

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

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

where:

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

$D(z)$ = Dose at position z ;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

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

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

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

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

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

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

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

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

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

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

where:

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water;

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

\overline{CTN}_w = of water.

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

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

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

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

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

"Conveyance" means:

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

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

"Cradle" means either:

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

2. A device:

- a. Whose patient support structure is interposed between the patient and the image receptor during normal use;
- b. Which is equipped with means for patient restraint; and
- c. Which is capable of rotation about its long (longitudinal) axis.

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

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

"CS" (See "Contrast scale").

"CT" (See "Computed tomography").

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

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

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

"CTN" (See "CT number").

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

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

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

Regulations

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

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

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

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

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

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

"Deep dose equivalent" or " H_d ," which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm^2).

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

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

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

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

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

"Detector" (See "Radiation detector").

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

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

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

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

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

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

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

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

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

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

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

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

"Diversion" means the unauthorized movement of radioactive material subject to 12VAC5-481-451 to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

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

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

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

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

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

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

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

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

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

"Effective dose equivalent" or " H_E " means the sum of the products of the dose equivalent (H_T) to each organ or tissue

and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

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

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

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

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

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

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

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

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

"Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

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

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

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

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

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

Regulations

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

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

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

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

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

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

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

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

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

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

"Fingerprint orders" means the requirements of 12VAC5-481-451 C or orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to Category 1 and Category 2 quantities of radioactive material or safeguards information-modified handling.

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

1. Fissile Class I: A package that may be transported in unlimited numbers and in any arrangement, and that requires no nuclear criticality safety controls during transportation. A transport index is not assigned for

purposes of nuclear criticality safety but may be required because of external radiation levels.

2. Fissile Class II: A package that may be transported together with other packages in any arrangement but, for criticality control, in numbers that do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

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

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

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

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptors, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

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

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

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

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

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

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

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

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

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

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

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

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

"Half-value layer" or "HVL" means the thickness of a specified material that attenuates the beam of radiation to an extent that the AKR is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

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

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

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

"Healing arts" means the art or science or group of arts or sciences dealing with the prevention and cure or alleviation of

ailments, diseases or infirmities, and has the same meaning as "medicine" when the latter term is used in its comprehensive sense.

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

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

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

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

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

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

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

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

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

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

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

"Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in

Regulations

which an individual might be unknowingly exposed to radiation from the waste.

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

"Individual" means any human being.

"Individual monitoring" means the assessment of:

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

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

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

"Inhalation class" (See "Class").

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

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

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

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

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

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

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

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

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

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

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

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

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

"kBq" means kilobecquerels.

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

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

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

"kV" means kilovolts.

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

"kWs" means kilowatt second.

"Land disposal facility" means the land, buildings, structures and equipment that is intended to be used for the disposal of wastes into the subsurface of the land. For purposes of this

chapter, a "geologic repository" as defined in 10 CFR Part 60 or 10 CFR Part 63 is not considered a land disposal facility.

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

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

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

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

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

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

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

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

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

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

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

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

"Limits" (See "Dose limits").

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential as follows:

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

where:

V_n = No-load line potential; and

V_l = Load line potential.

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

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

"Local law-enforcement agency" or "LLEA" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed Category 1 or Category 2 quantity of radioactive material is used, stored, or transported.

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

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

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

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

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

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

"Low specific activity material" or "LSA material" means radioactive material with limited specific activity that is nonfissile or is excepted under 12VAC5-481-2970 C, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific

Regulations

activity of the package contents. LSA material must be in one of three groups:

1. LSA-I

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

2. LSA-II

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

3. LSA-III

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

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

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

"Lung class" (See "Class").

"mA" means milliampere.

"mAs" means milliampere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four

times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this section.

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

"MBq" means megabecquerels.

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

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

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

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

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

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

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

"Misadministration" means either:

1. An x-ray teletherapy radiation dose:
 - a. Involving the wrong patient;
 - b. Involving the wrong mode of treatment;
 - c. Involving the wrong treatment site;
 - d. Where the calculated total administered dose differs from the total prescribed dose by more than 10% when the treatment consists of three or fewer fractions;
 - e. Where the calculated weekly administered dose differs from the weekly prescribed dose by 30%; or
 - f. Where the calculated total administered dose differs from the total prescribed dose by more than 20%; or
2. An x-ray brachytherapy radiation dose:
 - a. Involving the wrong patient;
 - b. Involving the wrong treatment site; or
 - c. Where the calculated administered dose differs from the prescribed dose by more than 20%.

"mm" means millimeters.

"Mobile device" means a piece of equipment containing licensed radioactive materials that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting, or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

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

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

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

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

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms. For Part XI (12VAC5-481-2330 et seq.) of this chapter, it means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Movement control center" means an operation center that is remote from the transport activity and that maintains the position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

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

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

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

"National Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration

certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.

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

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

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

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

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

"No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival times may not be more than six hours after the estimated arrival time for shipments of Category 2 quantities of radioactive material.

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

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

where:

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

μ_w = Linear attenuation coefficient of water.

Regulations

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

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

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

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

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

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

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

"Nominal treatment distance" means:

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

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

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

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

disposal site, or to a collection point for transport to a disposal site.

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

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

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

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

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

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

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

September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

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

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

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

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

"Particle accelerator" (See "Accelerator").

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

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

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

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

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

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, department of the Commonwealth other than the Department of Health, political subdivision of the Commonwealth, any other state or political subdivision or department thereof, and any legal successor, representative, agent, or department of the foregoing, but not including federal government agencies.

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

radiation, and in such proximity that immediate assistance can be given if required.

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

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

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

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

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

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

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

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

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

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

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

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

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

Positron emission tomography radionuclide production facility" or "PET" means a facility operating a cyclotron or other particle accelerator for the purpose of producing radionuclides that decay by positron emission.

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

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

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

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays. A further explanation may be

Regulations

found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb. 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Commission on Radiation Units and Measurements, September 15, 1984.

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

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

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

"Prescribed dose" means:

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

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

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

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

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

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

"Private inspector" means an individual who meets the requirements set forth in 12VAC5-481-340 and who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge, training and experience

to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Radiation dose" (See "Dose").

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

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

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

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

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

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

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

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

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

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

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

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

"Radiobioassay" (See "Bioassay").

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

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

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

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

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

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

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

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

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

"Radiography" means:

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

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

"Reasonably maximally exposed individual" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, a

Regulations

representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

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

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

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

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

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

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

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

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

"Reportable event" means the administration of either:

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

4. A brachytherapy x-ray dose where the calculated administered dose differs from the prescribed dose by 10% or more.

"Research and development" means (i) theoretical analysis, exploration, or experimentation; or (ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstrative purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

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

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

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

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

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

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

"Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials that are possessed by the licensee.

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

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

"Sabotage" means deliberate damage, with malevolent intent, to a Category 1 or Category 2 quantity of radioactive material, a device that contains a Category 1 or Category 2 quantity of radioactive material, or the components of the security system.

"Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law-enforcement authorities.

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

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

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

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

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

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

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

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

"Security zone" means any temporary or permanent area determined and established by the licensee for the physical

protection of Category 1 or Category 2 quantities of radioactive material.

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

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

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

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

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

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

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

"Shipping paper" means NRC Form 540 and, if required, NRC Form 540A, which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means the abbreviation for the International System of Units.

"SID" (See "Source-image receptor distance").

"Sievert" or "Sv" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

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

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

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a

Regulations

response by offsite response organizations to protect persons offsite.

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

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

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

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

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

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

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

"Source material" means:

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

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

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

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

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

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than five millimeters (0.2 in.); and

3. It satisfies the test requirements specified by the NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

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

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

$$\frac{175 \text{ grams contained U235}}{350} + \frac{50 \text{ grams U - 235}}{200} + \frac{50 \text{ grams Pu}}{200} = 1$$

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

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

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

"Stability" means structural stability.

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

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

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

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

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

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

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

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

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

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

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

1. SCO-I: A solid object on which:

- a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed four becquerel per cm² (1 E-04 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm² (1 E-05 μCi/cm²) for all other alpha emitters;
- b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1.0 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm² (0.1 μCi/cm²) for all other alpha emitters; and
- c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm² (0.1 μCi/cm²) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

- a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 400 becquerel per cm² (1 E-02 μCi/cm²) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm² (1 E-03 μCi/cm²) for all other alpha emitters;
- b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/cm²) for all other alpha emitters; and
- c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/cm²) for all other alpha emitters.

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

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

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

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

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

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperere-seconds (mAs);

Regulations

2. For field emission equipment rated for pulsed operation, peak tube potential in kilovolts (kV), and number of x-ray pulses;

3. For CT equipment designed for pulsed operation, peak tube potential in kilovolts (kV), scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in milliamperes-seconds (mAs);

4. For CT equipment not designed for pulsed operation, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in milliamperes-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in milliamperes-seconds (mAs).

"Telemetric position monitoring system" means a data transfer system that captures information by either instrumentation, measuring devices about the location or both, and status of a transport vehicle or package between the departure and destination locations.

"Teletherapy physicist" means an individual identified as a qualified teletherapy physicist on an agency license.

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

"Temporary job site" means any location where industrial radiography, wireline service, well-logging, portable gauge or x-ray ~~fluorescence~~ fluorescence use is performed and where licensed material may be stored other than those location(s) of use authorized on the license.

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

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

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

"These regulations" mean all parts of ~~these regulations~~ this chapter.

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

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

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

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

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

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

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

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

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

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

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

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

"Trustworthiness and reliability" means characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to Category 1 or Category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

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

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

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

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of 12VAC5-481-3770 or may be determined by procedures described in Table A-1 of 12VAC5-481-3770.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

"Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

"Unescorted access" means solitary access to an aggregated Category 1 or Category 2 quantity of radioactive material or the devices that contain the material.

"Uniform Low-Level Radioactive Waste Manifest" or "uniform manifest" means the combination of NRC Forms 540 and 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Unirradiated uranium" means uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

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

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

"Uranium - natural, depleted, enriched"

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

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

"Useful beam" means the radiation that passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

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

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

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

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

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

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

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

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

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

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

Regulations

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

"Waste processor" means an entity, operating under a specific license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Weighting factor " or " w_T " for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors

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

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

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

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

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

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

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

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

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

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

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

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

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

"X-ray control" means a device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness

stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

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

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

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

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

"X-ray high-voltage generator" means a device which that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

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

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

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

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

VA.R. Doc. No. R16-4630; Filed February 2, 2016, 5:32 p.m.

Forms

REGISTRAR'S NOTICE: Forms used in administering the following regulation have been filed by the State Board of Health. 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 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.

Title of Regulation: **12VAC5-640. Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings.**

Contact Information: Marcia Degen, Office of Environmental Health Services, Department of Health, 109 Governor Street, Richmond VA 23219, telephone (804) 387-1883, or email marcia.degen@vdh.virginia.gov.

FORMS (12VAC5-640)

~~Combined Application Virginia Department of Health Discharging System Application for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons Per Day and State Water Control Board Virginia Pollutant Discharge Elimination System General Permit Registration Statement for Domestic Sewage Discharges Less Than or Equal to 1,000 Gallons Per Day (rev. 9/2011)~~

~~Permit Transfer under 12 VAC 5-640-220.E (undated)~~

~~Completion Statement (undated)~~

[Combined Application-Virginia Department of Health Discharging System Application for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons Per Day and State Water Control Board Virginia Pollutant Discharge Elimination System General Permit Registration Statement for Domestic Sewage Discharges Less Than or Equal to 1,000 Gallons Per Day \(rev. 4/2014\)](#)

[Permit Transfer under 12 VAC 5-640-220.E \(rev. 2/2016\)](#)

[Completion Statement \(rev. 4/2014\)](#)

VA.R. Doc. No. R16-4632; Filed February 3, 2016, 2:10 p.m.

TITLE 15. JUDICIAL

VIRGINIA STATE BAR

Final Regulation

REGISTRAR'S NOTICE: The Virginia State Bar 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: **15VAC5-10. Regulations Governing Virginia Legal Aid Societies (amending 15VAC5-10-10).**

Regulations

Statutory Authority: § 54.1-3916 of the Code of Virginia.

Effective Date: March 23, 2016.

Agency Contact: Stephanie G. Blanton, Executive Assistant, Virginia State Bar, 1111 East Main Street, Suite 700, Richmond, VA 23219, telephone (804) 775-0576 or email blanton@vsb.org.

Summary:

The amendments revise the requirements to become a licensed legal aid society, clarify the reporting obligations of legal services providers holding themselves out to the public as "legal aid societies" or "legal aid" in Virginia, and allow sanctions against organizations misleading the public through the use of unauthorized naming and service description practices.

15VAC5-10-10. Function and operation of legal aid societies.

~~The bar recognizes the need to provide equal access to the system of justice in the Commonwealth for individuals who seek redress of grievances, to provide high quality legal assistance to those who would otherwise be unable to afford adequate legal counsel, to preserve attorney client relationships, and to protect the integrity of the adversary process.~~

- ~~1. The function of a legal aid society is to provide free legal assistance to those requiring such assistance but who are unable to pay therefor.~~
- ~~2. Only a nonprofit corporation can function as a legal aid society in the Commonwealth.~~
- ~~3. A legal aid society is defined as a nonprofit organization providing free legal assistance exclusively to those requiring such assistance but who are unable to pay therefor.~~
- ~~4. No legal aid society can function in the Commonwealth without being licensed by the Secretary Treasurer of the Virginia State Bar.~~
- ~~5. Upon application of a legal aid society, with supporting documents, the Secretary Treasurer of the Virginia State Bar shall issue a license if:
 - ~~a. The State Corporation Commission has issued a certificate of incorporation to the society.~~
 - ~~b. A majority of the members of the society's Board of Directors are active members of the Virginia State Bar.~~
 - ~~c. No member of the Virginia State Bar devoting his full time to, or receiving any compensation from, the society shall be a voting member of its board.~~
 - ~~d. The provisions of subdivisions 5 b and c shall be included in the bylaws of the society at all times.~~~~
- ~~6. No payment for the provision of legal assistance shall be received from clients by the society or its employees, except for necessary expenses or court costs.~~

~~7. Guidelines and procedures shall be established and maintained to insure that legal assistance is provided only to those who are unable to pay therefor. Legal assistance to elderly persons meeting standards of eligibility under the Older Americans Act and regulations thereto is deemed consistent with this requirement.~~

~~8. A legal aid society may appear before and practice in all the courts, administrative agencies and legislative bodies of the Commonwealth and all political subdivisions thereof, only through attorneys who are members of the Virginia State Bar or other persons who are permitted by law to so appear and practice.~~

~~9. A legal aid society holding a license issued by the Secretary Treasurer of the Virginia State Bar is deemed to be approved by the Virginia State Bar. Each licensee shall make an annual report and file it with the Secretary Treasurer of the Virginia State Bar. The annual report shall contain the following information:~~

- ~~a. Source of funding~~
- ~~b. Cost of operation~~
- ~~c. Number of cases handled~~
- ~~d. Type of cases handled~~
- ~~e. Number of lawyers employed and/or assisting~~
- ~~f. Any changes in the Articles of Incorporation or bylaws made since the last annual report.~~

~~10. A license shall be revoked by the Secretary Treasurer of the Virginia State Bar on his own motion or on the motion of any other person if it is found, after investigation and after giving the licensee reasonable notice and an opportunity to be heard, that the licensee has violated the law, the Code of Professional Responsibility or these regulations, or has been inactive for a period of one year or more or has failed to adhere to its charter or bylaws.~~

1. A nonprofit organization qualifying as a tax exempt entity under § 501(c)(3) of the Internal Revenue Code may apply to be a licensed legal aid society in the Commonwealth if its primary purpose is to provide free legal assistance exclusively to those requiring such assistance but who are unable to pay for it.

2. No person, organization, or corporation shall define itself or hold itself out to the public as a legal aid society in the Commonwealth without being licensed by the Secretary-Treasurer of the Virginia State Bar.

3. Upon application of a nonprofit organization seeking to become a licensed legal aid society, with supporting documents, the Secretary-Treasurer of the Virginia State Bar shall issue a license if:

- a. The State Corporation Commission has issued a certificate of incorporation to the applicant.
- b. A majority of the members of the applicant's board of directors are active members of the Virginia State Bar.

- c. No member of the Virginia State Bar devoting his full time to or receiving any compensation from the applicant shall be a voting member of its board.
 - d. The provisions of subdivisions 3 b and 3 c of this section shall be included in the bylaws of the applicant at all times.
 - e. The applicant has submitted a copy of its Internal Revenue Service determination letter.
 - f. The applicant provides for the prior fiscal year, if applicable, an acceptable audit conducted under standards set by the American Institute of Certified Public Accountants.
 - g. The applicant provides proof of acceptable professional liability insurance coverage for its operations that meets or exceeds an aggregate sum determined annually by the Virginia State Bar inclusive of coverage in the amount of \$250,000 per claim for lawyers who provide client legal services under the auspices of the program.
4. No fee for the provision of legal assistance shall be requested or received from clients by the licensed legal aid society or its employees, except for necessary expenses or costs.
5. A licensed legal aid society shall establish and maintain guidelines and procedures to ensure that legal assistance is provided only to those who are unable to pay for it. Legal assistance to persons meeting standards of eligibility under 42 USC § 2996 et seq. (Title X - Legal Services Corporation Act) and associated regulations is deemed consistent with this requirement.
6. A licensed legal aid society may appear before and practice in all the courts, administrative agencies, and legislative bodies of the Commonwealth and all political subdivisions thereof only through attorneys who are members of the Virginia State Bar or other persons who are permitted by law to so appear and practice.
7. A legal aid society holding a license issued by the Secretary-Treasurer of the Virginia State Bar is deemed to be an approved licensee. Each licensee shall make an annual report and file it with the Secretary-Treasurer of the Virginia State Bar within 90 days of the conclusion of the bar's fiscal year. The annual report shall contain the following information:
- a. Source of funding;
 - b. Cost of operation;
 - c. Number of cases handled;
 - d. Type of cases handled;
 - e. Staffing, providing the number and title of all employees and the number of volunteer attorneys assisting within the period covered by the report;
 - f. Change in the articles of incorporation or bylaws made since the last annual report;

- g. Current roster of the members of the board of directors indicating vacancies, names of appointing authorities, and each member's bar or lay statuses;
 - h. Audit conducted in accordance with generally accepted auditing standards of the American Institute of Certified Public Accountants, which shall be submitted within 180 days of the conclusion of the licensee's fiscal year;
 - i. Proof of required professional liability coverage and timely notice to the bar during the course of the year of any lapse or denial in coverage; and
 - j. Client eligibility guidelines.
8. A license shall be revoked by the Secretary-Treasurer of the Virginia State Bar on his own motion or on the motion of any other person if it is found, after investigation and after giving the licensee reasonable notice and an opportunity to be heard, that the licensee (i) has committed a substantial and material violation of law, its charter or bylaws, or this chapter; or (ii) has been inactive for a period of one year or more.
11. 9. From any decision of the Secretary-Treasurer of the Virginia State Bar in (i) granting, ~~or (ii) refusing or;~~ (iii) revoking, or (iv) refusing to revoke a license, any interested person may appeal to the Council of the Virginia State Bar.
12. The Council of the Virginia State Bar reserves the right to amend these regulations from time to time.

VA.R. Doc. No. R16-2753; Filed January 26, 2016, 1:09 p.m.



TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

COMMONWEALTH TRANSPORTATION BOARD

Final Regulation

REGISTRAR'S NOTICE: The Commonwealth Transportation Board is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 2, which excludes regulations that establish or prescribe agency organization, internal practice or procedures, including delegations of authority. The Commonwealth Transportation Board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **24VAC30-290. Guide for Additions, Abandonments and Discontinuances (repealing 24VAC30-290-10).**

Statutory Authority: § 33.2-210 of the Code of Virginia.

Effective Date: March 23, 2016.

Regulations

Agency Contact: Suzanne Ellison, Maintenance Division, Department of Transportation, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-0974, or email suzanne.ellison@vdot.virginia.gov.

Summary:

This action repeals the Guide for Additions, Abandonments and Discontinuances, which was prepared as a reference primarily for Virginia Department of Transportation (VDOT) personnel throughout the Commonwealth. In 2009, the Attorney General's Government and Regulatory Reform Task Force recommended that the regulation be repealed because the regulation appeared to be a guidance document for VDOT personnel and therefore did not need to be retained as a regulation. In addition, the Code of Virginia has been amended in recent years to provide more detailed information on making changes to the secondary system of state highways, making much of the current guide obsolete or unnecessary. Upon repeal of this regulation, VDOT will include a revised guide as part of its list of guidance documents.

VA.R. Doc. No. R16-3491; Filed January 29, 2016, 2:25 p.m.

GOVERNOR

EXECUTIVE ORDER NUMBER 52 (2016)

Development of Long-Term, Offsetting Methods within the Virginia Nutrient Credit Exchange Program

Importance of the Initiative

The Chesapeake Bay is a national treasure and an ecological and economic asset for Virginia. In 2005, the General Assembly established a watershed general permit and nutrient credit trading program to help manage total point source discharges of nitrogen and phosphorous into the Chesapeake Bay watershed. This market-based tool was designed to assist Virginia's point source dischargers, including municipal wastewater treatment plants and private industries, with complying with nutrient waste load allocations necessary to improve the health of the Chesapeake Bay and its tributaries. New sources are able to purchase available allocations and/or credits through the Virginia Nutrient Credit Exchange Program on a year-to-year basis. It is vital that this program continues to serve as a tool to protect and improve the health of the Chesapeake Bay watershed while allowing economic growth and the development of a new Virginia economy.

Accordingly, by virtue of the authority vested in me as Governor under Article V of the Constitution of Virginia and under the laws of the Commonwealth, I hereby direct the Secretaries of Commerce and Trade, Natural Resources, and Agriculture and Forestry to jointly convene a work group comprised of the Virginia Economic Development Partnership, the Department of Environmental Quality, the Virginia Manufacturers Association, the Virginia Association of Municipal Wastewater Agencies, the Virginia Nutrient Credit Exchange Association, the Chesapeake Bay Foundation, the James River Association and other interested stakeholders to study and recommend methods to facilitate the acquisition of nutrient allocations and/or credits through the Virginia Nutrient Credit Exchange Program to offset discharges of nutrients by point-source dischargers in the Chesapeake Bay watershed on a long-term (20+ year) basis.

Such methods shall be in accordance with the State Water Control Board's authority to establish and assign nutrient waste load allocations, and shall not cause or contribute to an exceedance of applicable water quality standards or the aggregate point source loading caps for Virginia's tributaries to the Chesapeake Bay.

Scope and Guidance

The Work Group should consider: (1) the protection of established nutrient allocations of existing facilities and investments that have been made pursuant to such allocations; (2) the needs of expanding and new point sources in the watershed; (3) the minimization of offset demands by new or expanding facilities by analysis of technologically and economically feasible alternatives; (4) the establishment of a

merit-based qualification process for nutrient credit acquisition to align offset supplies with state and local economic development goals; (5) the cost and value of existing infrastructure, of credit generation, of credit use for offset purposes, and of other offset methods; (6) support for innovation and voluntary incentives to promote credit generation, exchange and use to meet offset needs; (7) priorities for continued state investment in water quality improvement, including the Nutrient Offset Fund, the Water Quality Improvement Fund and other state economic development incentives; and (8) flexibility in achieving water quality standards under the Chesapeake Bay Total Maximum Daily Load (TMDL).

The Work Group shall complete its work, including the development of recommendations as to viable offset supply augmentation methods by November 1, 2016. The Secretaries shall provide a report on the recommendations of the Work Group to me by December 1, 2016.

Effective Date of the Executive Order

This Executive Order shall be effective upon its signing and shall remain in full force and effect for one year after its signing unless amended or rescinded by further executive order.

Given under my hand and under the Seal of the Commonwealth of Virginia this 28th Day of January, 2016.

/s/ Terence R. McAuliffe
Governor

GENERAL NOTICES/ERRATA

BOARD FOR BRANCH PILOTS

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Branch Pilots conducted a small business impact review of **18VAC45-11, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Board for Branch Pilots is publishing its report of findings dated January 28, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

1. The current regulations are necessary for the board to comply with § 2.2-4007.02 of the Code of Virginia and Chapter 321 of the 2008 Acts of Assembly.
2. No public comments were received.
3. The regulations are not complex in nature.
4. The regulations do not overlap, duplicate, or conflict with federal or state laws or regulations.
5. The regulations became effective on December 1, 2012, with the adoption of the model public participation guidelines pursuant to Chapter 321 of the 2008 Acts of Assembly.
6. No small business impact has been identified.

Contact Information: Kathleen R. Nosbisch, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email branchpilots@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Branch Pilots conducted a small business impact review of **18VAC45-20, Board for Branch Pilots Regulations**, and determined that this regulation should be retained in its current form. The Board for Branch Pilots is publishing its report of findings dated January 28, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

1. The current regulations are necessary to ensure that only minimally qualified individuals operate large vessels in Virginia's waterways; this is crucial to the protection of the public health, safety, and welfare.
2. No public comments were received.
3. The regulations are not complex in nature.
4. The regulations do not overlap, duplicate, or conflict with federal or state laws or regulations.
5. The last periodic review concluded October, 2011. There were further changes to the regulations that became effective December 1, 2012.

6. No small business impact has been identified.

Contact Information: Kathleen R. Nosbisch, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email branchpilots@dpor.virginia.gov.

BOARD OF CORRECTIONS

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board of Corrections conducted a small business impact review of **6VAC15-28, Regulations for Public/Private Joint Venture Work Programs Operated in a State Correctional Facility**, and determined that this regulation should be retained in its current form. The Board of Corrections is publishing its report of findings dated January 28, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

6VAC15-28, Regulations for Public/Private Joint Venture Work Programs Operated in a State Correctional Facility, is necessary to govern agreements between the Director of the Department of Corrections and a public or private entity to operate a work program in a state correctional facility for inmates confined in it. There have been no complaints or comments received from the public concerning the regulation. The regulation is not deemed to be overly complex nor does it overlap, duplicate, or conflict with federal or state law or regulation. Technology, economic conditions, or other factors have not significantly changed in the area affected by the regulation since it was last updated in 2011. There is no known small business impact of this regulation as its only function is to govern agreements between the Director of the Department of Corrections and a public or private entity.

Contact Information: Jim Bruce, Agency Regulatory Coordinator, Department of Corrections, P.O. Box 26963, Richmond, VA 23261-6963, telephone (804) 887-8215, or email james.bruce@vadoc.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board of Corrections conducted a small business impact review of **6VAC15-45, Regulations for Private Management and Operation of Prison Facilities**, and determined that this regulation should be retained in its current form. The Board of Corrections is publishing its report of findings dated January 28, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

6VAC15-45, Regulations for Private Management and Operation of Prison Facilities, is necessary as the Code of Virginia requires the Board of Corrections to make, adopt, and promulgate regulations governing private management and operation of prison facilities. There have been no

complaints or comments received from the public concerning the regulation. The regulation is not deemed to be overly complex nor does it overlap, duplicate, or conflict with federal or state law or regulation. Technology, economic conditions, or other factors have not significantly changed in the area affected by the regulation since it was last reviewed

in 2011. There is no known small business impact of this regulation.

Contact Information: Jim Bruce, Agency Regulatory Coordinator, Department of Corrections, P.O. Box 26963, Richmond, VA 23261-6963, telephone (804) 887-8215, or email james.bruce@vadoc.virginia.gov.

DEPARTMENT OF FORENSIC SCIENCE

Approval of Field Tests for Detection of Drugs

In accordance with 6VAC40-30, the Regulations for the Approval of Field Tests for Detection of Drugs, and under the authority of the Code of Virginia, the following field tests for detection of drugs are approved field tests:

ODV INCORPORATED
13386 INTERNATIONAL PARKWAY
JACKSONVILLE, FL 32218-2383

ODV NarcoPouch

Drug or Drug Type:

Heroin
Amphetamine
Methamphetamine
3,4–Methylenedioxyamphetamine (MDMA)
Cocaine Hydrochloride
Cocaine Base
Barbiturates
Lysergic Acid Diethylamide (LSD)
Marijuana
Hashish Oil
Marijuana
Hashish Oil
Phencyclidine (PCP)
Heroin
Methamphetamine
3,4–Methylenedioxyamphetamine (MDMA)
Heroin
Diazepam
Ketamine
Ephedrine
gamma – Hydroxybutyrate (GHB)

Manufacturer's Field Test:

902 – Marquis Reagent
902 – Marquis Reagent
902 – Marquis Reagent
902 – Marquis Reagent
904 or 904B – Cocaine HCl and Base Reagent
904 or 904B – Cocaine HCl and Base Reagent
905 – Dille-Koppanyi Reagent
907 – Ehrlich's (Modified) Reagent
908 – Duquenois – Levine Reagent
908 – Duquenois – Levine Reagent
909 – K N Reagent
909 – K N Reagent
914 – PCP Methaqualone Reagent
922 – Opiates Reagent
923 – Methamphetamine/Ecstasy Reagent
923 – Methamphetamine/Ecstasy Reagent
924 – Mecke's (Modified) Reagent
925 – Valium/Ketamine Reagent
925 – Valium/Ketamine Reagent
927 – Ephedrine Reagent
928 – GHB Reagent

General Notices/Errata

ODV NarcoTest

Drug or Drug Type:

Heroin
Amphetamine
Methamphetamine
3,4-Methylenedioxyamphetamine (MDMA)
Barbiturates
Lysergic Acid Diethylamide (LSD)
Marijuana
Hashish Oil
Marijuana
Hashish Oil
Cocaine Hydrochloride
Cocaine Base
Phencyclidine (PCP)
Heroin
Methamphetamine
3,4-Methylenedioxyamphetamine (MDMA)
Heroin
Diazepam
Ketamine
Ephedrine
gamma – Hydroxybutyrate (GHB)

Manufacturer's Field Test:

7602 – Marquis Reagent
7602 – Marquis Reagent
7602 – Marquis Reagent
7602 – Marquis Reagent
7605 – Dille-Koppanyi Reagent
7607 – Ehrlich's (Modified) Reagent
7608 – Duquenois Reagent
7608 – Duquenois Reagent
7609 – K N Reagent
7609 – K N Reagent
7613 – Scott (Modified) Reagent
7613 – Scott (Modified) Reagent
7614 – PCP Methaqualone Reagent
7622 – Opiates Reagent
7623– Methamphetamine/Ecstasy Reagent
7623– Methamphetamine/Ecstasy Reagent
7624 – Mecke's Reagent
7625 – Valium/Ketamine Reagent
7625 – Valium/Ketamine Reagent
7627 – Chen's Reagent - Ephedrine
7628 – GHB Reagent

SIRCHIE FINGERPRINT LABORATORIES
100 HUNTER PLACE
YOUNGSVILLE, NC 27596

NARK

Drug or Drug Type:

Narcotic Alkaloids
Heroin
Morphine
Amphetamine
Methamphetamine
Opium Alkaloids
Heroin
Morphine
Amphetamine

Manufacturer's Field Test:

1 – Mayer's Reagent
1 – Mayer's Reagent
1 – Mayer's Reagent
1 – Mayer's Reagent
1 – Mayer's Reagent
2 – Marquis Reagent
2 – Marquis Reagent
2 – Marquis Reagent
2 – Marquis Reagent

Methamphetamine	2 – Marquis Reagent
3,4–Methylenedioxymethamphetamine (MDMA)	2 – Marquis Reagent
Meperidine (Demerol) (Pethidine)	2 – Marquis Reagent
Heroin	3 – Nitric Acid
Morphine	3 – Nitric Acid
Cocaine Hydrochloride	4 – Cobalt Thiocyanate Reagent
Cocaine Base	4 – Cobalt Thiocyanate Reagent
Procaine	4 – Cobalt Thiocyanate Reagent
Tetracaine	4 – Cobalt Thiocyanate Reagent
Barbiturates	5 – Dille-Koppanyi Reagent
Heroin	6 – Mandelin Reagent
Morphine	6 – Mandelin Reagent
Amphetamine	6 – Mandelin Reagent
Methamphetamine	6 – Mandelin Reagent
Lysergic Acid Diethylamide (LSD)	7 – Ehrlich's Reagent
Marijuana	8 – Duquenois Reagent
Hashish	8 – Duquenois Reagent
Hashish Oil	8 – Duquenois Reagent
Tetrahydrocannabinol (THC)	8 – Duquenois Reagent
Marijuana	9 – NDB (Fast Blue B Salt) Reagent
Hashish	9 – NDB (Fast Blue B Salt) Reagent
Hashish Oil	9 – NDB (Fast Blue B Salt) Reagent
Tetrahydrocannabinol (THC)	9 – NDB (Fast Blue B Salt) Reagent
Cocaine Base	13 – Cobalt Thiocyanate/Crack Test

NARK II

Drug or Drug Type:

Narcotic Alkaloids
Heroin
Morphine
Amphetamine
Methamphetamine
3,4–Methylenedioxymethamphetamine (MDMA)
Morphine
Heroin
Barbiturates
Lysergic Acid Diethylamide (LSD)

Manufacturer's Field Test:

01 – Marquis Reagent
01 – Marquis Reagent
01 – Marquis Reagent
01 – Marquis Reagent
01 – Marquis Reagent
01 – Marquis Reagent
02 – Nitric Acid
02 – Nitric Acid
03 – Dille-Koppanyi Reagent
04 – Ehrlich's Reagent

General Notices/Errata

Marijuana	05 – Duquenois – Levine Reagent
Hashish	05 – Duquenois – Levine Reagent
Hashish Oil	05 – Duquenois – Levine Reagent
Tetrahydrocannabinol (THC)	05 – Duquenois – Levine Reagent
Cocaine Hydrochloride	07 – Scott's (Modified) Reagent
Cocaine Base	07 – Scott's (Modified) Reagent
Phencyclidine (PCP)	09 – Phencyclidine Reagent
Opiates	10 – Opiates Reagent
Heroin	10 – Opiates Reagent
Morphine	10 – Opiates Reagent
Buprenorphine	10 – Special Opiates Reagent
Heroin	11 – Mecke's Reagent
3,4-Methylenedioxyamphetamine (MDMA)	11 – Mecke's Reagent
Pentazocine	12 – Talwin/Pentazocine Reagent
Ephedrine	13 – Ephedrine Reagent
Diazepam	14 – Valium Reagent
Methamphetamine	15 – Methamphetamine (Secondary Amines Reagent)
Narcotic Alkaloids	19 – Mayer's Reagent
Heroin	19 – Mayer's Reagent
Morphine	19 – Mayer's Reagent
Amphetamine	19 – Mayer's Reagent
Methamphetamine	19 – Mayer's Reagent
3,4-Methylenedioxypropylamphetamine (MDPV)	24 – MDPV (Bath Salts) Reagent
Beta-keto-N-methyl-3,4-benzodioxymethamphetamine (other name: butylone)	24 – MDPV Synthetic Cathinones Reagent
3,4-methylenedioxyethylamphetamine (other name: ethylone)	24 – MDPV Synthetic Cathinones Reagent
3,4-methylenedioxymethylamphetamine (other name: methylone)	24 – MDPV Synthetic Cathinones Reagent
Naphthylpyrovalerone (other name: naphyrone)	24 – MDPV Synthetic Cathinones Reagent
Beta-keto-methylbenzodioxymethylamphetamine (other name: pentylone)	24 – MDPV Synthetic Cathinones Reagent
4-Methylmethcathinone (Mephedrone)	25 – Mephedrone (Bath Salts) Reagent
Alpha-pyrrolidinovalerophenone (other name: alpha-PVP)	26 – A-PVP (Synthetic Stimulant) Reagent
4-Bromo-2,5-dimethoxyphenethylamine (other name: 2C-B)	29 - 2C Reagent
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (other name: 2C-C)	29 – 2C Reagent
4-Ethyl-2,5-dimethoxyphenethylamine (other name: 2C-E)	29 – 2C Reagent
4-Iodo-2,5-dimethoxyphenethylamine (other name: 2C-I)	29 – 2C Reagent

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (other name: 29 – 2C Reagent
2C-N)

2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 29 – 2C Reagent
2C-T-7)

Psilocybin 30 – Psilocybin/Psilocin Reagent

Methamphetamine 31 – Liebermann Reagent

Morphine 31 – Liebermann Reagent

Fentanyl 33 – Fentanyl Reagent

Acetyl fentanyl (other name: desmethylfentanyl) 33 – Fentanyl Reagent

Heroin 33 – Fentanyl Reagent

ARMOR HOLDINGS, INCORPORATED
13386 INTERNATIONAL PARKWAY
JACKSONVILLE, FL 32218-2383

NIK

Drug or Drug Type:

Heroin

Amphetamine

Methamphetamine

3,4-Methylenedioxymethamphetamine (MDMA)

Morphine

Barbiturates

Lysergic Acid Diethylamide (LSD)

Marijuana

Hashish Oil

Tetrahydrocannabinol

Cocaine Hydrochloride

Cocaine Base

Cocaine Hydrochloride

Cocaine Base

Phencyclidine (PCP)

Heroin

Heroin

Gamma – Hydroxybutyrate (GHB)

Ephedrine

Pseudoephedrine

Diazepam

Methamphetamine

Manufacturer's Field Test:

Test A 6071 – Marquis Reagent

Test A 6071 – Marquis Reagent

Test A 6071 – Marquis Reagent

Test A 6071 – Marquis Reagent

Test B 6072 – Nitric Acid Reagent

Test C 6073 – Dille-Koppanyi Reagent

Test D 6074 – LSD Reagent System

Test E 6075 – Duquenois – Levine Reagent

Test E 6075 – Duquenois – Levine Reagent

Test E 6075 – Duquenois – Levine Reagent

Test G 6077 – Scott (Modified) Reagent

Test G 6077 – Scott (Modified) Reagent

6500 or 6501 – Cocaine ID Swab

6500 or 6501 – Cocaine ID Swab

Test J 6079 – PCP Reagent System

Test K 6080 – Opiates Reagent

Test L 6081 – Brown Heroin Reagent System

Test O 6090 – GHB Reagent

Test Q 6085 – Ephedrine Reagent

Test Q 6085 – Ephedrine Reagent

Test R 6085 – Valium Reagent

Test U 6087 – Methamphetamine Reagent

General Notices/Errata

3,4-Methylenedioxyamphetamine (MDMA)

Test U 6087 – Methamphetamine Reagent

Methadone

Test W 6088 – Mandelin Reagent System

MISTRAL SECURITY INCORPORATED
7910 WOODMONT AVENUE SUITE 820
BETHESDA, MD 20814

Drug or Drug Type:

Manufacturer's Field Test:

Heroin

Detect 4 Drugs Aerosol

Amphetamine

Detect 4 Drugs Aerosol

Methamphetamine

Detect 4 Drugs Aerosol

Marijuana

Detect 4 Drugs Aerosol

Hashish Oil

Detect 4 Drugs Aerosol

Methamphetamine

Meth 1 and 2 Aerosol

Heroin

Herosol Aerosol

Marijuana

Cannabispray 1 and 2 Aerosol

Hashish Oil

Cannabispray 1 and 2 Aerosol

Cocaine Hydrochloride

Coca-Test Aerosol

Cocaine Base

Coca-Test Aerosol

Marijuana

Pen Test – D4D

Phencyclidine

Pen Test – D4D

Amphetamine

Pen Test – D4D

Ketamine

Pen Test – D4D

Methamphetamine

Pen Test – D4D

Ephedrine

Pen Test – D4D

Heroin

Pen Test – D4D

Methadone

Pen Test – D4D

Buprenorphine

Pen Test – D4D

Opium

Pen Test – D4D

Phenobarbital

Pen Test – Barbitusol

Marijuana

Pen Test – Cannabis Test

Phencyclidine

Pen Test – Coca Test

Cocaine Hydrochloride

Pen Test – Coca Test

Cocaine Base

Pen Test – Coca Test

Buprenorphine

Pen Test – C&H Test

Cocaine Hydrochloride

Pen Test – C&H Test

Cocaine Base

Pen Test – C&H Test

Ephedrine

Pen Test – C&H Test

Ketamine

Pen Test – C&H Test

Heroin	Pen Test – C&H Test
Lysergic Acid Diethylamide (LSD)	Pen Test – C&H Test
Methadone	Pen Test – C&H Test
Methamphetamine	Pen Test – C&H Test
Heroin	Pen Test – Herosol
Methadone	Pen Test – Herosol
Lysergic Acid Diethylamide	Pen Test – LSD Test
Methamphetamine	Pen Test – Meth/X Test
3,4-Methylenedioxyamphetamine (MDMA)	Pen Test – Meth/X Test
Morphine	Pen Test – Opiatest
Opium	Pen Test – Opiatest
Diazepam	Pen Test – BZO
Ephedrine	Pen Test – Ephedrine
Pseudoephedrine	Pen Test – Ephedrine
Amphetamine	101 PDT Marquis Reagent
Heroin	101 PDT Marquis Reagent
3,4-Methylenedioxyamphetamine (MDMA)	101 PDT Marquis Reagent
Phenobarbital	107 PDT Dille-Koppanyi Reagent
Lysergic Acid Diethylamide	110 PDT Modified Ehrlich Reagent
Marijuana	119 PDT KN Reagent
Cocaine Hydrochloride	122 PDT Modified Scott Reagent
Cocaine Base	122 PDT Modified Scott Reagent
Methaqualone	143 PDT Methaqualone/PCP Reagent
Phencyclidine	143 PDT Methaqualone/PCP Reagent
Heroin	140 PDT Modified Mecke's Reagent
Gamma-Hydroxybutyrate (GHB)	149 PDT GHB Reagent
Ephedrine	155 PDT Chen's Reagent
Diazepam	158 PDT Valium/Rohypnol Reagent
Flunitrazepam	158 PDT Valium/Rohypnol Reagent
Ketamine	161 PDT Morris Reagent
Methamphetamine	164 PDT Methamphetamine (MDMA/Ecstasy) Reagent
3,4-Methylenedioxyamphetamine (MDMA)	164 PDT Methamphetamine (MDMA/Ecstasy) Reagent
Psilocybin	167 PDT Psilocybin Reagent
3,4-Methylenedioxypropylvalerone (MDPV)	170 PDT Bath Salts: MDPV Reagent
4-methylmethcathinone (Mephedrone)	173 PDT Bath Salts: Mephedrone Reagent
Morphine	137 PDT Opiates Reagent

General Notices/Errata

JANT PHARMACAL CORPORATION
16255 VENTURA BLVD., #505
ENCINO, CA 91436

Formerly available through:
MILLENNIUM SECURITY GROUP

Accutest IDenta

Drug or Drug Type:

Marijuana

Hashish Oil

Heroin

Cocaine Hydrochloride

Cocaine Base

3,4-Methylenedioxyamphetamine (MDMA)

Methamphetamine

COZART PLC
92 MILTON PARK
ABINGDON, OXFORDSHIRE ENGLAND OX14 4RY

Drug or Drug Type:

Cocaine

LYNN PEAVEY COMPANY
10749 WEST 84th TERRACE
LEXEXA, KS 66214

QuickCheck

Drug or Drug Type:

Marijuana

Marijuana

Hashish Oil

Hashish Oil

Heroin

Heroin

Cocaine Hydrochloride

Cocaine Base

Methamphetamine

Methamphetamine

MDMA

MDMA

Manufacturer's Field Test:

ACS3000 Marijuana/Hashish (Duquenois-Levine Reagent)

ACS3000 Marijuana/Hashish (Duquenois-Levine Reagent)

Heroin Step 1 and Step 2

Cocaine/Crack Step 1 and Step 2

Cocaine/Crack Step 1 and Step 2

MDMA Step 1 and Step 2

Methamphetamine Step 1 and Step 2

Manufacturer's Field Test:

Cocaine Solid Field Test

Manufacturer's Field Test:

Marijuana (Duquenois-Levine Reagent) – 10120

Marijuana – 10121

Marijuana (Duquenois-Levine Reagent) – 10120

Marijuana – 10121

Marquis – 10123

Heroin - 10125

Cocaine – 10124

Cocaine – 10124

Meth/Ecstasy – 10122

Marquis – 10123

Meth/Ecstasy – 10122

Marquis - 10123

M.M.C. INTERNATIONAL B.V.
FRANKENTHALERSTRAAT 16-18
4816 KA BREDA
THE NETHERLANDS

Drug or Drug Type:

Heroin
Morphine
Amphetamine
Methamphetamine
Codeine
Marijuana
Hashish Oil
Cocaine Hydrochloride
Cocaine Base
Heroin
Ketamine
Methadone
Methamphetamine
3,4-Methylenedioxyamphetamine (MDMA)
Morphine
Heroin
Ephedrine
Pseudoephedrine
Pentazocine
Buprenorphine
Gamma butyrolactone (GBL)
Gamma hydroxybutyric acid (GHB)
Oxycodone
Oxymetholone
Testosterone
Methandrostenolone
Phenylacetone
Lysergic Acid Diethylamide (LSD)
Phencyclidine (PCP)
Methaqualone
Amobarbital
Pentobarbital

Manufacturer's Field Test:

Opiates/Amphetamine Test (Ampoule)
Opiates/Amphetamine Test (Ampoule)
Opiates/Amphetamine Test (Ampoule)
Opiates/Amphetamine Test (Ampoule)
Opiates/Amphetamine Test (Ampoule)
Cannabis Test (Ampoule)
Cannabis Test (Ampoule)
Cocaine/Crack Test (Ampoule)
Cocaine/Crack Test (Ampoule)
Heroin Test (Ampoule)
Ketamine Test (Ampoule)
Methadone Test (Ampoule)
Crystal Meth/XTC Test (Ampoule)
Crystal Meth/XTC Test (Ampoule)
M&H Test (Ampoule)
M&H Test (Ampoule)
Ephedrine HCL Test (Ampoule)
Ephedrine HCL Test (Ampoule)
Pentazocine Test (Ampoule)
Buprenorphine HCL Test (Ampoule)
GBL Test (Ampoule)
GHB Test (Ampoule)
Oxycodone Test (Ampoule)
Steroids Test B (Ampoule)
Steroids Test B (Ampoule)
Steroids Test B (Ampoule)
PMK/BMK(BMK) Test (Ampoule)
LSD Test (Ampoule)
PCP Test (Ampoule)
Methaqualone Test (Ampoule)
Barbiturates Test (Ampoule)
Barbiturates Test (Ampoule)

General Notices/Errata

Phenobarbital	Barbiturates Test (Ampoule)
Secobarbital	Barbiturates Test (Ampoule)
Propoxyphene	Propoxyphene Test (Ampoule)
Diazepam	V&R Test (Ampoule)
Cocaine Hydrochloride	Cocaine/Crack Test (Spray)
Cocaine Base	Cocaine/Crack Test (Spray)
Cocaine Hydrochloride	Cocaine Trace Wipes
Cocaine Base	Cocaine Trace Wipes
Morphine	Opiate Cassette
Heroin	Opiate Cassette
3,4-Methylenedioxymethamphetamine (MDMA)	MDMA/Ecstasy Cassette
Methamphetamine	Methamphetamine Cassette
Amphetamine	Amphetamine Cassette
Cocaine Hydrochloride	Cocaine/Crack NarcoSpray [®]
Phencyclidine (PCP)	Cocaine/Crack NarcoSpray [®]
Methaqualone	Cocaine/Crack NarcoSpray [®]
gamma-Butyrolactone (GBL)	Cocaine/Crack NarcoSpray [®]
3,4-methylenedioxypyrovalerone (MDPV)	Cocaine/Crack NarcoSpray [®]
Cocaine Base	Cocaine/Crack NarcoSpray [®]
Ketamine	General Screening NarcoSpray [®]
Heroin	General Screening NarcoSpray [®]
Marijuana	General Screening NarcoSpray [®]
Methamphetamine	General Screening NarcoSpray [®]
3,4-methylenedioxymethamphetamine (MDMA)	General Screening NarcoSpray [®]
Phencyclidine (PCP)	General Screening NarcoSpray [®]

REDXDEFENSE
7642 STANDISH PLACE
ROCKVILLE, MD 20855

XCAT

Drug or Drug Type:

Cocaine Hydrochloride
Cocaine Base
Phencyclidine
Heroin
Amphetamine
Methamphetamine

Manufacturer's Field Test:

COC-210 Card
COC-210 Card
COC-210 Card
HER-110 Card
AMP-500 Card
AMP-500 Card

3,4-Methylenedioxyamphetamine (MDMA)	AMP-500 Card
Butylone	AMP-500 Card
Methedrone	AMP-500 Card
Methylone	AMP-500 Card
Mephedrone	AMP-500 Card
N-Benzylpiperazine (N-BZP)	AMP-500 Card
Mescaline	AMP-500 Card
2C-I	AMP-500 Card

DETECTACHEM LLC
4100 GREENBRIAR DR
SUITE 180
STAFFORD, TX 77477

SEEKERe

Drug or Drug Type:

Codeine
Morphine
Heroin
Cocaine Hydrochloride
Cocaine Base
Methamphetamine
3,4-methylenedioxyamphetamine (MDMA)
Marijuana
JWH-018
Ketamine

Manufacturer's Field Test:

SEEKERe/Opiates Test Card
SEEKERe/Opiates Test Card
SEEKERe/Opiates Test Card
SEEKERe/Cocaine Test Card
SEEKERe/Cocaine Test Card
SEEKERe/Meth/MDMA Test Card
SEEKERe/Meth/MDMA Test Card
SEEKERe/Marijuana/THC Test Card
SEEKERe/Synthetic Cannabinoids Test Card
SEEKERe/Ketamine Test Card

VIRGINIA LOTTERY

Director's Orders

The following Director's Orders of the Virginia Lottery were filed with the Virginia Registrar of Regulations on February 3, 2016. The orders may be viewed at the Virginia Lottery, 900 East Main Street, Richmond, VA, or at the office of the Registrar of Regulations, 201 North 9th Street, 2nd Floor, Richmond, VA.

Director's Order Number Three (16)

Certain Virginia Instant Game Lotteries; End of Games.

In accordance with the authority granted by §§ 2.2-4002 B 15 and 58.1-4006 A of the Code of Virginia, I hereby give

notice that the following Virginia Lottery instant games will officially end at midnight on January 15, 2016:

Game 1484	10X The Money
Game 1508	Jewel 7's
Game 1521	Cash King
Game 1523	\$250,000 Jackpot Doubler
Game 1536	Aces & 8's
Game 1541	The Color of Money
Game 1542	\$3,000,000 Silver Spectacular
Game 1551	Find the 9's

General Notices/Errata

Game 1552	5X the Money
Game 1554	Red White and Blue Winnings
Game 1558	Money, Money, Money
Game 1570	Spades
Game 1574	Lucky Streak
Game 1581	Treasure Hunt
Game 1591	Spooktacular Fast \$50's
Game 1593	Turkey Tripler
Game 1595	Season's Winnings
Game 1596	Happy Holidays
Game 1597	Season's Greetings
Game 1598	Holiday Double Match
Game 1599	Merry Money

The last day for lottery retailers to return for credit unsold tickets from any of these games will be March 1, 2016. The last day to redeem winning tickets for any of these games will be July 13, 2016, 180 days from the declared official end of the game. Claims for winning tickets from any of these games will not be accepted after that date. Claims that are mailed and received in an envelope bearing a postmark of the United States Postal Service or another sovereign nation of July 13, 2016, or earlier, will be deemed to have been received on time. This notice amplifies and conforms to the duly adopted State Lottery Board regulations for the conduct of lottery games.

This order is available for inspection and copying during normal business hours at the Virginia Lottery headquarters, 900 East Main Street, Richmond, Virginia, and at any Virginia Lottery regional office. A copy may be requested by mail by writing to Director's Office, Virginia Lottery, 900 East Main Street, Richmond, Virginia 23219.

This Director's Order becomes effective on the date of its signing and shall remain in full force and effect unless amended or rescinded by further Director's Order.

/s/ Paula I. Otto
Executive Director
January 11, 2016

Director's Order Number Four (16)

"Miller Mart Pump Ad Retailer Incentive Promotion" Virginia Lottery Retailer Incentive Program Requirements (This Director's Order becomes effective on March 1, 2016, and shall remain in full force and effect until ninety (90) days after the conclusion of the incentive program, unless otherwise extended by the Director)

Director's Order Number Five (16)

"Coastal Investments Pump Ad Retailer Incentive Promotion" Virginia Lottery Retailer Incentive Program Requirements (This Director's Order becomes effective on March 1, 2016, and shall remain in full force and effect until ninety (90) days after the conclusion of the incentive program, unless otherwise extended by the Director)

Director's Order Number Six (16)

"Pit Stop Pump Ad Retailer Incentive Promotion" Virginia Lottery Retailer Incentive Program Requirements (This Director's Order becomes effective on March 1, 2016, and shall remain in full force and effect until ninety (90) days after the conclusion of the incentive program, unless otherwise extended by the Director)

Director's Order Number Seven (16)

Virginia's Lottery Scratch Game 1638 "Cash Multiplier" Final Rules for Game Operation (effective January 21, 2016)

Director's Order Number Eight (16)

Certain Virginia Game Promotion; Promotion Correction - Lucky Lines Promotion (100 15) (effective January 8, 2016)

Director's Order Number Nine (16)

Virginia's Lottery Scratch Game 1630 "Lucky \$50's" Final Rules for Game Operation (effective January 21, 2016)

Director's Order Number Ten (16)

Virginia's Lottery Scratch Game 1631 "Mustache Cash" Final Rules for Game Operation (effective January 21, 2016)

Director's Order Number Eleven (16)

Virginia's Lottery Scratch Game 1647 "Super Red Hot Crossword" Final Rules for Game Operation (effective January 21, 2016)

Director's Order Number Twelve (16)

Virginia's Lottery Scratch Game 1636 "Cupcake Cash" Final Rules for Game Operation (effective January 21, 2016)

Director's Order Number Thirteen (16)

Virginia's Computer-Generated Lottery Game "Print 'N Play Smokin' Hot Crossword" Final Rules for Game Operation (This Director's Order becomes effective on Sunday, April 3, 2016, and shall remain in full force and effect unless amended or rescinded by further Director's Order)

Director's Order Number Fourteen (16)

Virginia Lottery's "Premium Registration Coupon Promotion" Final Rules for Operation (This Director's Order becomes effective on January 21, 2016, fully replaces the prior Virginia Lottery Premium Registration Coupon Rules)

(DO 121(15)), and shall remain in full force and effect unless amended or rescinded by further Director's Order)

Director's Order Number Fifteen (16)

Virginia Lottery's "Farm Fresh Super Ticket Promotion" Final Rules for Operation (This Director's Order becomes effective on February 2, 2016, and shall remain in full force and effect through the end promotion date unless amended or rescinded by further Director's Order)

Director's Order Number Twenty-Three (16)

Virginia's Lottery Scratch Game 1649 "Super Ticket™ Jewels" Final Rules for Game Operation (effective January 29, 2016)

Director's Order Number Thirty (16)

Virginia's Lottery Scratch Game 1626 "Loteria™" Final Rules for Game Operation (effective February 2, 2016)

Director's Order Number Thirty-Three (16)

Certain Virginia Game Promotion; Game Name Correction. In accordance with the authority granted by §§ 2.2-4002 B 15 and 58.1-4006 A of the Code of Virginia, the following Virginia Lottery promotion - eXTRA Chances Scratcher Promotion (173 15) - Fiscal Year Quarter 3 - is amended as follows in order to correct the name of one of the eligible scratchers:

Section F. Eligibility - the game name in the last row becomes "Super Ticket Jewels".

With the exception of the foregoing change, all terms, conditions, and requirements of the original order and the original game rules continue to apply and remain in full force and effect.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Notice of Intent to Change the Reimbursement Methodology for Pharmacy Services

Notice is hereby given that the Department of Medical Assistance Services (DMAS) intends to change the reimbursement methodology for pharmacy services pursuant to the department's authority under Title XIX of the *Social Security Act*. 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). The changes contained in this public notice are occurring in response to Chapter 665 of the 2015 Acts of the Assembly, Item 301 QQ.

In order to comply with a new requirements in a final federal rule entitled "Medicaid Program; Covered Outpatient Drugs" that was published in the Federal Register on February 1, 2016, DMAS proposes the following new payment methodology for pharmacy services effective July 1, 2016:

A. Reimbursement for covered legend and nonlegend drugs shall be the lowest of subdivisions 1 through 3 of this section:

1. The National Average Drug Acquisition Cost (NADAC) of the drug.
2. In cases where no NADAC is available, DMAS will reimburse at Wholesale Acquisition Cost (WAC).
3. The provider's usual and customary (U&C) charge to the public, as identified by the claim charge.

B. The Public Health Services (PHS) Act § 340B covered entities and federally qualified health centers, or their contracted agents, that fill Medicaid member's prescriptions with drugs purchased at the prices authorized under § 340B must bill Medicaid for the actual acquisition cost.

C. Payment for pharmacy services will be as described above; however, payment for legend and nonlegend drugs will include the allowed cost of the drug plus only one professional dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The professional dispensing fee for all drugs is \$10.65.

D. There is no expected annual increase or decrease in expenditures. The change is expected to be budget-neutral.

A copy of this notice is available for public review from the contact listed below. Comments or inquiries may be submitted, in writing, within 30 days of this notice publication to Donna Proffitt at donna.proffitt@dmass.virginia.gov and such comments are available for review at the same address.

Contact Information: Donna Proffitt, Manager, Pharmacy Services, Department of Medical Assistance Services, Health Care Services, 600 East Broad Street, Richmond, VA 23219, telephone (804)371-0428, or email donna.proffitt@dmass.virginia.gov.

Notice of Public Comment Period: Amendments to 1915(c) Home and Community Based Services Medicaid Waivers

The Department of Medical Assistance Services (DMAS) and Department of Behavioral Health and Developmental Services (DBHDS) will welcome public comment regarding the submission to the Centers for Medicare and Medicaid Services (CMS) amendments to the following 1915(c) Home and Community Based Services (HCBS) Medicaid Waivers: Intellectual Disability (ID); Individual and Family Developmental Disability (DD) Supports; Day Support (DS). For more information and instructions on how to submit comments, please go to: http://www.dmass.virginia.gov/Content_pgs/ltc-home.aspx.

General Notices/Errata

Contact Information: Deana Parker, Policy Analyst, Department of Behavioral Health and Developmental Services, P.O. Box 1797, Richmond, VA 23219, telephone (804) 774-2278, FAX (804) 692-0077, or email deana.parker@dbhds.virginia.gov.

REAL ESTATE BOARD

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Real Estate Board conducted a small business impact review of **18VAC135-11, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Real Estate Board is publishing its report of findings dated January 26, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 2.2-4007.02 of the Code of Virginia mandates the agency to solicit the input of interested parties in the formation and development of its regulations. Therefore, the continued need for the regulation is established in statute. The regulation is necessary to protect public health, safety, and welfare by establishing public participation guidelines that promote public involvement in the development, amendment, or repeal of an agency's regulation. By soliciting the input of interested parties, the agency is better equipped to effectively regulate the occupation or profession.

Since no complaints or comments were received during the public comment period, there does not appear to be a reason to amend or repeal the regulation. The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or contravene federal or state law or regulation.

The most recent periodic review of the regulation occurred in 2012.

On January 21, 2016, the board discussed the regulation and, for the reasons stated determined that the regulation should not be amended or repealed but should be retained in its current form.

Contact Information: Christine Martine, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8552, FAX (866) 826-8863, or email reboard@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Real Estate Board conducted a small business impact review of **18VAC135-20, Virginia Real Estate Board Licensing Regulations**, and determined that this regulation should be retained in its current form. The Real Estate Board is publishing its report of findings dated January 26, 2016, to

support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 54.1-201.5 of the Code of Virginia mandates the Real Estate Board to promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation. The Real Estate Board provides protection to the safety and welfare of the citizens of the Commonwealth by ensuring that only those individuals who meet specific criteria set forth in the statutes and regulations are eligible to receive a real estate license and business registration. The board is also tasked with ensuring that its regulants meet standards of practice that are set forth in the regulations.

No complaints were received during the public comment period. The regulation is clearly written, easily understandable, and does not overlap, duplicate, or conflict with federal or state law or regulation.

The most recent evaluation occurred in 2012.

The board discussed the regulation and, for the reasons stated determined that the regulation should not be amended or repealed but should be retained in its current form.

Contact Information: Christine Martine, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8552, FAX (866) 826-8863, or email reboard@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Real Estate Board conducted a small business impact review of **18VAC135-50, Fair Housing Regulations**, and determined that this regulation should be retained in its current form. The Real Estate Board is publishing its report of findings dated January 26, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 54.1-201.5 of the Code of Virginia mandates the Real Estate Board to promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation. The Real Estate Board and the Fair Housing Board provide protection to the safety and welfare of the citizens of the Commonwealth by ensuring enforcement of the Fair Housing Law. The boards are also tasked with ensuring that its regulants meet standards of practice that are set forth in the regulations.

No comments or complaints were received during the public comment period. The regulation is clearly written, easily understandable, and does not overlap, duplicate, or conflict with federal or state law or regulation.

The most recent evaluation occurred in 2012.

The board discussed the regulation and, for the reasons stated determined that the regulation should not be amended or repealed but should be retained in its current form

Contact Information: Christine Martine, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8552, FAX (866) 826-8863, or email reboard@dpor.virginia.gov.

STATE WATER CONTROL BOARD

Proposed Consent Order for Associated Asphalt Partners, LLC

An enforcement action has been proposed for Associated Asphalt Partners, LLC for violations in Rockbridge County, Virginia. The State Water Control Board proposes to issue a consent order to Associated Asphalt Partners, 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. 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 February 22, 2016, March 23, 2016.

Proposed Consent Special Order for Henry County Public Service Authority

An enforcement action has been proposed with the Henry County Public Service Authority for violations in Henry 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 February 22, 2016, to March 23, 2016.

Total Maximum Daily Load for Beaver Creek Watershed

The Department of Environmental Quality (DEQ) seeks written and oral comments from interested persons on a proposed modification to the completed bacteria and benthic total maximum daily load study for Beaver Creek Watershed located in Bristol City and Washington County, Virginia.

Project description: Bacteria and Benthic TMDL Study Modification located in Bristol City and Washington County: This total maximum daily load (TMDL) was approved by the Environmental Protection Agency on July 6, 2004, and can be found at the following website: <http://www.deq.virginia.gov/portals/0/DEQ/Water/TMDL/ap>

[ptmdls/tenbigvr/beaver.pdf](http://www.deq.virginia.gov/portals/0/DEQ/Water/TMDL/ap). DEQ proposed to revise the TMDL to accommodate the addition of a new permitted discharge in the watershed, to reconfigure the model and update original source assessment estimates based on significant changes to land use.

Public meeting: The public meeting on the TMDL modification will be held on March 1, 2016, from 6 p.m. to 8 p.m. at the Southwest Virginia Higher Education Center, Room CR222 located at One Partnership Circle, Abingdon, VA 24210. In the event of inclement weather, the meeting will be held at the same location on March 8, 2016.

The public comment period will begin March 1, 2016, and end April 1, 2016. An advisory committee to assist in the redevelopment of this TMDL was convened on May 23, 2013 and November 13, 2013.

A component of a TMDL is the wasteload allocations (WLAs); therefore, this notice is provided pursuant to § 2.2-4006 A 14 of the Administrative Process Act for any future adoption of the TMDLs associated WLAs. Information on the development of the TMDLs for these impairments is available upon request. Questions or information requests should be addressed to Martha Chapman, Department of Environmental Quality, Southwest Regional Office, 355-A Deadmore Street, Abingdon, VA 24210, telephone (276) 676-4800, or email martha.chapman@deq.virginia.gov.

Please note, all written comments should include name, address, and telephone number of the person submitting the comments and should be sent to the Department of Environmental Quality contact person listed above.

Total Maximum Daily Load for Cunningham Creek and its Tributaries

Committee meeting: A community meeting will be held Monday, February 29, 2016, at 6.30 p.m. at the Fluvanna County Public Library at 214 Commons Boulevard, Palmyra, VA 22963. This meeting will be open to the public and all are welcome. In the case of inclement weather, the meeting will be postponed until Monday, March 7, 2016, at 6.30 p.m. For more information, please contact Tara Sieber at email tara.sieber@deq.virginia.gov, or telephone (540) 574-7870.

Purpose of notice: The Department of Environmental Quality (DEQ) and its contractors, Virginia Tech's Biological Systems Engineering Department, will discuss population data for the development of a water quality study known as a total maximum daily load (TMDL) for Cunningham Creek and its tributaries. This is an opportunity for local residents to learn about the condition of these streams, share information about the area, and become involved in the process of local water quality improvement. A public comment period (February 29, 2016, through March 28, 2016) will follow the meetings.

General Notices/Errata

Meeting description: A public meeting will be held to introduce to the local community the water quality improvement process in Virginia, known as the TMDL process, invite their participation and solicit their contributions, and review the next steps. 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.

Description of study: These streams do not host a healthy and diverse population of aquatic life, and subsequently was listed as impaired for the "General Benthic (Aquatic life)" water quality standards. In addition, the Middle Fork of Cunningham Creek has an excess of bacteria. The bacteria standard preserves the "Primary Contact (recreational or swimming)" designated use for Virginia waterways. Excessive bacteria levels may pose a threat to human health. This water quality study reports on the sources of bacterial contamination and recommends reductions to meet TMDLs for the impaired waters. A TMDL is the total amount of a pollutant a water body can contain and still meet water quality standards. To restore water quality, bacterial levels need to be reduced to the TMDL amount. Virginia agencies are working to identify sources of bacteria and will determine the cause of the benthic impairments through a weight of evidence approach. Reductions and a TMDL for the cause of the impairment will be developed.

Stream	County	Impairment
Cunningham Creek	Fluvanna County	Aquatic Life
Cunningham Creek - North Fork	Fluvanna County	Aquatic Life
Cunningham Creek - Middle Fork	Fluvanna County	Bacteria, Aquatic Life

How to comment and participate: The meetings of the TMDL process are open to the public and all interested parties are welcome. Written comments will accepted through March 28, 2016, and should include the name, address, and telephone number of the person submitting the comments. For more information or to submit written comments, please contact Tara Sieber, Department of Environmental Quality, Valley Regional Office, P.O. Box 3000, Harrisonburg, VA 22801, telephone (540) 574-7870, FAX (540) 574-7878, or email tara.sieber@deq.virginia.gov.

Total Maximum Daily Load Studies in Waters in Northampton and Accomack Counties

The Virginia Department of Environmental Quality (DEQ) will host a Work Group meeting on water quality studies for Little Mosquito Creek and Assawoman Creek in Accomack County, and Nassawadox Creek with several tributaries located in Northampton County on Thursday, March 10, 2016.

The meeting will start at 6 p.m. in the Accomack-Northampton Planning District Commission building (A-NPDC) located at 23372 Front Street, Accomack, Virginia 23301. The purpose of the meeting is to provide information and discuss the final outcomes of the studies with community members and local government.

Little Mosquito Creek and Assawoman Creek were identified in Virginia's 2014 Water Quality Assessment & Integrated Report as impaired due to violations of the state's water quality standards for dissolved oxygen and do not support the Designated Use for Aquatic Life. Additionally, Nassawadox Creek and several tributaries have been identified as impaired since they do not meet the water quality standards for Shellfish or Recreation Uses due to elevated levels of bacteria.

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the Code of Virginia, require DEQ to develop total maximum daily loads (TMDLs) for pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL Priority List and Report and subsequent water quality assessment reports.

As a result of the studies, DEQ has developed a total maximum daily load for the impaired waters. A TMDL is the total amount of a pollutant a water body can contain and still meet water quality standards. To restore water quality, pollutant levels have to be reduced to the TMDL amount. The Virginia Departments of Environmental Quality, Conservation and Recreation, and Health, along with local governments, are working to identify the sources of pollution in the watersheds of these streams.

The public comment period on materials presented at this meeting will extend from March 11, 2016, to April 11, 2016. For additional information or to submit comments, contact Jennifer Howell, Virginia Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, by telephone at (757) 518-2111, or by email at jennifer.howell@deq.virginia.gov. Additional information is also available on the DEQ website at www.deq.virginia.gov/tmdl.

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.

