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THE 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

Unless exempted by law, an agency wishing to adopt, amend, or repeal regulations must follow the procedures in the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). Typically, this includes first publishing 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 proposed regulation 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 of Regulations 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 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 the final regulation contains changes made after publication of the proposed regulation that 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*. Pursuant to § 2.2-4007.06 of the Code of Virginia, any person may request that the agency solicit additional public comment on certain changes made after publication of the proposed regulation. The agency shall suspend the regulatory process for 30 days upon such request from 25 or more individuals, 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 alternative to the standard process set forth in the Administrative Process Act for regulations deemed by the Governor to be noncontroversial. To use this process, the Governor's concurrence is required and advance notice must be provided to certain legislative committees. Fast-track regulations become effective on the date noted in the regulatory action if fewer than 10 persons object to using the process in accordance with § 2.2-4012.1.

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency may adopt emergency regulations if necessitated by an emergency situation or when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or fewer from its enactment. In either situation, approval of the Governor is required. The emergency regulation is effective upon its filing with the Registrar of Regulations, unless a later date is specified per § 2.2-4012 of the Code of Virginia. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under the circumstances noted in § 2.2-4011 D. Emergency regulations are published as soon as possible in the *Virginia Register* and are on the Register of Regulations website at register.dls.virginia.gov.

During the time the emergency regulation is in effect, the agency may proceed with the adoption of permanent regulations in accordance with the Administrative Process Act. 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. **34:8 VA.R. 763-832 December 11, 2017**, refers to Volume 34, Issue 8, pages 763 through 832 of the *Virginia Register* issued on December 11, 2017.

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; Marcus B. Simon, Vice Chair; Ward L. Armstrong; Nicole Cheuk; Rita Davis; Leslie L. Lilley; Jennifer L. McClellan; Christopher R. Nolen; Don L. Scott, Jr.; Charles S. Sharp; Samuel T. Towell; Malfourd W. Trumbo.

Staff of the Virginia Register: Karen Perrine, Registrar of Regulations; Anne Bloomsburg, Assistant Registrar; Nikki Clemons, Regulations Analyst; Rhonda Dyer, Publications Assistant; Terri Edwards, Senior Operations Staff Assistant.

PUBLICATION SCHEDULE AND DEADLINES

This schedule is available on the Virginia Register of Regulations website (<http://register.dls.virginia.gov>).

August 2021 through August 2022

<u>Volume: Issue</u>	<u>Material Submitted By Noon*</u>	<u>Will Be Published On</u>
37:26	July 28, 2021	August 16, 2021
38:1	August 11, 2021	August 30, 2021
38:2	August 25, 2021	September 13, 2021
38:3	September 8, 2021	September 27, 2021
38:4	September 22, 2021	October 11, 2021
38:5	October 6, 2021	October 25, 2021
38:6	October 20, 2021	November 8, 2021
38:7	November 3, 2021	November 22, 2021
38:8	November 15, 2021 (Monday)	December 6, 2021
38:9	December 1, 2021	December 20, 2021
38:10	December 15, 2021	January 3, 2022
38:11	December 29, 2021	January 17, 2022
38:12	January 12, 2022	January 31, 2022
38:13	January 26, 2022	February 14, 2022
38:14	February 9, 2022	February 28, 2022
38:15	February 23, 2022	March 14, 2022
38:16	March 9, 2022	March 28, 2022
38:17	March 23, 2022	April 11, 2022
38:18	April 6, 2022	April 25, 2022
38:19	April 20, 2022	May 9, 2022
38:20	May 4, 2022	May 23, 2022
38:21	May 18, 2022	June 6, 2022
38:22	June 1, 2022	June 20, 2022
38:23	June 15, 2022	July 4, 2022
38:24	June 29, 2022	July 18, 2022
38:25	July 13, 2022	August 1, 2022
38:26	July 27, 2022	August 15, 2022
39:1	August 10, 2022	August 29, 2022

*Filing deadlines are Wednesdays unless otherwise specified.

PERIODIC REVIEWS AND SMALL BUSINESS IMPACT REVIEWS

TITLE 9. ENVIRONMENT

STATE AIR POLLUTION CONTROL BOARD

Public Comment Period Extension - State Air Pollution Control Board Public Participation Guidelines (9VAC5-5)

Notices of a periodic review of the State Air Pollution Control Board Public Participation Guidelines (9VAC5-5) was published in [37:22 VA.R. 3389 June 21, 2021](#). The notice included a 21-day public comment period ending on July 12, 2021.

This notice announces an extension of the public comment period for the regulation through August 20, 2021.

As previously noticed, the review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in their current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Contact Information: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4178, or email melissa.porterfield@deq.virginia.gov.

Agency Notice

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the following regulations are undergoing a periodic review and a small business impact review: **9VAC5-60, Hazardous Air Pollutant Sources**, and **9VAC5-140, Regulation for Emissions Trading Programs**. The review of these regulations will be guided by the principles in Executive Order 14 (as amended July 16, 2018). The purpose of this review is to determine whether each regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to these regulations, including whether each regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Public comment period begins August 2, 2021, and ends August 23, 2021.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Virginia Regulatory Town Hall and published in the Virginia Register of Regulations.

Contact Information: Gary E. Graham, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 689-4103.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Public Comment Period Extension - Department of Environmental Quality Public Participation Guidelines (9VAC15-11)

Notices of periodic reviews of Department of Environmental Quality Public Participation Guidelines (9VAC15-11) was published in [37:22 VA.R. 3389 June 21, 2021](#). The notice included a 21-day public comment period ending on July 12, 2021.

This notice announces an extension of the public comment period for the regulation through August 20, 2021.

As previously noticed, the review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in their current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Contact Information: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4318, or email melissa.porterfield@deq.virginia.gov.

Agency Notice

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the following regulation is undergoing a periodic review and a small business impact review: **9VAC15-90, Uniform Environmental Covenants Act Regulation**. The review will be guided by the principles in Executive Order 14 (as amended

Periodic Reviews and Small Business Impact Reviews

July 16, 2018). The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Public comment period begins August 2, 2021, and ends August 23, 2021.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Virginia Regulatory Town Hall and published in the Virginia Register of Regulations.

Contact Information: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238.

VIRGINIA WASTE MANAGEMENT BOARD

Public Comment Period Extension - Virginia Waste Management Board Public Participation Guidelines (9VAC20-11)

Notices of periodic reviews of the Virginia Waste Management Board Public Participation Guidelines (9VAC20-11) was published in [37:22 VA.R. 3390 June 21, 2021](#). The notice included a 21-day public comment period ending on July 12, 2021.

This notice announces an extension of the public comment period for the regulation through August 20, 2021.

As previously noticed, the review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in their current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Contact Information: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-

4238, FAX (804) 698-4178, or email melissa.porterfield@deq.virginia.gov.

STATE WATER CONTROL BOARD

Public Comment Period Extension - State Water Control Board Public Participation Guidelines (9VAC25-11)

Notices of periodic reviews of the State Water Control Board Public Participation Guidelines (9VAC25-11) was published in [37:22 VA.R. 3390 June 21, 2021](#). The notice included a 21-day public comment period ending on July 12, 2021.

This notice announces an extension of the public comment period for the regulation through August 20, 2021.

As previously noticed, the review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in their current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Contact Information: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4178, or email melissa.porterfield@deq.virginia.gov.

Agency Notice

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the following regulations are undergoing a periodic review and a small business impact review: **9VAC25-40, Regulation for Nutrient Enriched Waters and Dischargers within the Chesapeake Bay Watershed**, and **9VAC25-191, Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Concentrated Animal Feeding Operations**. The review of these regulations will be guided by the principles in Executive Order 14 (as amended July 16, 2018). The purpose of this review is to determine whether each regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to these regulations, including whether each regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of

Periodic Reviews and Small Business Impact Reviews

applicable law; and (iii) is clearly written and easily understandable.

Public comment period begins August 2, 2021, and ends August 23, 2021.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Virginia Regulatory Town Hall and published in the Virginia Register of Regulations.

Contact Information: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238.

NOTICES OF INTENDED REGULATORY ACTION

TITLE 9. ENVIRONMENT

STATE WATER CONTROL BOARD

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board intends to consider amending **9VAC25-860, Virginia Pollutant Discharge Elimination System General Permit for Potable Water Treatment Plants**. The purpose of the proposed action is to establish permitting requirements for discharges from potable water treatment plants to protect the health, safety, and welfare of citizens. The existing general permit expires on June 30, 2023, and must be reissued to cover existing and new potable water treatment plants.

Issues that may need to be addressed include (i) requiring online registrations and electronic discharge monitoring report submittals when this method becomes available by the Department of Environmental Quality, (ii) reviewing effluent limitations and monitoring frequencies based on past compliance history, (iii) reviewing total daily maximum load requirements, and (iv) reviewing special conditions to ensure they are updated and protective of water quality.

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

Statutory Authority: §§ 62.1-44.15 and 62.1-44.16 of the Code of Virginia; § 402 of the Clean Water Act.

Public Comment Deadline: September 1, 2021.

Agency Contact: Eleanore Daub, Guidance and Regulation Coordinator, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4111, FAX (804) 698-4178, or email elleanore.daub@deq.virginia.gov.

VA.R. Doc. No. R21-6872; Filed July 12, 2021, 9:47 a.m.

REGULATIONS

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

Symbol Key

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

TITLE 9. ENVIRONMENT

STATE WATER CONTROL BOARD

Forms

REGISTRAR'S NOTICE: Forms used in administering the regulation have been 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, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

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.

Agency Contact: Gary Graham, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4103, FAX (804) 698-4178, or email gary.graham@deq.virginia.gov.

FORMS (9VAC25-110)

[VPDES Change of Ownership Agreement Form \(eff. 7/2010\)](#)

[Virginia DEQ Registration Statement - VPDES General Permit for Domestic Sewage Discharges Less than or Equal to 1,000 Gallons Per Day \(2021 Reissuance \(rev. 8/2021\)\)](#)

[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 \(eff. 4/2014\)](#)

VA.R. Doc. No. R21-6856; Filed July 9, 2021, 8:39 a.m.



TITLE 10. FINANCE AND FINANCIAL INSTITUTIONS

STATE CORPORATION COMMISSION

Final Regulation

REGISTRAR'S NOTICE: The State Corporation Commission is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts courts, any agency of the Supreme Court, and any agency that by the Constitution is expressly granted any of the powers of a court of record.

Title of Regulation: 10VAC5-200. Payday Lending (amending 10VAC5-200-10, 10VAC5-200-20, 10VAC5-200-30, 10VAC5-200-60 through 10VAC5-200-120; repealing 10VAC5-200-33, 10VAC5-200-35, 10VAC5-200-40).

Statutory Authority: §§ 6.2-1815 and 12.1-13 of the Code of Virginia.

Effective Date: August 1, 2021.

Agency Contact: Susan Hancock, Deputy Commissioner, Bureau of Financial Institutions, State Corporation Commission, 1300 East Main Street, P.O. Box 640, Richmond, VA 23218, telephone (804) 371-9703, FAX (804) 371-9416, or email susan.hancock@scc.virginia.gov.

Summary:

The amendments align the regulation with the revisions effected by Chapters 1215 and 1258 of the 2020 Acts of Assembly; eliminate obsolete provisions and references from the regulations; and clarify certain aspects of the legislation. Other amendments proposed were summarized in the Order to Take Notice that was entered by the commission on November 30, 2020. As a result of comments received by the public, the commission made numerous changes to the proposed regulation including: (i) in 10VAC5-200-20 A, the geographic limitation on the liquid asset requirement has been removed; (ii) 10VAC5-200-20 I has been modified to permit licensees under Chapter 18 to require or accept multiple checks as security for a short-term loan; (iii) in 10VAC-200-70 A, the posting requirement was amended to also be applicable to licensees that operate over the Internet; (iv) 10VAC5-200-70 E has been modified to clarify that consumers may sign and date their loan applications either by hand or electronically; (v) in 10VAC5-200-80, language has been added to the required text of the short-term lending pamphlet to apprise consumers

Regulations

of some of the new protections that were added by Chapters 1215 and 1258 of the 2020 Acts of Assembly; (vi) in 10VAC5-200-110 F 11, the proposed requirement that a licensee transmit an applicant's gross monthly income and net monthly income to the short-term lending database has been removed; and (vii) 10VAC5-200-115 has been modified to state that the database inquiry fee shall be set by the commission.

AT RICHMOND, JULY 12, 2021

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. BFI-2020-00109

Ex Parte: In the matter of Adopting
Revisions to the Regulations Governing
Licensees under Chapter 18 of Title 6.2
of the Code of Virginia

ORDER ADOPTING REGULATIONS

On November 30, 2020, the State Corporation Commission ("Commission") entered an Order to Take Notice of a proposal by the Bureau of Financial Institutions ("Bureau") to amend the Commission's regulations governing licensees under Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 ("Chapter 18") of the Code of Virginia ("Code"), which are set forth in Chapter 200 of Title 10 of the Virginia Administrative Code ("Chapter 200"). The Bureau submitted the proposed amendments to the Commission because Chapters 1215 and 1258 of the 2020 Virginia Acts of Assembly ("Chapters 1215 and 1258") made extensive revisions to Chapter 18 that became effective on January 1, 2021. The proposed regulations sought to align Chapter 200 with the revisions effected by Chapters 1215 and 1258, eliminate obsolete provisions and references from Chapter 200, and clarify certain aspects of the legislation. The Bureau also proposed an assortment of other changes, which are summarized in the Commission's Order to Take Notice.

The Order to Take Notice and the proposed regulations were published in the Virginia Register of Regulations on December 21, 2020, posted on the Commission's website, and sent to all Chapter 18 licensees, Veritec Solutions, LLC ("Veritec"), and other interested persons. The Order to Take Notice invited all interested persons to participate and required that any comments or requests for a hearing on the proposed regulations be submitted in writing on or before January 5, 2021.

Comments on the proposed regulations were timely filed by Senator Mamie E. Locke and Delegate Lamont Bagby; Delegate C. Todd Gilbert; the Office of the Attorney General; The Pew Charitable Trusts; the Virginia Poverty Law Center ("VPLC"); Anykind Check Cashing, LC ("Anykind"); Check City; EZ Loans of Virginia, Inc. ("EZ Loans"); Populus Financial Group, Inc. d/b/a ACE Cash Express ("ACE"); Possible Financial Inc. d/b/a Possible ("Possible"); and the

Online Lenders Alliance. The Commission did not receive any requests for a hearing.

The Bureau considered the comments filed and responded to them in its Response to Comments ("Response"), which the Bureau filed with the Clerk of the Commission on April 12, 2021. In its Response, the Bureau recommended that the Commission further amend various sections of the proposed regulations.

NOW THE COMMISSION, having considered this matter, finds that the proposed regulations should be modified to incorporate the specific changes the Bureau recommended in its Response, as specified herein, and that the modified proposed regulations should be adopted effective August 1, 2021. The Commission expresses appreciation to those who submitted written comments for our consideration.

The Bureau initially proposed, among other things, including the actual amount of the database inquiry fee in 10 VAC 5-200-115, which reflected an increase based on a request from Veritec. The Commission received numerous comments expressing concern or objecting to Veritec's proposed fee increase in this proceeding.¹ In its Response, the Bureau recommended that the Commission bifurcate this proceeding to afford Veritec the opportunity to furnish the Commission with information pertaining to the cost of operating the Chapter 18 database along with any additional information that Veritec would like to proffer in support of its request.²

We will not amend 10 VAC 5-200-115 to specify the actual amount of the database inquiry fee, nor will we change the database inquiry fee in this proceeding. Accordingly, the fee shall remain at \$1.98 per loan pursuant to the Commission's March 11, 2019 Order Modifying Database Inquiry Fee.³ We adopt the Bureau's other proposed changes to 10 VAC 5-200-115, which shall be modified to state that the database inquiry fee will be "set by the Commission."

Accordingly, IT IS ORDERED THAT:

(1) The proposed regulations, as modified herein and attached hereto, are adopted effective August 1, 2021.

(2) This Order and the attached regulations shall be made available on the Commission's website: scc.virginia.gov/pages/Case-Information.

(3) The Commission's Division of Information Resources shall provide a copy of this Order and the regulations to the Virginia Registrar of Regulations for appropriate publication in the Virginia Register of Regulations.

(4) This case is dismissed, and the papers filed herein shall be placed in the Commission's file for ended causes.

A COPY of this Order and the attached regulations shall be sent by the Clerk of the Commission to the Commission's Office of General Counsel and to the Commissioner of Financial Institutions, who shall send by e-mail or U.S. mail a

copy of this Order and the attached regulations to all Chapter 18 licensees, those persons who submitted comments in this proceeding, and such other interested persons as he may designate. The Clerk of the Commission shall also send a copy of this Order and the attached regulations by electronic mail to: Thomas Reinheimer, Chief Executive Officer, Veritec Solutions, LLC, at thomas.reinheimer@veritecs.com.

¹Senator Mamie E. Locke and Delegate Lamont Bagby, Delegate C. Todd Gilbert, The Pew Charitable Trusts, VPLC, Anykind, Check City, EZ Loans, ACE, and Possible all expressed concern with, or objected to, the database inquiry fee increase.

²Bureau's Response at 12-16.

³Commonwealth of Virginia, ex rel. State Corporation Commission, Ex Parte: In re: database inquiry fee. Case No. BFI-2019-00007, 2019 S.C.C. Ann. Rept. 27, Order Modifying Database Inquiry Fee (March 11, 2019).

Chapter 200
Payday Short-Term Lending

10VAC5-200-10. Definitions.

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

"Act" means Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia.

"Advertisement" means a commercial message in any medium that promotes, directly or indirectly, a short-term loan. This includes a communication sent to a consumer as part of a solicitation of business, but excludes messages on promotional items such as pens, pencils, notepads, hats, and calendars.

~~"Bureau" means the Bureau of Financial Institutions.~~

~~"Business day" for purposes of clause 1 (vi) of § 6.2-1816 of the Code of Virginia the Act and this chapter means a day on which the licensee's office is open for business as posted as required by subsection A of 10VAC5-200-70 licensee is able to make loans pursuant to the Act.~~

~~"Commission" means the State Corporation Commission.~~

~~"Duplicate original" for purposes of subdivision 2 of § 6.2-1816 of the Code of Virginia and this chapter means an exact copy of a signed original, an exact copy with signatures created by the same impression as the original, or an exact copy bearing an original signature.~~

"Good funds instrument" for purposes of ~~clause 1 (vi) of § 6.2-1816 of the Code of Virginia the Act~~ and this chapter means a certified check, cashier's check, money order or, if the licensee is equipped to handle such payments, payment effected by use of a credit card, prepaid card, ~~or~~ debit card, or the Automated Clearing House system.

"Liquid assets" for purposes of the Act and this chapter means ~~cash on hand and in~~ funds held in a checking account or savings

account at a depository institutions institution, money market funds, commercial paper, and treasury bills.

"Member of the military services of the United States" for purposes of the Act and this chapter means a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer.

"Other dependent of a member of the military services of the United States" for purposes of the Act and this chapter means (i) an individual under the age of 18 whose mother or father is a member of the military services of the United States or (ii) an individual for whom a member of the military services of the United States provided more than one-half of the individual's financial support for 180 days immediately preceding the date the individual applied for a payday short-term loan.

"Payday loan" means a loan made pursuant to the Act and this chapter prior to January 1, 2021.

~~"Prepaid card" for purposes of the Act and this chapter means a card with a network logo (e.g., Visa, MasterCard, American Express, or Discover) that is used by a cardholder to access money that has been loaded onto the card in advance.~~

~~"Short maturity loan," as used in the definition of "payday loan" in § 6.2-1800 of the Code of Virginia, means a loan with a term not exceeding 120 days.~~

~~"Small," as used in the definition of "payday loan" in § 6.2-1800 of the Code of Virginia, means \$2,500 or less.~~

B. Other terms used in this chapter shall have the ~~meaning~~ meanings set forth in § 6.2-100 or 6.2-1800 of the Code of Virginia.

10VAC5-200-20. Requirements for licensees; operating rules; acquisitions.

A. A licensee shall maintain unencumbered liquid assets per place of business [~~in Virginia~~] of at least \$25,000 at all times. The minimum liquid assets required to be maintained pursuant to this subsection shall be separate and apart from, and in addition to, any minimum liquid assets that the licensee is required to maintain in connection with any other business conducted in the same office.

B. Any person submitting an application to acquire, directly or indirectly, 25% or more of the voting shares of a corporation or 25% or more of the ownership of any other person licensed to conduct business under the Act shall pay a nonrefundable application fee of \$500.

~~C. Each original license shall be prominently posted in each place of business of the licensee. In order for a licensee to receive a replacement or reissued license, a licensee shall pay a fee of \$50 per place of business to the commission. Licenses will only be replaced or reissued if the licensee is in compliance with all laws and regulations applicable to the~~

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~~conduct of the licensee's business~~ Loans made pursuant to the Act prior to January 1, 2021, that remain outstanding on or after January 1, 2021, may be collected in accordance with the preexisting terms of the loan contracts provided that such terms were permitted by law when the loans were made.

D. If a person has filed a bond with the bureau, as required by § 6.2-1804 of the Code of Virginia, such bond shall be retained by the bureau notwithstanding the occurrence of any of the following events:

1. The person's license is surrendered, suspended, or revoked; ~~or~~
2. The person ceases engaging in business as a payday short-term lender; ~~or~~
3. The person's application for a license is withdrawn or denied.

E. Upon becoming licensed, a licensee shall give written notice to the bureau [~~of its commencement of business~~] within 10 days [~~thereafter after it commences business~~].

F. ~~For purposes of clause 1 (v) of § 6.2-1816 of the Code of Virginia, the number of days in a borrower's pay cycle and the corresponding minimum loan term shall be determined by a licensee in accordance with the following:~~

1. ~~If a borrower is paid on a weekly or more frequent basis, there are seven days in the borrower's pay cycle and the minimum loan term shall be 14 days.~~
2. ~~If a borrower is paid on a biweekly basis, there are 14 days in the borrower's pay cycle and the minimum loan term shall be 28 days.~~
3. ~~If a borrower is paid on a semimonthly basis, there are 15 days in the borrower's pay cycle and the minimum loan term shall be 31 days.~~
4. ~~If a borrower is paid on a monthly basis, there are 30 days in the borrower's pay cycle and the minimum loan term shall be 62 days.~~
5. ~~If a borrower is paid either (i) less frequently than monthly, or (ii) on an irregular basis (but less frequently than weekly), there are 30 days in the borrower's pay cycle and minimum loan term shall be 62 days.~~

G. ~~A licensee shall retain supporting documentation for a borrower's pay cycle in each loan file, which may consist of (i) a copy of a borrower's pay stub or similar periodic earnings statement that clearly reflects the borrower's pay cycle, or (ii) a representation by the borrower in the written loan application.~~

H. ~~F. A licensee shall not (i) electronically debit a borrower's deposit account or otherwise obtain any funds from a borrower by electronic means, including the use of the Automated Clearing House network, electronic funds transfers, electronic check conversions, or re-presented check entries; or (ii) obtain~~

any agreement from a borrower that gives the licensee or a third party the authority to create or otherwise prepare a check that is drawn upon the borrower's account at a depository institution. ~~However, this subsection shall not be construed to prohibit a licensee from printing a replacement security check on behalf of a borrower, at the borrower's request, at such time that the borrower is present in the licensed office and makes a payment on an extended payment plan or an extended term loan. A replacement security check shall be (i) dated as of the date the loan or final installment is due, (ii) issued for the remaining amount owed to the licensee, (iii) manually signed by the borrower, and (iv) exchanged for the check that was previously held as security.~~

~~I. With the exception of the check given by a borrower to a licensee as security for a payday loan, a licensee shall not collect or receive from a borrower any interest or fees permitted by § 6.2-1817 of the Code of Virginia, either in whole or in part, prior to the date of loan maturity unless the borrower is voluntarily making a full or partial prepayment pursuant to 10VAC5-200-40. If a borrower enters into an extended payment plan or extended term loan, a licensee shall not collect or receive any interest or fees, either in whole or in part, prior to the due date of a scheduled installment unless the borrower is voluntarily making a payment in advance.~~

~~J. G. The amount of the check given by a borrower to a licensee as security for a payday short-term loan shall not exceed the sum of the principal amount advanced to the borrower and the interest and fees and charges permitted by § 6.2-1817 of the Code of Virginia. If a borrower enters into an extended payment plan at the time a loan is obtained, the amount of the check shall not include any interest.~~

~~K. H. Upon satisfaction of a loan or upon learning that a loan has been satisfied, a licensee shall attach to each loan agreement retain either (i) a copy of the signed and dated receipt for the payment that satisfied the loan or (ii) if a judgment was obtained and satisfied, a copy of the judgment marked satisfied.~~

~~L. Except as otherwise provided in subdivision B 2 of 10VAC5-200-33 or subdivision D 1 of 10VAC5-200-35, the check used to secure a payday loan shall be dated as of the date the loan is due. I. A licensee shall not deposit or otherwise present for payment a check given as security for a loan, including an extended term loan or a loan that a borrower elected to repay by means of an extended payment plan, prior to the date stated on the face of the check. A licensee [~~shall not may~~] require or accept multiple checks [~~or any additional or alternative security~~] in connection with a payday short-term loan. [~~However, a licensee shall not require or accept any additional or alternative security in connection with a short-term loan.~~]~~

~~M. J. If a borrower (i) cancels or rescinds a loan in accordance with subsection G of 10VAC5-200-40, or (ii) repays a loan in full with cash or a good funds instrument and not with the a~~

check securing the loan, the licensee shall immediately return ~~the~~ any check given as security for the loan to the borrower.

~~N.~~ K. A licensee or former licensee shall provide the following information to the bureau within 10 days after such person's license is surrendered or revoked or the licensed business is otherwise closed: (i) the names, addresses, telephone numbers, ~~fax numbers~~, and email addresses of a designated contact person, the person responsible for updating information in the ~~payday short-term~~ lending database, and the person who consumers may contact to make payment arrangements for outstanding payday loans or short-term loans; (ii) the location of the licensee's or former licensee's payday loan or short-term loan records; and (iii) any additional information that the bureau may reasonably require. A licensee or former licensee shall maintain current information with the bureau until the licensee or former licensee has no outstanding payday loans or short-term loans.

~~O.~~ L. A person shall remain subject to the provisions of the Act and this chapter applicable to licensees in connection with all ~~payday~~ [short-term] loans that the person made while licensed [~~as a~~] ~~payday~~ [short-term lender under the Act] notwithstanding the occurrence of any of the following events:

1. The person's license is surrendered, suspended, or revoked; or
2. The person ceases making ~~payday~~ [short-term] loans [under the Act].

~~P.~~ M. If a licensee or former licensee disposes of records containing a consumer's personal financial information, such records shall be shredded, incinerated, or otherwise disposed of in a secure manner. A licensee or former licensee may arrange for service from a business record destruction vendor.

~~Q.~~ N. Within 15 days following the occurrence of any of the following events, a licensee shall file a written report with the ~~Commissioner of Financial Institutions~~ commissioner describing the event and its expected impact, if any, on the activities of the licensee in Virginia:

1. Bankruptcy, reorganization, or receivership proceedings are filed by or against the licensee.
2. The Attorney General or any other Virginia governmental authority institutes an action against the licensee under the Virginia Consumer Protection Act (§ 59.1-196 et seq. of the Code of Virginia).
3. Any local, state, or federal governmental authority institutes revocation, suspension, or other formal administrative, regulatory, or enforcement proceedings against the licensee.
4. Any local, state, or federal governmental authority (i) revokes or suspends the licensee's ~~payday short-term~~ lender license, ~~deferred presentment~~ license, or similar license; (ii) takes formal administrative, regulatory, or enforcement

action against the licensee relating to its ~~payday short-term~~ lending, ~~deferred presentment~~, or similar business; or (iii) takes any other action against the licensee relating to its ~~payday short-term~~ lending, ~~deferred presentment~~, or similar business where the total amount of restitution or other payment from the licensee exceeds \$20,000. A licensee shall not be required to provide the ~~Commissioner of Financial Institutions~~ commissioner with information about such event to the extent that such disclosure is prohibited by the laws of another state.

5. Based on allegations by any local, state, or federal governmental authority that the licensee violated any law or regulation applicable to the conduct of its licensed ~~payday short-term~~ lending, ~~deferred presentment~~, or similar business, the licensee enters into, or otherwise agrees to the entry of, a settlement or consent order, decree, or agreement with or by such governmental authority.

6. The licensee surrenders its license to engage in ~~payday short-term~~ lending, ~~deferred presentment~~, or similar business in another state in lieu of threatened or pending license revocation, license suspension, or other administrative, regulatory, or enforcement action.

7. The licensee is denied a license to engage in ~~payday short-term~~ lending, ~~deferred presentment~~, or similar business in another state.

8. The licensee or any of its members, partners, directors, officers, principals, or employees is indicted [for] or convicted of a felony.

~~R.~~ O. Pursuant to ~~subsection B of~~ § 6.2-1801 of the Code of Virginia, a licensee shall not make a ~~payday short-term~~ loan that has been arranged or brokered by another person. This provision shall not be construed to prohibit a licensee from originating ~~payday short-term~~ loans through its own employees.

~~S.~~ P. A licensee shall comply with all federal laws and regulations applicable to the conduct of its business, including ~~but not limited to~~ the Truth in Lending Act (15 USC § 1601 et seq.), Regulation Z (12 CFR Part 1026), the Equal Credit Opportunity Act (15 USC § 1691 et seq.), Regulation B (12 CFR Part 1002), and the Standards for Safeguarding Customer Information (16 CFR Part 314).

~~T.~~ Q. A licensee shall not obtain or receive a personal identification number (PIN) for a credit card, prepaid card, debit card, or any other type of card in connection with a ~~payday short-term~~ loan transaction.

~~U.~~ R. A licensee shall not provide any information to a borrower or prospective borrower that is false, misleading, or deceptive.

~~V.~~ S. A licensee shall not engage in any activity that directly or indirectly results in an evasion of the provisions of the Act or this chapter.

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~~T. Any person licensed under the Act to make payday loans as of December 31, 2020, shall be deemed licensed and authorized to make short-term loans pursuant to the Act beginning on January 1, 2021. Licenses issued by the commission prior to January 1, 2021, shall remain in force until they have been surrendered, revoked, or suspended.~~

~~U. A licensee shall continuously maintain the requirements and standards for licensure prescribed in § 6.2-1806 of the Code of Virginia.~~

~~10VAC5-200-30. Notice and payday Short-term lending pamphlet.~~

~~A. Before entering into a payday loan transaction, a licensee shall provide each prospective borrower applicant for a short-term loan with a pamphlet which explains the borrower's rights and responsibilities. This pamphlet shall use that uses the exact language appearing in the "Payday Lending Pamphlet" set forth in 10VAC5-200-80. The form pamphlet shall be printed or typed without alteration separate from all other papers or documents obtained by the licensee in type of size not less than that known as 12 point. The title of the pamphlet ("Payday Short-Term Lending in the Commonwealth of Virginia—Borrower Rights and Responsibilities") and the headings for the individual sections of the pamphlet (e.g., "In General," "Notice from Lender," "Short-Term Lending Database," "Limitations on Security Interest / Obtaining PINs," etc.) shall be in bold-face print or type.~~

~~B. Prior to furnishing a prospective borrower with a loan application or receiving any information relating to loan qualification, a licensee shall provide each prospective borrower with a printed notice which states the following: "WARNING: A payday loan is not intended to meet long term financial needs. It is recommended that you use a payday loan only to meet occasional or unusual short term cash needs."~~

~~1. The notice and acknowledgement shall be printed or typed on 8 1/2 x 11 paper without alteration, be separate from all other papers or documents obtained by the licensee, and be in type not less than that known as 24 point. The notice must also end of each application form shall contain an acknowledgement a separate acknowledgment stating the following: "I acknowledge that I have received a copy of this notice and the pamphlet entitled "Payday Short-Term Lending in the Commonwealth of Virginia—Borrower Rights and Responsibilities."~~

~~2. The notice acknowledgment must be signed initialed and dated by each prospective borrower applicant for a short-term loan. A duplicate original of the acknowledged notice shall be kept in the separate loan file maintained with respect to the loan for the period specified in § 6.2-1809 of the Code of Virginia.~~

~~10VAC5-200-33. Extended payment plans. (Repealed.)~~

~~A. In any rolling 12 month period, an eligible borrower may elect to pay an outstanding payday loan from any licensee by means of an extended payment plan. A borrower shall not be eligible to obtain an extended payment plan if the borrower obtained an extended payment plan within the preceding 12 months.~~

~~B. A borrower may enter into an extended payment plan at any time on or after the date a loan is made through the date that the loan is due to be repaid. A borrower shall not be permitted to repay a past due payday loan by means of an extended payment plan. If a loan is past due and a borrower cannot obtain an extended payment plan, a licensee may voluntarily accept payments from a borrower in accordance with subsection H of 10VAC5-200-70.~~

~~1. If an eligible borrower elects an extended payment plan, a licensee shall permit the borrower to repay the amount owed in at least four equal installments over a term of at least 60 days. The dollar amount of each installment shall be the same and the installment due dates shall be spread out evenly over the term of the extended payment plan (e.g., if the term is 60 days and there are four installments, an installment shall be due every 15 days).~~

~~2. If a borrower enters into an extended payment plan on the date a loan is made, the check used to secure the loan shall be dated as of the date the final installment is due. A licensee shall not require or accept multiple checks or any additional or alternative security in connection with an extended payment plan. A borrower shall have the option of exchanging security checks with a licensee at the time the borrower makes a payment on an extended payment plan. If a borrower wishes to exchange security checks, a licensee shall upon receipt of the payment return the check held as security to the borrower and the borrower shall deliver to the licensee a replacement security check, dated as of the date the final installment is due, for the remaining amount owed to the licensee.~~

~~3. A borrower who elects to repay a payday loan with an extended payment plan shall not be eligible for another payday loan until 90 days after the borrower has repaid or satisfied in full the balance of the loan.~~

~~C. A licensee shall provide notice to borrowers of the potential availability of the extended payment plan option in accordance with the provisions of this subsection.~~

~~1. A licensee shall conspicuously post in each licensed location a written notice in at least 24 point bold type informing borrowers that they may be eligible to enter into an extended payment plan. The minimum size for such written notice shall be 24 inches by 18 inches.~~

~~2. The title of the written notice, which shall appear in at least 48 point bold type, shall be "NOTICE—EXTENDED~~

~~PAYMENT PLANS AVAILABLE TO ELIGIBLE BORROWERS AT NO ADDITIONAL COST."~~

3. The required text of the written notice shall be as follows:

~~If you are eligible, you have the option of repaying a payday loan by means of an extended payment plan. You may only obtain an extended payment plan once in any rolling 12 month period (even if you obtain loans from different lenders or locations). You may obtain an extended payment plan at any time on or after the date that you receive your loan through the date that your loan is due to be repaid. Under an extended payment plan, you will be permitted to repay the amount you owe in at least four equal installments over a term of at least 60 days. You will not be charged any additional interest or fees in connection with an extended payment plan, and interest will not accrue during the term of an extended payment plan. When you make a payment on an extended payment plan, you will have the option of providing a replacement security check for the remaining amount you owe. Please be advised that if you obtain an extended payment plan, you will not be permitted to get another payday loan from any lender for a period of 90 days after you fully repay or satisfy the extended payment plan.~~

~~4. If the payday lending database referred to in 10VAC5-200-110 advises a licensee that an applicant is eligible for an extended payment plan, the licensee shall immediately provide oral notice to the applicant that (i) the applicant is eligible to repay the payday loan through an extended payment plan; (ii) information about extended payment plans may be found on the poster in the licensee's office or in the "Borrower Rights and Responsibilities" pamphlet; and (iii) the licensee is available to answer any questions that the applicant may have about extended payment plans. When providing this notice, the licensee shall also direct the applicant to the specific locations of both the poster referred to in subdivision 1 of this subsection and the section of the pamphlet entitled "Extended Payment Plans."~~

~~D. A licensee shall immediately give a borrower receipts, signed and dated by the licensee, for all payments made in connection with an extended payment plan. The receipts shall also state the loan balance due after each payment.~~

~~E. A licensee shall retain the written and signed extended payment plan document identifying the terms of the extended payment plan and provide the borrower with a duplicate original. A licensee shall also retain copies of receipts provided in accordance with subsection D of this section. Upon full repayment or satisfaction of an extended payment plan, a licensee shall mark both the original loan agreement and original extended payment plan document with the word "paid" or "canceled," return both items to the borrower, and retain copies in its loan records.~~

~~10VAC5-200-35. Five payday loans within 180 days. (Repealed.)~~

~~A. A borrower obtaining a fifth payday loan within any rolling 180 day period may elect, at the option of the borrower, (i) to repay the loan through an extended payment plan, unless the borrower previously elected an extended payment plan within the preceding 12 months, or (ii) to obtain the loan in the form of an extended term loan.~~

~~B. If a borrower does not obtain an extended payment plan or extended term loan in connection with his fifth payday loan in 180 days, the borrower shall not be eligible for another payday loan until 45 days after the date the fifth payday loan is paid or otherwise satisfied in full.~~

~~C. If a borrower previously obtained an extended payment plan within the preceding 12 month period, the borrower shall not be eligible to repay a fifth payday loan obtained in any rolling 180 day period by means of an extended payment plan. However, if an eligible borrower elects to repay a fifth payday loan obtained in any rolling 180 day period by means of an extended payment plan, the provisions of 10VAC5-200-33 shall apply. A borrower who elects to repay such loan by means of an extended payment plan shall not be eligible for another payday loan until 90 days after the borrower has repaid or satisfied in full the balance of the loan.~~

~~D. The following provisions shall apply to extended term loans:~~

~~1. An extended term loan is a payday loan, as this term is defined in § 6.2-1800 of the Code of Virginia. As with other payday loans, an extended term loan shall be secured by a check that does not exceed the sum of the principal amount advanced to the borrower and the interest and fees permitted by § 6.2-1817 of the Code of Virginia. The check used to secure an extended term loan shall be dated as of the date the final installment is due. A licensee shall not require or accept multiple checks or any additional or alternative security in connection with an extended term loan. A borrower shall have the option of exchanging security checks with a licensee at the time the borrower makes a payment on an extended term loan. If a borrower wishes to exchange security checks, a licensee shall upon receipt of the payment return the check held as security to the borrower and the borrower shall deliver to the licensee a replacement security check, dated as of the date the final installment is due, for the remaining amount owed to the licensee.~~

~~2. If an eligible borrower elects an extended term loan, a licensee shall permit the borrower to repay the amount owed in four equal installments over a term of 60 days. The dollar amount of each installment shall be the same and the installment due dates shall be spread out evenly over the term of the extended term loan (i.e., an installment shall be due every 15 days).~~

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3. The terms of an extended term loan shall be set forth in a written agreement signed and dated by the borrower. An eligible borrower may elect the extended term loan option only on the date a payday loan is made.

4. A borrower who obtains an extended term loan shall not be eligible for another payday loan during the longer of 90 days following the date the extended term loan is paid or otherwise satisfied in full, or 150 days following the date the extended term loan is obtained. Subject to one of the applicable waiting periods associated with a fifth loan in any rolling 180 day period, a borrower may be eligible for consecutive extended term loans or multiple extended term loans in any rolling 12 month period.

5. A licensee shall immediately give a borrower receipts, signed and dated by the licensee, for all payments made in connection with an extended term loan. The receipts shall also state the loan balance due after each payment.

6. A licensee shall retain the written and signed extended term loan agreement and provide the borrower with a duplicate original. A licensee shall also retain copies of receipts provided in accordance with subdivision 5 of this subsection. Upon full repayment or satisfaction of an extended term loan, a licensee shall mark the original extended term loan agreement with the word "paid" or "canceled," return it to the borrower, and retain a copy in its loan records.

E. A licensee shall provide notice to borrowers of the potential availability of the extended term loan option in accordance with the provisions of this subsection.

1. A licensee shall conspicuously post in each licensed location a written notice in at least 24 point bold type informing borrowers that they may be eligible to obtain an extended term loan. The minimum size for such written notice shall be 24 inches by 18 inches.

2. The title of the written notice, which shall appear in at least 48 point bold type, shall be "NOTICE EXTENDED TERM LOANS AVAILABLE TO BORROWERS OBTAINING A FIFTH PAYDAY LOAN WITHIN 180 DAYS."

3. The required text of the written notice shall be as follows:

Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia gives borrowers obtaining their fifth payday loan within 180 days the option to receive it in the form of an extended term loan. An extended term loan is a payday loan under which you are permitted to repay the amount you owe in four equal installments spread out evenly over a term of 60 days. You may obtain an extended term loan even if you previously obtained another extended term loan or an extended payment plan. If you want an extended term loan, you must choose this option on the date you obtain the payday loan. When you make a payment on an extended

term loan, you will have the option of providing a replacement security check for the remaining amount you owe. Please be advised that if you obtain an extended term loan, you will not be permitted to get another payday loan from any lender for a period of 90 days after you fully repay or satisfy the extended term loan or 150 days after you obtain the extended term loan (whichever is longer). However, even if you do not choose an installment payment arrangement, you will still be unable to obtain another payday loan from any lender for a period of 45 days after you fully repay or satisfy your fifth payday loan.

4. If the payday lending database referred to in 10VAC5-200-110 advises a licensee that an applicant is eligible for an extended term loan, the licensee shall immediately provide oral notice to the applicant that (i) the applicant is eligible to obtain an extended term loan; (ii) information about extended term loans may be found on the poster in the licensee's office or in the "Borrower Rights and Responsibilities" pamphlet; and (iii) the licensee is available to answer any questions that the applicant may have about extended term loans. When providing this notice, the licensee shall also direct the applicant to the specific locations of both the poster referred to in subdivision 1 of this subsection and the section of the pamphlet entitled "Five Payday Loans within 180 days." In addition, if the payday lending database advises a licensee that an applicant is eligible for an extended payment plan, the licensee shall also comply with subdivision C 4 of 10VAC5-200-33.

10VAC5-200-40. Borrower prepayment; right to cancel. (Repealed.)

A. In order to prepay a payday loan in full, a borrower shall only be required to pay the principal amount advanced as well as any accrued and unpaid fees. A borrower shall be permitted to make partial payments, in increments of not less than \$5.00, on the loan at any time without charge. The licensee shall give the borrower signed, dated receipts for each payment made, which shall state the balance due on the loan.

B. For purposes of the Act and this chapter, the interest and loan fee permitted by subsections A and B of § 6.2-1817 of the Code of Virginia shall be deemed accrued on a straight line basis over the term of a payday loan. A licensee shall calculate interest charges using either a 360 day year or a 365 day year. The verification fee permitted by subsection C of § 6.2-1817 of the Code of Virginia shall be deemed accrued in full at the time a payday loan is made.

C. 1. A borrower choosing to prepay his payday loan in full shall only be responsible for the verification fee and the pro-rata portion of the total interest and loan fee based upon the number of days that have elapsed between the loan disbursement date and the date of repayment. (For example, if a \$400 loan with a simple annual interest rate of 36%, a 20% loan fee, a \$5.00 verification fee, a term of 28 days, and a 360-day year is prepaid in full after seven days, the borrower shall

only be required to pay in cash or good funds instrument \$427.80 (\$400 + \$2.80 interest + \$20 loan fee + \$5.00 verification fee) to the licensee.)

2. A borrower choosing to make partial payments on a payday loan shall only be responsible for the verification fee and the pro rata portion of the total interest and loan fee based upon the timing and amount of such partial payments. (For example, given a \$500 loan with a simple annual interest rate of 36%, a 20% loan fee, a \$5.00 verification fee, a term of 31 days, and a 360 day year, a borrower making a partial payment of \$200 after 15 days shall only be required to pay a total of \$603.91 to the licensee (\$500 principal + \$103.91 interest and fees). In this example, \$60.89 of the borrower's \$200 partial payment would be applied toward interest (\$7.50) and fees (\$48.39 loan fee + \$5.00 verification fee) and the remaining \$139.11 would be applied toward principal, thereby resulting in an outstanding balance of \$360.89 until maturity. Based on this outstanding balance, the charges for the remainder of the term are \$5.77 (interest on \$360.89 for 16 days) + \$37.25 (loan fee on \$360.89 pro-rated for 16 days).)

D. If a borrower enters into an extended payment plan and subsequently elects to prepay it in full, the borrower shall only be responsible for the verification fee, any interest that accrued prior to the borrower entering into the extended payment plan, and the pro rata portion of the total loan fee based upon the number of days that have elapsed between the loan disbursement date and the date the loan would have been due if the borrower had not entered into the extended payment plan. The total payoff amount shall be reduced by the amount of any installment payments made by the borrower prior to prepaying the extended payment plan in full.

1. Example: Assume that a borrower who is paid on a semimonthly basis (minimum term of 31 days) obtains a \$500 loan on April 1 with an extended payment plan, an extended payment plan term of 60 days, no interest (interest does not accrue during the term of an extended payment plan), a 20% loan fee, a \$5.00 verification fee, and installment payments of \$151.25 due on April 16, May 1, May 16, and May 31. Since the borrower is paid on a semimonthly basis, the loan fee shall accrue over a period of 31 days. If the borrower prepays the extended payment plan in full on April 21, the borrower shall only be required to pay in cash or good funds instrument the principal (\$500), a pro rata portion of the loan fee (\$64.52), and the verification fee (\$5.00) for a total of \$569.52 to the licensee. If the borrower made an installment payment of \$151.25 on April 16, the payoff amount on April 21 would be \$418.27 (\$569.52 - \$151.25).

2. Example: Assume that a borrower who is paid on a semimonthly basis obtains a \$500 loan on April 1 with a simple annual interest rate of 36%, a 20% loan fee, a \$5.00 verification fee, a term of 31 days, and a 360 day year. Next

assume that the borrower elects an extended payment plan on April 23 with a term of 60 days and installment payments of \$154 due on May 8, May 23, June 7, and June 22. If the borrower prepays the extended payment plan in full on June 2, the borrower shall only be required to pay in cash or good funds instrument the principal (\$500), the interest that accrued prior to the borrower electing an extended payment plan (\$11), the entire loan fee (\$100), and the verification fee (\$5.00) for a total of \$616 to the licensee. If the borrower made installment payments of \$154 on both May 8 and May 23, the payoff amount on June 2 would be \$308 (\$616 - \$154 - \$154).

E. If a borrower enters into an extended term loan and subsequently elects to prepay it in full, the borrower shall only be responsible for the verification fee and the pro rata portion of the total interest and loan fee based upon the number of days that have elapsed between the loan disbursement date and the loan maturity date (i.e., the date the fourth installment is due). The total payoff amount shall be reduced by the amount of any installment payments made by the borrower prior to prepaying the extended term loan in full.

Example: Assume that a borrower obtains a \$500 extended term loan on April 1 with a simple annual interest rate of 36%, a 20% loan fee, a \$5.00 verification fee, a 360 day year, a 60-day term, and installment payments of \$158.75 due on April 16, May 1, May 16, and May 31. If the borrower prepays the extended term loan in full on May 20, the borrower shall only be required to pay in cash or good funds instrument the principal (\$500), the interest that accrued for 49 days (\$24.50), a pro rata portion of the loan fee (\$81.67), and the verification fee (\$5.00) for a total of \$611.17 to the licensee. If the borrower made installment payments of \$158.75 on April 16, May 1, and May 16, the payoff amount on May 20 would be \$134.92 (\$611.17 - \$158.75 - \$158.75 - \$158.75).

F. Unless it results in the prepayment in full of an extended payment plan or extended term loan pursuant to subsection D or E of this section, a partial payment, excess payment, installment payment, or other payment received by a licensee in advance of the date the funds are due under the terms of the extended payment plan or extended term loan shall not result in a modification of the payment schedule or a pro rata adjustment of the total interest, if any, or loan fee. Payments made by a borrower pursuant to an extended payment plan or extended term loan shall be first applied to any past due installment and then to the next regularly scheduled installment.

G. Notwithstanding any provision of this section, a borrower shall have the right to cancel a payday loan (including an extended term loan or a loan repayable by means of an extended payment plan) at any time before the close of business on the next business day following the date of the loan by paying to the licensee, in the form of cash or good funds instrument, the principal amount advanced to the borrower.

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~~The licensee shall not be entitled to charge or receive any interest or fees, including a verification fee, when a borrower cancels a payday loan.~~

10VAC5-200-60. Posting of charges.

A. A licensee shall conspicuously post the following in ~~its~~ each licensed location and on its website:

1. A schedule of payments, fees and interest charges, with examples using (i) a \$300 loan payable in 14 days that is repaid in three months; (ii) a \$300 \$500 loan payable in 30 days that is repaid in five months; and (iii) a \$300 \$1,000 loan payable in 31 days; (iv) a \$300 loan payable in 62 days; and (v) a \$300 extended term loan that is repaid in 10 months. A licensee may post additional examples when posting the information required by this subsection.

2. A notice with this statement: "If you wish to file a complaint against us, you may contact the Virginia Bureau of Financial Institutions at (800) 552-7945 or at scc.virginia.gov."

B. A licensee shall display its fees and interest charges not only as a dollar amount, but also as an Annual Percentage Rate, which shall be stated using this term, calculated in accordance with Regulation Z (12 CFR Part 1026).

10VAC5-200-70. Additional business requirements and restrictions.

A. A licensee shall ~~conspicuously~~ post [on its website, and] in or on its licensed locations [so that the posting is legible from the outside,] the days and hours during which it is open for business [so that the posting is legible from outside].

~~B. A licensee shall not deposit or otherwise present for payment more than two times any check given by a borrower as security for a loan, and in no event shall a licensee recover from a borrower more than a total of \$25 attributable to returned check fees incurred by the licensee with respect to a single check. Subject to subdivision 11 or 12 of § 6.2-1816 of the Code of Virginia, if applicable, a licensee may charge and collect from a borrower the actual amount of one or more deposit item return fees incurred by the licensee provided that (i) the conditions prescribed in § 6.2-1817 A 3 of the Code of Virginia are met, and (ii) the amount charged and collected does not exceed \$25 per deposit item return fee.~~

C. A licensee shall not knowingly make a payday short-term loan to a member of the military services of the United States, or the spouse or other dependent of a member of the military services of the United States. To enable a licensee to make this determination, a licensee shall clearly and conspicuously include the following questions in its written loan application, which the licensee shall require each applicant to answer before ~~obtaining~~ making a payday short-term loan. A licensee shall not make a payday short-term loan to an applicant unless the applicant answers "no" to all of these questions:

1. Are you a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer?

2. Are you married to a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer?

3. Are you under the age of 18 and the son or daughter of a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer?

4. Was more than one-half of your financial support for the past 180 days provided by a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer?

D. A licensee shall maintain in its licensed offices such books, accounts, and records as the ~~Commissioner of Financial Institutions~~ commissioner may reasonably require in order to determine whether such licensee is complying with the provisions of the Act and all rules and regulations adopted in furtherance thereof. Such books, accounts, and records shall be maintained apart and separate from those relating to any other business in which the licensee is involved. Such records relating to loans, including loan applications, shall be retained for at least three years after final payment is made on any loan.

~~E. A licensee shall report, in accordance with § 6.2-1812 of the Code of Virginia, the institution of an action against the licensee under the Virginia Consumer Protection Act (§ 59.1-496 et seq. of the Code of Virginia) by the Attorney General or any other governmental authority require each applicant for a short-term loan to sign and date a written loan application prior to the licensee making a credit decision. [An applicant may sign and date the loan application by hand or electronically.]~~

F. A licensee shall endeavor to provide the loan documents, ~~printed notice,~~ and pamphlet required by 10VAC5-200-30; in a language other than English when a prospective borrower is unable to read the materials printed in English.

~~G. A licensee shall not file or initiate a legal proceeding against a borrower until 60 days after the date of default on a payday loan, including defaults under extended payment plans or extended term loans, during which time the licensee and borrower may voluntarily enter into a repayment arrangement.~~

H. Nothing in the Act or this chapter shall be construed to prohibit a licensee from voluntarily accepting a payment on an outstanding loan from a borrower after the date that such payment was due to the licensee. However, except as otherwise permitted by the Act and this chapter, the licensee shall not

collect, receive, or otherwise recover any additional interest, fees, or charges from the borrower.

H. If a licensee disburses loan proceeds by means of a check, the licensee shall not (i) charge the borrower a fee for cashing the check or (ii) permit either an affiliate or any person in the same office as the licensee to charge the borrower a fee for cashing the check.

10VAC5-200-75. Annual reporting requirements.

~~When~~ Unless otherwise directed by the commissioner, licensees shall provide the following data regarding loans made pursuant to the Act when making the annual report required by § 6.2-1811 of the Code of Virginia, in addition to other information required by the commissioner, licensees shall provide the following data:

1. The total number and dollar amount of payday loans made.
2. The total number of individual borrowers to whom loans were made.
3. The minimum, and maximum, ~~and average dollar amount of payday loans made~~ contracted loan amount.
4. The average contracted annual percentage rate, ~~and range of annual percentage rates, charged on payday loans made.~~
5. The average number of days, ~~and the range of number of days, of the term of payday loans made~~ total amount of contracted loan charges.
6. The total amount of loan charges actually paid.
7. ~~The total number and dollar amount of returned checks ultimately paid.~~
8. ~~The total number and dollar amount of returned checks charged off as uncollectible defaulted loans.~~
9. The total number of charged-off loans and the total dollar amount of returned check fees collected from borrowers whose checks are returned for insufficient funds charged off.
10. The total number of individual borrowers against whom ~~lawsuits were instituted~~ civil actions were brought.
11. ~~The number of individual borrowers who received more than one loan but less than 13 loans, and the number of individual borrowers who received 13 loans or more~~ Any additional information required by the commissioner.

10VAC5-200-80. Payday Short-term lending pamphlet text.

The required text of the payday short-term lending pamphlet referred to in 10VAC5-200-30 is as follows:

PAYDAY SHORT-TERM LENDING IN THE COMMONWEALTH OF VIRGINIA

BORROWER RIGHTS AND RESPONSIBILITIES

Please take the time to carefully review the information contained in this pamphlet. It is designed to advise you of your rights and responsibilities in connection with obtaining a payday short-term loan in Virginia under Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia. If you have any questions about payday short-term lending or want additional information, you may contact the Virginia State Corporation Commission's Bureau of Financial Institutions toll-free at (800) 552-7945 or ~~on the Internet at~~ http://www.scc.virginia.gov/bfi scc.virginia.gov. ~~The Bureau of Financial Institutions has available a "Consumer Guide to Payday Lending" that may be viewed at this website or obtained by calling the toll free telephone number listed above.~~

In General: You are responsible for evaluating whether a payday short-term loan is right for you. Alternatives may include among other things less expensive short-term financing from another financial institution, family, [~~or~~] friends, [or] a cash advance on a credit card [~~or an account with overdraft protection~~], ~~or a loan repayable over several months.~~

Advertisements: A lender is prohibited from sending you an envelope or other written material that gives the false impression that it is an official communication from a governmental entity, unless it is required by the United States Postal Service.

Notice from Lender: ~~The lender is required to provide you with a clear and conspicuous printed notice advising you that a payday loan is not intended to meet long term financial needs and that you should use a payday loan only to meet occasional or unusual short term cash needs.~~

Information from Lender: Virginia law prohibits the lender from providing you with any false, misleading, or deceptive information.

Payday Short-Term Lending Database: Before making a payday short-term loan to you, a lender is required by Virginia law to access a database that ~~contains detailed information about payday loans made to Virginia residents by all lenders licensed to do business in Virginia.~~ The database will inform the lender whether you are eligible for a payday short-term loan. The Bureau of Financial Institutions is unable to advise you of your eligibility for a payday short-term loan. If you are ineligible for a payday loan, the lender will provide you with the toll-free telephone number of the database provider, which you can use to find out the specific reason for your ineligibility. To enable the lender to check the database, you will be required to provide the lender with a written signed and dated loan application and ~~your~~ the original or a copy of your current driver's license or identification card issued by a state driver's licensing authority (e.g., Department of Motor Vehicles for the Commonwealth of Virginia). ~~If you wish to obtain a payday loan but do not have a driver's license or identification card,~~

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you will need to obtain a driver's license or identification card from the driver's licensing authority in your home state.

Prohibition on Loans to Individuals with Certain Previous or Outstanding Loans: Virginia law prohibits a lender from making a payday loan to you if (i) you currently have an outstanding payday loan; (ii) you paid or satisfied in full a previous payday loan on the same day that you are applying for a new payday loan; (iii) in the past 90 days you paid or satisfied in full a previous payday loan by means of an extended payment plan; (iv) in the past 45 days you paid or satisfied in full a fifth payday loan that you obtained within a period of 180 days; (v) in the past 90 days you paid or satisfied in full an extended term loan; or (vi) in the past 150 days you entered into an extended term loan.

It is important to note that the previous or outstanding payday loans referred to above include loans made by the same lender as well as any other lender conducting payday lending business in Virginia.

Verification of Income: Before making a short-term loan to you, a lender must make a reasonable attempt to verify and document your income.

Prohibition on Loans to Members of the Military and their Spouses and Dependents: Virginia law prohibits lenders from making payday short-term loans to members of the military services of the United States as well as their spouses and dependents. If you are a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer, the lender is prohibited from making a payday short-term loan to you. The lender is also prohibited from making a loan to you if (i) you are married to such a member, (ii) you are less than 18 years old and the son or daughter of such a member, or (iii) more than one-half of your financial support for the past 180 days was provided by such a member.

Limitations on Security Interest / Prohibition on Obtaining Funds Electronically / Obtaining PINs: The lender [~~cannot may~~] require you to provide [one or] more [~~than one check checks~~] as security for [any your] payday short-term loan. The check [or checks] must be dated ~~as of~~ no earlier than the date your loan is due of the first required loan payment shown in your loan agreement. The lender cannot require you to provide any security for your payday short-term loan other than [a check one or more checks] payable to the lender. ~~The lender is also prohibited from electronically debiting your deposit account or obtaining any of your funds by electronic means.~~ The lender also cannot obtain any agreement from you that gives the lender or a third party the authority to prepare a check that is drawn upon your deposit account. Additionally, the lender is prohibited from obtaining or receiving a personal identification number (PIN) for a credit card, prepaid card, debit card, or any other type of card in connection with your loan.

One Loan at a Time / \$500 \$2,500 Maximum: The lender cannot have Virginia law prohibits you from having more than one short-term loan outstanding to you at any one time. If you currently have an outstanding payday a short-term loan or a motor vehicle title loan from any lender that is licensed to make these types of loans, then you cannot obtain another payday are prohibited from obtaining a short-term loan. The maximum loan amount is \$500 \$2,500.

Minimum Loan Term: Under Virginia law, your loan term must be at least twice as long as your pay cycle. For example, if you are paid on a weekly basis, your minimum loan term would be 14 days cannot be more than 24 months. Your loan term also cannot be less than four months unless your total monthly payment will not exceed the greater of (i) 5.0% of your verified gross monthly income or (ii) 6.0% of your verified net monthly income.

Fees, Charges, and Interest: Your loan is payable in substantially equal installments of principal, fees, and interest combined. The lender is permitted to charge you (i) interest at a simple annual rate of ~~not to exceed 36%,~~ (ii) ~~a loan fee not exceeding 20% of the amount of money advanced to you (i.e., \$20 per \$100 advanced),~~ and (iii) ~~a verification fee not exceeding \$5.00;~~ and (ii) a monthly maintenance fee that does not exceed the lesser of \$25 or 8.0% of your originally contracted loan amount, provided that the maintenance fee is not added to your loan balance on which interest is charged. [For example, if the lender advances you] ~~\$300 for 31 days, the lender may charge you up to \$9.30 interest, a loan fee of \$60, and a verification fee of \$5.00 for a total of \$74.30 [\$500 and your loan is repayable in five substantially equal monthly installments, the lender may charge you interest totaling \$45.90 and monthly maintenance fees totaling \$125 for a combined total cost of \$170.90. If the lender advances you] \$300 for 62 days, the lender may charge you up to \$18.60 interest, a loan fee of \$60, and a verification fee of \$5.00 for a total of \$83.60 [\$1,000 and your loan is repayable in 10 substantially equal monthly installments, the lender may charge you interest totaling \$172.30 and monthly maintenance fees totaling \$250 for a combined total cost of \$422.30.] Other than the specific fees and costs discussed in this section and the section of this pamphlet entitled "Failure to Repay" (see below), no additional amounts may be directly or indirectly charged, contracted for, collected, received, or recovered by the lender. Note that if your originally contracted loan amount is \$1,500 or less, the lender cannot charge or receive from you a total amount of fees and charges greater than 50% of your loan amount. If your loan amount is more than \$1,500, the total amount of fees and charges cannot exceed 60% of your loan amount.~~

In addition to interest and the monthly maintenance fee, the lender may charge you a deposit item return fee for the actual amount incurred by the lender, not to exceed \$25, if your check or electronic payment is returned unpaid because the account on which it was drawn was closed by you or contained insufficient funds, or you stopped payment on the check or

electronic payment. If you make a payment more than seven calendar days after its due date, the lender may also impose a late charge of up to 5.0% of the amount of the payment, but not to exceed \$20.

You will receive your loan proceeds in the form of either cash or a check from the lender. The lender cannot charge you a fee for cashing their check. Similarly, a check-casher affiliated with an affiliate of the lender or a person in the lender's office cannot charge you a fee for cashing the lender's check.

The fees, charges, and interest mentioned in this section may not be charged, collected, or received unless they are included in your written loan agreement.

Written Agreement: The lender must provide you with a written loan agreement, which must be signed by both you and an authorized representative of the lender. The loan agreement is a binding, legal document that requires you to repay the loan. Make sure you read the entire loan agreement carefully before signing and dating it. The lender must provide you with a duplicate original copy of the signed loan agreement at the time of your loan transaction. If any provision of your loan agreement violates Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia, the provision will not be enforceable against you.

~~**Extended Payment Plans:** Under Virginia law eligible borrowers have the option of repaying a payday loan by means of an extended payment plan. You may only obtain an extended payment plan once in any rolling 12-month period (even if you obtain loans from different lenders or locations). You may obtain an extended payment plan at any time on or after the date that you received your loan through the date that your loan is due to be repaid.~~

~~Under an extended payment plan, you are permitted to repay the amount you owe in at least four equal installments spread out evenly over a term of at least 60 days. You will not be charged any additional interest or fees in connection with an extended payment plan, and interest will not accrue during the term of an extended payment plan.~~

~~If you obtain an extended payment plan, you will not be able to get another payday loan from any lender for a period of 90 days after you fully repay or satisfy the extended payment plan.~~

~~**Five Payday Loans within 180 Days:** If you are obtaining a fifth payday loan within a rolling 180-day period, you have the option to (i) repay the fifth loan through an extended payment plan, unless you previously obtained an extended payment plan within the preceding 12 months, or (ii) obtain the loan in the form of an extended term loan.~~

~~You do not have to choose either one of these options. However, even if you do not obtain an extended payment plan or extended term loan, you will not be able to obtain another payday loan from any lender for a period of 45 days after you fully repay or satisfy your fifth payday loan.~~

~~Extended payment plans are discussed above. If you are eligible to repay your fifth payday loan by means of an~~

~~extended payment plan and choose to do so, you will not be able to obtain another payday loan from any lender for a period of 90 days after you fully repay or satisfy the extended payment plan.~~

~~An extended term loan is a payday loan under which you are permitted to repay the amount you owe in four equal installments spread out evenly over a term of 60 days. You may obtain an extended term loan even if you previously obtained another extended term loan or an extended payment plan. If you want an extended term loan, you must choose this option on the date you obtain the payday loan. If you obtain an extended term loan, you will not be able to get another payday loan from any lender for a period of 90 days after you fully repay or satisfy the extended term loan or 150 days after you obtain the extended term loan (whichever is longer).~~

~~**Other Businesses:** A lender is prohibited by statute from engaging in other businesses, besides check-cashing, unless permitted by order of the State Corporation Commission. A lender is also prohibited by statute from selling you any type of insurance coverage.~~

~~**Loans for Other Products & Services:** You are prohibited from using any of the money from your payday short-term loan to purchase any other product or service sold (i) at the lender's business location, or (ii) on or through the lender's website or mobile application.~~

~~**Right to Cancel or Rescind:** You have the right to cancel or rescind your short-term loan at any time prior to the close 5 p.m. of the third business on the next day immediately following the day the lender is open following the date your loan is made you entered into the loan agreement by returning the loan proceeds check or paying the lender the amount advanced to you in cash, certified check, cashier's check, money order or, if the lender is equipped to handle such payments, by using a credit card, prepaid card, ~~or~~ debit card, or the Automated Clearing House system. If you timely cancel or rescind your loan, the lender must mark your original loan agreement with the word "canceled" and return it to you along with any check that you provided as security for the loan.~~

~~**Partial Payments and Prepayments:** You have the right to make partial payments (in increments of not less than \$5.00) on your payday loan at any time prior to its specified due date without penalty. If you make a partial payment, the total interest and loan fee you pay will be reduced (unless you have an extended payment plan or extended term loan — see "Payments on Extended Payment Plans and Extended Term Loans" below). [The lender is required to accept any loan payment that you or another person acting on your behalf make provided that the payment is in the form of cash, certified check, cashier's check, money order or, if the lender is equipped to handle such payments, by use of a credit card, prepaid card, debit card, or the Automated Clearing House system. The lender is required to credit your loan account on the date that the lender receives your payment.] You have the right to receive signed, dated receipts for each payment made~~

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along with a statement of the balance remaining on your payday loan. If you have authorized electronic payments for your loan, you have the right to remove your authorization at any time. [If the lender presents your check, negotiable order of withdrawal, share draft, or other negotiable instrument for payment and it is dishonored for any reason and returned to the lender, then the lender is prohibited from presenting it for payment again unless the lender obtains a new written authorization from you to present the previously returned item. Similarly, if the lender attempts on two consecutive occasions to transfer or withdraw funds electronically from your account and both attempts fail, then the lender is prohibited from making an additional attempt unless the lender obtains a new written authorization from you to transfer or withdraw funds electronically from your account.] You also have the right to prepay your loan in full before its specified due maturity date without penalty by paying the lender in cash, certified check, cashier's check, money order or, if the lender is equipped to handle such payments, by use of a credit card, prepaid card, or debit card, or the Automated Clearing House system, the amount of money advanced to you remaining outstanding balance as well as any accrued and unpaid interest and fees. If you prepay your loan in full or your loan is refinanced with another short-term loan, the lender must refund to you a prorated portion of fees and charges, except for any deposit item return fees and late charges, based on a ratio of the number of days the loan was outstanding and the number of days for which the loan was originally contracted. [The lender must provide you with the refund in the form of cash or a business check as soon as reasonably possible but no later than two business days after receiving payment from you.]

Payments on Extended Payment Plans and Extended Term Loans: You have the right to prepay an extended payment plan or extended term loan without penalty. However, unless it results in the prepayment in full of an extended payment plan or extended term loan, a partial payment, excess payment, installment payment, or other payment you give to the lender in advance of the date the funds are due does not result in either a change to your payment schedule or a pro-rata adjustment of the total interest, if any, or loan fee that you will be required to pay. Payments you make on an extended payment plan or extended term loan are first applied to any past due installment and then to your next regularly scheduled installment. The lender must give you receipts, signed and dated by the lender, for all payments you make on an extended payment plan or extended term loan. When you make a payment on an extended payment plan or extended term loan, you have the option to give the lender a replacement security check for the remaining amount you owe. At your request, the lender may print a replacement security check on your behalf when you are in the lender's office and make a payment on an extended payment plan or extended term loan.

Lender to Return Original Loan Agreement: Upon repayment of your loan in full, the lender must mark your original loan agreement with the word "paid" or "canceled" and

return it to you. If you obtained an extended payment plan, the lender is also required to mark your original extended payment plan document with the word "paid" or "canceled" and return it to you.

Lender to Return Security Check: If your loan is secured by a check and you cancel or rescind your loan (see "Right to Cancel or Rescind" above) or repay it in full with cash or by certified check, cashier's check, money order or, if the lender is equipped to handle such payments, by using a credit card, prepaid card, or debit card, the lender must immediately return the check you gave as security for the loan.

No Rollovers, Extensions, Etc.: The lender cannot refinance, renew, extend, or rollover your payday loan.

Failure to Repay: Pay back your loan! Know when your payment is payments are due and be sure to repay your loan on time and in full. You are responsible for having sufficient funds in your checking account on the due date of your loan so that your check does not bounce if the lender deposits it in his account. If you do not repay your loan by the specified due date, the lender may begin accruing interest on the principal amount of your loan at a maximum rate of 6.0% per year. [If you fail to make a payment on your loan in accordance with your loan agreement, the loan agreement may permit the lender to terminate your loan in advance of the maturity date and demand repayment of the entire outstanding balance along with prorated interest and fees earned up to the date of termination. However, at least 10 days after your payment was due, the lender must provide you with written notice that it is terminating your loan.]

In collecting or attempting to collect a payday short-term loan, the lender is required to comply with the restrictions and prohibitions applicable to debt collectors contained in the Fair Debt Collection Practices Act, 15 USC § 1692 et seq., regarding harassment or abuse, false or misleading misrepresentations, and unfair practices in collections. The lender is also prohibited from threatening or beginning criminal proceedings against you if a check you provide to the lender bounces or if you fail to pay any amount owed according to your loan agreement. If a lender knowingly violates this prohibition, the lender is required to pay you a civil monetary penalty equal to three times the amount of the dishonored check.

If you cannot or do not repay the loan: (i) the lender is permitted to recover from you any fee charged to the lender (maximum of \$25) as a result of your check being returned due to your account being closed by you or containing insufficient funds, or if you stopped payment on your check; and (ii) if the lender seeks and obtains judgment against you as a result of your returned check, the lender may obtain court costs and reasonable attorney's fees (total may not exceed \$250) if such costs and fees are awarded by the court.

The If you default on your loan, the lender cannot file or initiate a legal proceeding may bring a civil action against you until 60 days or more after the date that you default on a payday loan,

~~including a default under an extended payment plan or extended term loan.~~ During this 60-day period the lender may voluntarily enter into a repayment arrangement with you.

Legal Action Against Lender: You have the right to bring a civil action against the lender if you suffer a loss as a result of the lender violating any provision of Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia. If you are successful in your civil action, you have the right to be reimbursed for reasonable attorney's fees, expert witness fees, and court costs you have incurred in connection with your civil action. Losses suffered as the result of the lender's violation of Chapter 18 of Title 6.2 of the Code of Virginia may also be pursued under the Virginia Consumer Protection Act (§ 59.1-196 et seq. of the Code of Virginia), which in some cases permits consumers to recover actual and punitive damages.

Complaints and Contacting the Bureau of Financial Institutions: For assistance with any complaints you may have against a payday short-term lender, please contact the Bureau of Financial Institutions toll free at (800) 552-7945 or ~~on the Internet at <http://www.scc.virginia.gov/bfi>~~ [scc.virginia.gov](http://www.scc.virginia.gov). Complaints must be filed in writing with the Bureau of Financial Institutions and include copies of supporting documentation. ~~Complaints should be mailed to Bureau of Financial Institutions, Attn: Complaints, P.O. Box 640, Richmond, Virginia 23218-0640, or faxed to Bureau of Financial Institutions, Attn: Complaints, at (804) 371-9416.~~

10VAC5-200-85. Advertising.

A. A licensee shall disclose the following information in its advertisements ~~in a conspicuous manner:~~

1. The name of the payday short-term lender as set forth in the license issued by the commission.
2. A statement that the payday short-term lender is "licensed by the Virginia State Corporation Commission."
3. The license number assigned by the commission to the payday short-term lender (i.e., PL-XXX).

B. A licensee shall not deliver or cause to be delivered to a consumer any envelope or other written material that gives the false impression that the mailing or written material is an official communication from a governmental entity, unless required by the United States Postal Service.

C. Every advertisement used by, or published on behalf of, a licensee shall comply with the disclosure requirements for advertisements contained in Regulation Z (12 CFR Part 1026).

D. ~~For purposes~~ The information required by subsection A of this section, the term "conspicuous" shall have the meaning set forth be disclosed in accordance with the disclosure standards prescribed in subdivision 20 subsection C of § 6.2-1816 6.2-1819 of the Code of Virginia.

E. Every licensee shall retain for at least three years after it is last published, delivered, transmitted, or made available, an

example of every advertisement used, including but not limited to solicitation letters, print media proofs, commercial scripts, and recordings of all radio and television broadcasts, but excluding copies of Internet web pages.

10VAC5-200-90. Schedule of annual fees for the examination, supervision, and regulation of payday short-term lenders.

Pursuant to § 6.2-1814 of the Code of Virginia, the commission sets the following schedule of annual fees to be paid by ~~payday lenders licensed~~ licensees under ~~Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia the Act.~~ Such fees are to defray the costs of the examination, supervision, and regulation of licensees by the bureau. The fees are related to the actual costs of the bureau, to the number of offices operated by licensees, to the volume of business of licensees, and to other factors relating to their supervision and regulation.

The annual fee shall be \$500 per office plus \$.47 per payday loan made by each licensee. The annual fee shall be computed on the basis of (i) the number of offices, authorized and opened, as of December 31 of the year preceding the year of the assessment, and (ii) the number of payday loans made under ~~Chapter 18 (§ 6.2-1800 et seq.) of Title 6.2 of the Code of Virginia the Act~~ during the calendar year preceding the year of the assessment.

Fees shall be assessed on or before September 15 for the current calendar year. The assessment shall be paid by licensees on or before October 15.

The annual report, due March 25 each year, of each licensee provides the basis for its assessment ~~(i.e., the number of offices and payday loans made). In cases where a license has been granted between January 1 and September 15 of the year of the assessment, the licensee shall pay \$250 per office, authorized and opened, as of September 15 of that year.~~

Fees prescribed and assessed pursuant to this schedule are apart from, and do not include, the reimbursement for expenses authorized by subsection B of § 6.2-1814 of the Code of Virginia.

10VAC5-200-100. Other Conducting other business in payday lending offices.

A. This section governs the conduct of any business other than payday short-term lending where a licensed payday short-term lending business is conducted. As used in this section, the term "other business operator" refers to a ~~licensed payday lender licensee~~ licensee or third party, including an affiliate or subsidiary of the ~~licensed payday lender licensee~~ licensee, who conducts or wants to conduct other business from one or more payday short-term lending offices.

1. Pursuant to § 6.2-1820 of the Code of Virginia, a licensee shall not conduct the business of making payday short-term loans at any office, suite, room, or place of business where

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any other business is solicited or conducted, except a ~~registered~~ check cashing business registered under Chapter 21 (§ 6.2-2100 et seq.) of Title 6.2 of the Code of Virginia, a motor vehicle title lending business licensed under Chapter 22 (§ 6.2-2200 et seq.) of Title 6.2 of the Code of Virginia, or such other business as the commission determines should be permitted, and subject to such conditions as the commission deems necessary and in the public interest.

2. Notwithstanding any provision of this section or order entered by the commission prior to October 1, 2010, the following other businesses shall not be conducted from any office, suite, room, or place of business where a licensed ~~payday~~ short-term lending business is conducted:

a. Selling insurance or enrolling borrowers under group insurance policies.

b. Making loans under an open-end credit plan as described in § 6.2-312 of the Code of Virginia. ~~However, if prior to October 1, 2010, a licensee received commission authority for an other business operator to conduct open end credit business or open end auto title lending business from the licensee's payday lending offices, the other business operator may continue collecting payments on any outstanding open end loans (i) in accordance with the terms of its existing open end credit agreements and (ii) subject to the conditions imposed by this section.~~

3. Pursuant to ~~§ 6.2-2107 of the Code of Virginia, no person registered or required to be registered as a check casher under Chapter 21 (§ 6.2-2100 et seq.) of Title 6.2 of the Code of Virginia shall make loans from any location, including an office, suite, room, or place of business where a licensed payday lending business is conducted, unless the person is licensed under the Act and the loans are made in accordance with the Act~~ This section shall not apply to any other business that is transacted solely with persons residing outside of the Commonwealth.

4. Notwithstanding any provision of this section or order entered by the commission prior to January 1, 2021, a licensee shall not make short-term loans at the same location at which the licensee, or any affiliate or owner of the licensee, conducts business under Chapter 15 (§ 6.2-1500 et seq.) of Title 6.2 of the Code of Virginia. ~~However, if prior to January 1, 2021, a licensee obtained authority under § 6.2-1820 for the licensee or its affiliate or owner to make consumer finance loans from the licensee's payday lending offices, then the licensee or its affiliate or owner may continue collecting payments on any outstanding consumer finance loans (i) in accordance with the preexisting terms of the loan contracts provided that such terms were permitted by law when the loans were made, and (ii) subject to the general conditions set forth in subsection E of this section.~~

5. If a licensee accepts loan applications, sends or receives loan-related information or documents, disburses loan funds,

or accepts loan payments on or through the licensee's website or mobile application, and any other products or services are or will be offered or sold to Virginia residents on or through such website or mobile application, then the offer or sale of such other products or services shall constitute the conduct of other business and shall be subject to all of the provisions of this section to the same extent as if such other business was conducted by an other business operator from the licensee's short-term lending offices.

B. No other business shall be conducted in a location where a licensee conducts a ~~payday~~ short-term lending business unless the proposed other business is financial in nature and the licensee obtains prior approval from the commission. Applications for approval shall be made in writing on a form provided by the ~~Commissioner of Financial Institutions, commissioner~~ and shall be accompanied by payment of ~~the a~~ \$300 fee required by law and any information relating to the application that the ~~Commissioner of Financial Institutions, commissioner~~ may require. In acting upon an application, the commission shall consider (i) whether the other business operator has the general fitness to warrant belief that the business will be operated in accordance with law; (ii) whether the applicant has been operating its ~~payday lending~~ business in accordance with the Act and this chapter; and (iii) any other factors that the commission deems relevant.

1. The commission shall in its discretion determine whether a proposed other business is "financial in nature," and shall not be obliged to consider the meaning of this term under federal law. A business is financial in nature if it primarily deals with the offering of debt, money or credit, or services directly related thereto.

2. Prior approval from the commission shall not be required for a licensee to conduct a short-term lending business from one or more locations where an other business operator will conduct (i) a registered check cashing business under Chapter 21 (§ 6.2-2100 et seq.) of Title 6.2 of the Code of Virginia, or (ii) a licensed motor vehicle title lending business under Chapter 22 (§ 6.2-2200 et seq.) of Title 6.2 of the Code of Virginia. However, the conduct of these other businesses from a licensee's short-term lending offices shall otherwise be governed by this section, including the conditions prescribed in subsections E, F, and G of this section.

C. Nonfinancial other business may be conducted pursuant to any order of the commission entered on or before June 15, 2004. However, this subsection shall not be construed to authorize any person to begin engaging in such other business at ~~payday lending~~ locations where such other business was not conducted as of June 15, 2004.

D. ~~Written~~ Except as provided in subdivision B 2 of this section, written evidence of commission approval of each other business conducted by an other business operator should be

maintained at each approved location ~~where such other business is conducted.~~

E. Except as otherwise provided in subsection O of this section, all ~~approved~~ other businesses in payday short-term lending offices shall be conducted in accordance with the following conditions:

1. The licensee shall not make a payday short-term loan to a borrower to enable the borrower to purchase or pay any amount owed in connection with the (i) goods or services sold, or (ii) loans offered, facilitated, or made, by the other business operator at the licensee's payday short-term lending offices.
2. The other business operator shall comply with all federal and state laws and regulations applicable to its other business, including any applicable licensing or registration requirements.
3. The other business operator shall not use or cause to be published any advertisement or other information that contains any false, misleading, or deceptive statement or representation concerning its other business, including the rates, terms, or conditions of the products, services, or loans that it offers. The other business operator shall not make or cause to be made any misrepresentation as to (i) its being licensed to conduct the other business, or (ii) the extent to which it is subject to supervision or regulation.
4. The licensee shall not make a payday short-term loan or vary the terms of a payday short-term loan on the condition or requirement that a person also (i) purchase a good or service from, or (ii) obtain a loan from or through, the other business operator. The other business operator shall not (a) sell its goods or services, (b) offer, facilitate, or make loans, or (c) vary the terms of its goods, services, or loans, on the condition or requirement that a person also obtain a payday short-term loan from the licensee.
5. The other business operator shall maintain books and records for its other business separate and apart from the licensee's payday short-term lending business and in a different location within the licensee's payday short-term lending offices. The bureau shall be given access to all such books and records and be furnished with any information and records that it may require in order to determine compliance with all applicable conditions, laws, and regulations.

F. ~~If a licensee received commission authority for an other business operator to conduct open end credit~~ conducts a check cashing business or open end auto title lending business from the licensee's payday short-term lending offices, the following additional conditions shall be applicable:

1. The other business operator shall ~~not (i) enter into any new open end credit agreements or (ii) make any new loans pursuant to its existing open end credit agreements~~ be

registered or exempt from registration under Chapter 21 (§ 6.2-2100 et seq.) of Title 6.2 of the Code of Virginia.

2. ~~The licensee shall not make a payday loan to a person if (i) the person has an outstanding open end loan from the other business operator, or (ii) on the same day the person repaid or satisfied in full an open end loan from~~ If the other business operator is registered under Chapter 21 (§ 6.2-2100 et seq.) of Title 6.2 of the Code of Virginia, then the other business operator shall not make any loans unless the other business operator is licensed under the Act and the loans are made in accordance with the Act.

3. The other business operator shall not charge a fee to cash a check issued by the licensee or any other person operating in the licensee's short-term lending offices.

G. ~~If a licensee received or receives commission authority for an other business operator to conduct~~ conducts a motor vehicle title lending business from the licensee's payday short-term lending offices, the following additional conditions shall be applicable:

1. The other business operator shall be licensed or exempt from licensing under Chapter 22 (§ 6.2-2200 et seq.) of Title 6.2 of the Code of Virginia.
2. The licensee shall not make a payday short-term loan to a person if (i) the person has an outstanding motor vehicle title loan from the other business operator, or (ii) on the same day the person repaid or satisfied in full a motor vehicle title loan from the other business operator.
3. The other business operator shall not make a motor vehicle title loan to a person if (i) the person has an outstanding payday short-term loan from the licensee, or (ii) on the same day the person repaid or satisfied in full a payday short-term loan from the licensee.
4. The other business operator and the licensee shall not make a motor vehicle title loan and a payday short-term loan contemporaneously or in response to a single request for a loan or credit.
5. The licensee and other business operator shall provide each applicant for a payday short-term loan or motor vehicle title loan with a separate disclosure, signed by the applicant, that clearly identifies all of the loan products available in the licensee's payday short-term lending offices along with the corresponding Annual Percentage Rate, interest rate, and other costs associated with each loan product. The disclosure shall also identify the collateral, if any, that will be used to secure repayment of each loan product.

H. If a licensee received or receives commission authority for an other business operator to conduct business as an authorized delegate or agent of a money order seller or money transmitter from the licensee's payday short-term lending offices, the other business operator shall be and remain a party to a written agreement to act as an authorized delegate or agent of a person

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licensed or exempt from licensing as a money order seller or money transmitter under Chapter 19 (§ 6.2-1900 et seq.) of Title 6.2 of the Code of Virginia. The other business operator shall not engage in money order sales or money transmission services on its own behalf or on behalf of any person other than a licensed or exempt money order seller or money transmitter with whom it has a written agreement.

I. If a licensee received or receives commission authority for an other business operator to conduct the business of (i) tax preparation ~~and or~~ electronic tax filing services, or (ii) facilitating third party tax preparation ~~and or~~ electronic tax filing services, from the licensee's payday short-term lending offices, the following additional conditions shall be applicable:

1. The licensee shall not make, ~~arrange, or broker~~ a payday short-term loan that is secured by an interest in a borrower's tax refund, ~~or in whole or in part by (i) any other assignment of income payable to a borrower, or (ii) any assignment of an interest in a borrower's account at a depository institution.~~ This condition shall not be construed to prohibit the licensee from making a payday loan that is secured solely by a check payable to the licensee drawn on a borrower's account at a depository institution.

2. The other business operator shall not engage in the business of (i) accepting funds for transmission to the Internal Revenue Service or other government instrumentalities, or (ii) receiving tax refunds for delivery to individuals, unless licensed or exempt from licensing under Chapter 19 (§ 6.2-1900 et seq.) of Title 6.2 of the Code of Virginia.

J. If a licensee received or receives commission authority for an other business operator to conduct the business of facilitating or arranging tax refund anticipation loans or tax refund payments from the licensee's payday short-term lending offices, the following additional conditions shall be applicable:

1. The other business operator shall not facilitate or arrange a tax refund anticipation loan or tax refund payment to enable a person to pay any amount owed to the licensee as a result of a payday short-term loan transaction.

2. The other business operator and the licensee shall not facilitate or arrange a tax refund anticipation loan or tax refund payment and make a payday short-term loan contemporaneously or in response to a single request for a loan or credit.

3. The licensee shall not make, ~~arrange, or broker~~ a payday short-term loan that is secured by an interest in a borrower's tax refund, ~~or in whole or in part by (i) any other assignment of income payable to a borrower, or (ii) any assignment of an interest in a borrower's account at a depository institution.~~ This condition shall not be construed to prohibit the licensee from making a payday loan that is secured solely by a check payable to the licensee drawn on a borrower's account at a depository institution.

4. The other business operator shall not engage in the business of receiving tax refunds or tax refund payments for delivery to individuals unless licensed or exempt from licensing under Chapter 19 (§ 6.2-1900 et seq.) of Title 6.2 of the Code of Virginia.

5. The licensee and other business operator shall provide each applicant for a payday short-term loan or tax refund anticipation loan with a separate disclosure, signed by the applicant, that clearly identifies all of the loan products available in the licensee's payday short-term lending offices along with the corresponding Annual Percentage Rate, interest rate, and other costs associated with each loan product. The disclosure shall also identify the collateral, if any, that will be used to secure repayment of each loan product.

K. If a licensee received or receives commission authority for an other business operator to conduct a consumer finance business from the licensee's payday short-term lending offices, the following additional conditions shall be applicable:

1. The other business operator shall be licensed or exempt from licensing under Chapter 15 (§ 6.2-1500 et seq.) of Title 6.2 of the Code of Virginia.

2. Pursuant to subdivision A 4 of this section, the other business shall be conducted by a person other than the licensee or an affiliate or owner of the licensee.

3. The licensee shall not make a payday short-term loan to a person if (i) the person has an outstanding consumer finance loan from the other business operator, or (ii) on the same day the person repaid or satisfied in full a consumer finance loan from the other business operator.

~~2.~~ 4. The other business operator shall not make a consumer finance loan to a person if (i) the person has an outstanding payday short-term loan from the licensee, or (ii) on the same day the person repaid or satisfied in full a payday short-term loan from the licensee.

~~3.~~ 5. The licensee and other business operator shall not make a payday short-term loan and a consumer finance loan contemporaneously or in response to a single request for a loan or credit.

4. 6. The licensee and other business operator shall provide each applicant for a payday short-term loan or consumer finance loan with a separate disclosure, signed by the applicant, that clearly identifies all of the loan products available in the licensee's payday short-term lending offices along with the corresponding Annual Percentage Rate, interest rate, and other costs associated with each loan product. The disclosure shall also identify the collateral, if any, that will be used to secure repayment of each loan product.

L. If a licensee received or receives commission authority for an other business operator to conduct the business of operating

an automated teller machine from the licensee's payday short-term lending offices, the other business operator shall not charge a fee or receive other compensation in connection with the use of its automated teller machine by a person when the person is withdrawing funds in order to make a payment on a payday loan from that was made by the licensee or any other lender conducting business from the licensee's short-term lending offices.

M. The commission may impose any additional conditions upon the conduct of other business in payday short-term lending offices that it deems necessary and in the public interest.

N. Except as otherwise provided in subsection O of this section, the conditions set forth or referred to in subsections E through M of this section shall supersede the conditions set forth in the commission's approval orders entered prior to January 1, ~~2011~~ 2021.

O. If prior to January 1, 2011, a licensee received commission authority for an other business operator to conduct a business not identified in subsections F through L of this section, the conditions that were imposed by the commission at the time of the approval shall remain in full force and effect.

P. Failure by a licensee or other business operator to comply with any provision of this section or any condition imposed by the commission, or failure by a licensee to comply with the Act, this chapter, or any other law or regulation applicable to the conduct of the licensee's business, may result in revocation of the authority to conduct other business or any form of enforcement action specified in 10VAC5-200-120.

10VAC5-200-110. Payday Short-term lending database.

A. This section sets forth the rules applicable to the payday short-term lending database referred to in § 6.2-1810 of the Code of Virginia.

B. Except as otherwise provided in this section, a licensee shall transmit all information to the database via the Internet. In order to maintain the confidentiality and security of the information, a licensee shall not transmit information to the database using publicly accessible computers, computers that are not under the licensee's control, unsecured wireless (Wi-Fi) connections, or other connections that are not secure. A licensee shall maintain generally accepted security safeguards to protect the confidentiality of the information transmitted to the database, including but not limited to installing and regularly updating malware protection (antivirus and antispyware) software and a firewall.

C. After receiving a completed written loan application but prior to making a payday short-term loan, a licensee shall transmit the following information to the database for purposes of determining whether an applicant is eligible for a payday short-term loan. The licensee shall obtain the applicant

information required by this subsection in accordance with the provisions of subsection D of this section.

1. Name of licensee and license number.
2. Office location of licensee.
3. First and last name or identification number of employee entering information into the database.
4. Applicant's first and last name.
5. Last four digits of applicant's driver's license number or identification card number.
6. Applicant's address.
7. Applicant's date of birth.
8. Type of card (e.g., driver's license or identification card issued by a state driver's licensing authority) provided by the applicant pursuant to subdivision D 1 of this section.

D. 1. A licensee shall obtain the information required by subdivisions C 4, 5, 6, 7, and 8 of this section ~~directly~~ from the applicant's unexpired ~~original~~ driver's license or identification card issued by a state driver's licensing authority (e.g., Department of Motor Vehicles for the Commonwealth of Virginia), regardless of whether the information on the driver's license or identification card is still accurate. A licensee ~~shall not~~ may accept photocopies, facsimiles, or other reproductions of a driver's license or identification card.

2. A licensee shall ~~photocopy~~ retain a copy of the applicant's driver's license or identification card, ~~partially redact the in its records. The driver's license number or identification card number shall be partially redacted by the licensee so that only the last four digits of the number remain visible, and retain the redacted photocopy in its records.~~

3. A licensee shall not accept a driver's license or identification card from an applicant when there is reason to believe that (i) it belongs to an individual other than the applicant or (ii) it is fake, counterfeit, or has been altered, fraudulently obtained, forged, or is otherwise nongenuine or illegitimate.

E. If the database advises a licensee that an applicant is ineligible for a payday short-term loan, then the licensee shall inform the applicant of his ineligibility, instruct the applicant to contact the database provider for information about the specific reason for his ineligibility, and provide the applicant with the toll-free telephone number of the database provider.

F. ~~Except as otherwise provided in subsection O of this section, if~~ the database advises a licensee that an applicant is eligible for a payday short-term loan, then the licensee shall transmit the following additional information to the database prior to making a payday short-term loan:

1. Application date.
2. Loan number.

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3. Date of loan.
4. Principal amount of loan.
5. Interest rate.
6. Dollar amount of precomputed interest to be charged until date of loan maturity.
7. Dollar amount of ~~loan~~ monthly maintenance fee to be charged.
8. Dollar amount of ~~verification fee to be charged~~ each payment.
9. Dollar amount of total ~~finance fees and~~ charges.
10. Annual Percentage Rate (APR) of loan.
11. ~~Number of days in applicant's pay cycle [Applicant's verified (i) gross monthly income and (ii) net monthly income.~~
- ~~12.] Number Total number of days in loan term payments.~~
- ~~[13. 12.] Date of loan is due maturity.~~
- ~~[14. 13.] Dollar If applicable, dollar amount of check given by applicant to secure the loan (i.e., at the time the loan is made).~~

~~G. If the database advises a licensee that an applicant is eligible for an extended payment plan or extended term loan and the applicant subsequently elects an extended payment plan or extended term loan, then the licensee shall transmit the following additional applicable information to the database no later than the time the licensee closes for business on the date the applicant enters into the extended payment plan or extended term loan:~~

- ~~1. Date the extended payment plan or extended term loan is entered into.~~
- ~~2. Principal amount owed under the extended payment plan or extended term loan.~~
- ~~3. Number of installment payments and the amount of each payment to be made under the extended payment plan or extended term loan.~~
- ~~4. Date each installment payment is due under the extended payment plan or extended term loan.~~
- ~~5. Number of days in term of extended payment plan or extended term loan.~~

~~H. For purposes of this section, a licensee closes for business when it officially shuts its doors to the general public on a business day, or within one hour thereafter.~~

~~I. G. A licensee shall generate a separate printout from the database showing the results of each loan eligibility query, including whether an applicant is eligible for an extended payment plan or extended term loan, and retain the printout in its loan records.~~

~~J. H. Except as otherwise provided in subsection O of this section and subdivisions 3, 7, and 8 of this subsection, a licensee shall transmit the following additional information relating to loans made under the Act, as applicable, to the database no later than the time the licensee closes for end of the business day on the date of the event:~~

- ~~1. If a borrower cancels or rescinds a payday loan, the date of the cancellation or rescission.~~
- ~~2. If a payday loan (including an extended term loan or a loan that a borrower elected to repay by means of an extended payment plan) is repaid or otherwise satisfied in full, (i) the date of repayment or satisfaction, and (ii) the total net dollar amount ultimately paid by the borrower in connection with the loan (i.e., principal amount of loan plus all fees and charges received or collected pursuant to §§ 6.2-1817 and 6.2-1818 of the Code of Virginia, less any amount refunded to the borrower as a result of overpayment).~~
- ~~3. If a borrower's check used to repay a loan in full is returned unpaid or electronic draft is returned unpaid because the account on which it was drawn was closed by the borrower or contained insufficient funds, (i) the date the check or electronic draft is returned unpaid, and (ii) the dollar amount of the check or electronic draft. A licensee shall transmit such information to the database no later than five calendar days after the date the check or electronic draft is returned unpaid.~~
- ~~4. If a licensee collects a returned check deposit item return fee from a borrower, the dollar amount of the returned check deposit item return fee.~~
- ~~5. If a licensee initiates brings a legal proceeding civil action against a borrower for nonpayment of a payday loan, the date the proceeding is initiated and the total dollar amount sought to be recovered.~~
- ~~6. If a licensee obtains a judgment against a borrower, the date and total dollar amount of the judgment.~~
- ~~7. If a judgment obtained by a licensee against a borrower is satisfied, the date of satisfaction. A licensee shall transmit such information to the database on the date the licensee learns that the judgment has been satisfied.~~
- ~~8. If a licensee obtains a judgment against a borrower and collects any court damages or costs or attorney's fees from a the borrower, the dollar amount of the court damages or costs or attorney's fees. A licensee shall transmit such information to the database on the date the licensee learns that the court damages or costs or attorney's fees have been paid.~~
- ~~9. If a licensee charges off a payday loan as uncollectible, the date the loan is charged off and the total dollar amount charged off.~~

~~K. I.~~ 1. If any information required to be transmitted by a licensee to the database is automatically populated or calculated by the database provider, the licensee shall verify the information and immediately correct any inaccuracies or other errors.

2. If a licensee becomes aware of any changes, inaccuracies, or other errors in the information previously verified or transmitted by the licensee to the database, the licensee shall immediately update or correct the database.

~~L. J.~~ The following provisions address a licensee's inability to access the database via the Internet at the time of loan application:

1. If at the time a licensee receives a loan application the licensee is unable to access the database via the Internet due to technical problems beyond the licensee's control, then the licensee shall to the extent possible use the database provider's alternative means of database access, such as a telephone interactive voice response system, for purposes of transmitting the information required by this section and obtaining applicant eligibility information from the database.

2. If a licensee makes a payday short-term loan based on applicant eligibility information obtained from the database provider's alternative means of database access, then the licensee shall transmit to the database any remaining information required by this section no later than ~~the time the licensee closes for business on~~ the date that the database becomes accessible to the licensee via the Internet.

3. If at the time a licensee receives a loan application the licensee is unable to access the database via the Internet due to technical problems beyond the licensee's control and the database provider's alternative means of database access is unavailable or otherwise unable to provide the licensee with applicant eligibility information (~~including eligibility for an extended payment plan or extended term loan~~), then the licensee may make a payday short-term loan to an applicant if the applicant signs and dates a separate document containing all of the representations and responses to the questions set forth below and the prospective loan otherwise complies with the provisions of the Act and this chapter. The document shall be ~~printed~~ in a type size of not less than 14 point and contain a statement that the representations and questions relate to loans obtained from either the licensee or another payday short-term lender. The licensee shall retain the original document in its loan file and provide the applicant with a duplicate original.

a. The representations to be made by an applicant are as follows:

(1) I do not currently have any outstanding payday loans or short-term loans under Chapter 18 of Title 6.2 of the Code of Virginia.

~~(2) I did not repay or otherwise satisfy in full a payday loan today.~~

~~(3) In the past 90 days I did not repay or otherwise satisfy in full a payday loan by means of an extended payment plan.~~

~~(4) In the past 45 days I did not repay or otherwise satisfy in full a fifth payday loan that was obtained within a period of 180 days.~~

~~(5) In the past 90 days I did not repay or otherwise satisfy in full an extended term loan.~~

~~(6) I did not obtain an extended term loan within the past 150 days.~~

~~(7)~~ (2) I am not a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer.

~~(8)~~ (3) I am not married to a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer.

~~(9)~~ (4) I am not under the age of 18 and the son or daughter of a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer.

~~(10)~~ (5) One-half or less (including none) of my financial support for the past 180 days was provided by a regular or reserve member of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or National Guard serving on active duty under a call or order that does not specify a period of 30 days or fewer.

~~b. The questions to be presented to an applicant are as follows:~~

~~(1) In the past 12 months, have you obtained an extended payment plan in order to repay a payday loan? If the applicant's response is "no" and the applicant is eligible for a payday loan, then the licensee shall immediately provide the applicant with the oral notice prescribed in subdivision C 4 of 10VAC5-200-33.~~

~~(2) Have you obtained four or more payday loans within the past 180 days? If the applicant's response is "yes" and the applicant is eligible for a payday loan, then the licensee shall immediately provide the applicant with the oral notice prescribed in subdivision E 4 of 10VAC5-200-35.~~

e. ~~b.~~ If a licensee makes a payday short-term loan pursuant to subdivision 3 of this subsection, then the licensee shall transmit to the database the information required by this section no later than ~~the time the licensee closes for business on~~ the date that the database becomes accessible

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to the licensee, via either the Internet or the database provider's alternative means of database access.

4. If at the time a licensee receives a loan application the licensee is unable to access the database via the Internet due to technical problems beyond the licensee's control, then the licensee shall document in its records the technical problems it experienced and the date and time that it sought to access the database.

~~M. K.~~ The following provisions address a licensee's inability to access the database via the Internet subsequent to making a loan:

1. If a licensee is required to transmit to the database information regarding a loan that has already been made, but the licensee is unable to access the database via the Internet due to technical problems beyond the licensee's control, then the licensee shall to the extent possible use the database provider's alternative means of database access, such as a telephone interactive voice response system, for purposes of transmitting the information required by this section to the database. If the database provider's alternative means of database access is unavailable or otherwise unable to accept the information, then the licensee shall transmit to the database the information required by this section no later than ~~the time the licensee closes for business on~~ the date that the database becomes accessible to the licensee, via either the Internet or the database provider's alternative means of database access.

2. If a licensee is required to transmit to the database information regarding a loan that has already been made, but the licensee is unable to access the database via the Internet due to technical problems beyond the licensee's control, then the licensee shall document in its records the technical problems it experienced and the date and time that it sought to transmit the information to the database.

~~N. L.~~ A licensee shall have limited access to the information contained in the database. The database shall only provide a licensee with the following information: (i) whether an applicant is eligible for a new payday short-term loan; and (ii) if an applicant is ineligible for a new payday short-term loan, the general reason for the ineligibility (e.g., the database may state that the applicant has an outstanding payday short-term loan but it shall not furnish any details regarding the outstanding loan); ~~and (iii) if an applicant is eligible for a new payday loan, whether the applicant is also eligible for an extended payment plan or extended term loan.~~ The database shall also permit a licensee to access information that the licensee is required to transmit to the database provided that such access is for the sole purpose of verifying, updating, or correcting the information. Except as otherwise provided in this subsection or 10VAC5-200-113, a licensee shall be prohibited from accessing or otherwise obtaining any information contained in or derived from the database.

~~O. M.~~ If the ~~Commissioner of Financial Institutions commissioner~~ determines that a licensee or former licensee has ceased business but still has one or more outstanding payday loans or short-term loans that cannot be repaid due to the licensee's or former licensee's closure, the ~~Commissioner of Financial Institutions commissioner~~ may authorize the database provider to ~~administratively~~ close the outstanding loans in the database in order to enable the affected borrowers to obtain payday short-term loans in the future. A licensee or former licensee shall be deemed by the ~~Commissioner of Financial Institutions commissioner~~ to have ceased business if it (i) fails to respond to the bureau after two written requests mailed to the address on file with the bureau or (ii) fails to maintain its contact information in accordance with subsection ~~N. K.~~ of 10VAC5-200-20.

~~P. 1. N.~~ Payday loans made ~~on or after October 1, 2008, and~~ prior to January 1, ~~2009~~ 2021, that ~~remained~~ remain outstanding on January 1, ~~2009~~ 2021, shall be considered for purposes of determining a borrower's eligibility for a payday short-term loan.

~~2. For every payday loan made on or after October 1, 2008, that remained outstanding as of January 1, 2009, a licensee shall (i) transmit to the database all applicable information required by subsection J of this section within the time prescribed therein and (ii) retain the photocopies specified in subdivision D 2 of this section in accordance with § 6.2-1809 of the Code of Virginia.~~

O. If the database provider is unable to complete the modifications to the database that are needed to accommodate the transmission of certain information required by this section, then the commissioner shall notify all licensees of this in writing and identify the specific information that they are not required to transmit until the commissioner further notifies them that the database provider has completed the modifications. Once the modifications have been completed, licensees shall not be required to transmit any information that they were previously unable to transmit due to the database being unable to accommodate it. The database provider shall complete all of the modifications no later than January 1, 2022.

10VAC5-200-113. Limited disclosure of data from payday short-term lending database.

A. Pursuant to § 6.2-1810 of the Code of Virginia, the information contained in the payday short-term lending database is confidential. However, provided that it does not directly or indirectly identify or pertain to any specific borrowers, licensees, or loan transactions, aggregate data and data that is otherwise derived from information contained in the database is not confidential and may be furnished by the database provider to the public. The database provider may charge and collect a fee to defray the cost of compiling and furnishing such data.

B. The database provider shall notify the bureau prior to furnishing data pursuant to this section.

10VAC5-200-115. Database inquiry fee.

Pursuant to subdivision B 4 of § 6.2-1810 of the Code of Virginia, a ~~licensed payday lender~~ licensee shall pay a database inquiry fee to the database provider in connection with every ~~payday~~ short-term loan consummated by the licensee. The amount of the database inquiry fee shall ~~not exceed \$5.00~~ be [\$6.98 per loan set by the commission], ~~which and all database inquiry fees~~ shall be remitted by each licensee directly to the database provider on a weekly basis.

10VAC5-200-120. Enforcement.

A. Failure to comply with any provision of the Act or this chapter may result in ~~fines~~ civil penalties, license suspension, or license revocation.

B. Pursuant to § 6.2-1824 of the Code of Virginia, a licensee shall be subject to a separate ~~fine~~ civil penalty of up to \$1,000 for every violation of the Act, this chapter, or other law or regulation applicable to the conduct of the licensee's business. If a licensee violates any provision of the Act, this chapter, or other law or regulation applicable to the conduct of the licensee's business in connection with multiple loans or borrowers, the licensee shall be subject to a separate ~~fine~~ civil penalty for each loan or borrower. For example, if a licensee makes five loans and the licensee violates two provisions of this chapter that are applicable to the five loans, the licensee shall be subject to a maximum ~~fine~~ civil penalty of \$10,000.

C. If a licensee (i) fails to transmit information to the ~~payday~~ short-term lending database in accordance with the Act or 10VAC5-200-110, (ii) transmits incorrect information to the database, or (iii) transmits information to the database in an untimely manner, the licensee shall be subject to a separate ~~fine~~ civil penalty under § 6.2-1824 of the Code of Virginia for each item of data that is omitted, incorrect, or untimely. For example, if a licensee makes three loans and fails to transmit two items of information to the database in connection with each of the three loans, the licensee shall be subject to a maximum ~~fine~~ civil penalty of \$6,000.

VA.R. Doc. No. R21-6571; Filed July 13, 2021, 1:10 p.m.



TITLE 12. HEALTH

STATE BOARD OF HEALTH

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 regulation provided such regulations do not differ materially from those required by federal law or regulation. The State Board of Health is also claiming an exemption from the Administrative Process Act in accordance with § 2.2-4006 A 3 of the Code of Virginia, which excludes regulations that consist only of changes in style or form or corrections of technical errors. The board 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, 12VAC5-481-440, 12VAC5-481-451, 12VAC5-481-480, 12VAC5-481-590, 12VAC5-481-1350, 12VAC5-481-1490, 12VAC5-481-1690, 12VAC5-481-1700, 12VAC5-481-1720, 12VAC5-481-1730, 12VAC5-481-1750, 12VAC5-481-1760, 12VAC5-481-1770, 12VAC5-481-1780, 12VAC5-481-1910, 12VAC5-481-1930, 12VAC5-481-1940, 12VAC5-481-1950, 12VAC5-481-1980, 12VAC5-481-1990, 12VAC5-481-2000, 12VAC5-481-2001, 12VAC5-481-2010, 12VAC5-481-2016, 12VAC5-481-2018, 12VAC5-481-2019, 12VAC5-481-2020, 12VAC5-481-2030, 12VAC5-481-2040, 12VAC5-481-2043, 12VAC5-481-2048, 12VAC5-481-2070, 12VAC5-481-2080, 12VAC5-481-2850, 12VAC5-481-3000, 12VAC5-481-3120, 12VAC5-481-3290).

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

Effective Date: January 14, 2022.

Agency Contact: Lea Anna Perlas, Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8170, FAX (804) 864-8155, or email lea.perlas@vdh.virginia.gov.

Summary:

The amendments revise the Radiation Protection Regulations (12VAC5-481, Virginia Radiation Protection Regulations) to make the provisions of the radiation protection program compatible with 2018, 2019, and 2020 revisions to Title 10 of the Code of Federal Regulations by the U.S. Nuclear Regulatory Commission (NRC), which Virginia agrees to do as an NRC Agreement State. Included are (i) changes to medical event definitions and training and experience requirements; (ii) corrections to NRC organizational references; and (iii) updates to requirements for individual monitoring devices, access authorization, general security program, physical protection, and prevention of social security fraud.

12VAC5-481-10. Definitions.

The following words and terms as used in this chapter shall have the 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 F.

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"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 F.

"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 (42 USC § 2021(b)).

"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 Appendix B to 10 CFR Part 20; 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 off site.

"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 Appendix B to 10 CFR Part 20.

"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.

"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.

"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.

"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.

"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.

"Associate radiation safety officer" means an individual who (i) meets the requirements of 12VAC5-481-1750 and 12VAC5-481-1790 and (ii) is currently identified as an associate radiation safety officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the radiation safety officer on (a) a specific medical use license issued by the agency, NRC, or another agreement state or (b) a medical use permit issued by a NRC master material licensee.

"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;

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c. A permit issued by an NRC or another Agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-440 I 2.

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

1. Meets the requirements in 12VAC5-481-1790 and any of the following:

a. 12VAC5-481-1910;

b. 12VAC5-481-1940;

c. 12VAC5-481-1980;

d. 12VAC5-481-1990;

e. 12VAC5-481-2000;

f. 12VAC5-481-2018;

g. 12VAC5-481-2030;

h. 12VAC5-481-2040 A; 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, 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 or useful beam.

"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 U.S. Environmental Protection Agency, the U.S. Secretary of Energy, the U.S. 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" 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

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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 P.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.

"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 taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this chapter that has a reasonable nexus to radiological health and safety.

"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 " $H_{E,50}$ " means 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.

"Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to this chapter. The term "construction" does not include:

1. Changes for temporary use of the land for public recreational purposes;
2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this chapter;
5. Excavation;
6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

9. Taking any other action that has no reasonable nexus to radiological health and safety.

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

"Contamination" means, as applicable to Part XIII (12VAC5-481-2950 et seq.) of this chapter, the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm² (1 x 10⁻⁵ μCi/cm²) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm² (1 x 10⁻⁶ μCi/cm²) for all other alpha emitters.

1. Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport.

2. Nonfixed contamination means contamination that can be removed from a surface during normal conditions of transport.

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

$$\overline{CS} = \frac{\mu_x - \mu_w}{CTN_x - CTN_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water;

CTN_x = of the material of interest;

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.

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"Conventional simulator" means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

"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, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 12VAC5-481-3040, 12VAC5-481-3051, and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment, or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment, or conveyance.

"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 scale of CTN is used;

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

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

"Curie" is 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 chapter, 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 P.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 (P.L. 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 USC § 5814, effective January 19, 1975) and retransferred to the U.S. Secretary of Energy pursuant to § 301(a) of the Department of Energy Organization Act (P.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 Appendix B to 10 CFR Part 20.

"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.) of this chapter, 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

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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 ($H_E = \sum w_T H_T$).

"Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"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 the U.S. Environmental Protection Agency 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.

"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 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 B 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 U.S. Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, (42 USC § 2011 et seq.) 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

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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 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 (42 USC § 2021) (e.g., waste generated as a result of decontamination or recycle activities).

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

"Gray" or "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 U.S. 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 which an individual might be unknowingly exposed to radiation from the waste.

"Indian tribe" means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the U.S. Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 USC § 479a).

"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.

"Intensity modulated radiation therapy" or "IMRT" means radiation therapy that uses nonuniform radiation beam intensities that have been determined by various computer-based optimization techniques.

"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 kilobecquerel.

"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

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dEtr is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus $K=dEtr/dm$, in units of J/kg, where the special name for the units of kerma is gray (Gy). When the materials is air, the quantity is referred to as "air kerma."

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

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

"kV" means kilovolts.

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

"kW" means kilowatt second.

"Land disposal facility" means the land, buildings, structures and equipment that are 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 or the radiation therapy system 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 the area illuminated by light, simulating the radiation field.

"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 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 radionuclides that are intended to be processed for the use of these radionuclides;
- b. Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;
- c. Radioactive material other than fissile 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 radioactive material in which the activity is distributed throughout and the estimated 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, excluding any shielding material, 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 milliamperere.

"mAs" means milliamperere second.

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

"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.

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"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 electronic brachytherapy service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

"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.

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 chapter 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.

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"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.

"Ophthalmic physicist" means an individual who (i) meets the requirements of 12VAC5-481-1790 and 12VAC5-481-2016 A 2 and (ii) is identified as an ophthalmic physicist on a specific medical use license issued by the agency, NRC, or another agreement state; permit issued by agency, NRC, or another agreement state broad scope licensee; medical use permit issued by a NRC master material licensee; or a permit issued by a NRC master material broad scope medical use permittee.

"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 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, or an associate 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;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique; 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 purposes 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.

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"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.

"Qualified inspector" means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic and therapeutic medical physics.

"Qualified medical physicist" means an individual qualified in accordance with 12VAC5-481-3390 D.

"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.

"Radiation therapy system" means a device that delivers radiation to a specific area of the body where cancer cells or tumors are located.

"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 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.

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"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 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 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

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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 requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the NRC requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015, in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015, may continue to be used. Any other special form encapsulation must meet requirements of this definition.

"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, (42 USC § 2071) determines to be special nuclear material, but does not include source material; or
2. Any material artificially enriched by any of the foregoing but does not include source material.

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

$$(175 \text{ grams contained U235/350}) + (50 \text{ grams U} - 233/200) + (50 \text{ grams Pu/200}) = 1$$

"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 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 this chapter, "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.

"Target-skin distance" or "TSD" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source, or both, to the surface of the irradiated object or patient.

"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.

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"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 milliampere-seconds (mAs);
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 milliampere-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 milliampere-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and
5. For all other equipment, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs).

"Telemetric position monitoring system" means a data transfer system that captures information by either instrumentation or measuring devices, or both, about the location 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 use is performed and where licensed material may be stored other than those locations of use authorized on the license.

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

"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. For the purpose of this chapter, devices used

to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

"These regulations" mean all parts of 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 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 that meets all applicable requirements of the 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 feet)).

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

"Tribal official" means the highest ranking individual that represents tribal leadership, such as the chief, president, or tribal council leadership.

"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 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 1 of 12VAC5-481-3770 F or may be determined by procedures described in 12VAC5-481-3770 A through E.

"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 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. Processing does not include sieving or encapsulating of ore or preparation of samples for laboratory analysis.

"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 (which may be chemically separated) 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 simulator" means a computed tomography (CT) unit used in conjunction with relevant software that recreates the treatment machine and that allows import, manipulation, display, and storage of images from CT or other imaging modalities, or both.

"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.

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"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, 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."

"Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal 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 authorized user's written order for the administration of radioactive material, radiation from radioactive material, or radiation from a radiation producing machine to a specific patient or human research subject.

"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 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 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 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 tubes, 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 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 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.

12VAC5-481-440. Filing application for specific licenses.

A. Applications for specific licenses shall be filed on a form prescribed by the agency.

B. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

D. An application for a license may include a request for a license authorizing one or more activities.

E. Applications and documents submitted to the agency may be made available for public inspection in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia). The agency may withhold records in accordance with specific exemptions in the Virginia Freedom of Information Act or as otherwise specified by law.

F. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:

1. Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or an Agreement state under equivalent regulations;
2. Contain the information in 10 CFR 32.210(c);
3. For sources or devices containing radioactive material manufactured prior to October 23, 2012, that are not registered with the NRC under 10 CFR 32.210 or with an Agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant shall provide:
 - a. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and
 - b. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect

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health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test;

4. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

5. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used in lieu of identifying each sealed source and device.

G. Each application to possess radioactive material in unsealed form, on a foil or plated source, or sealed in glass in excess of the quantities in 12VAC5-481-3740 shall contain one of the following:

1. An evaluation showing that the projected dose to a person offsite due to a release of radioactive material would not exceed 0.01 Sv (1 rem) total effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or

2. An emergency plan, reviewed and commented on by offsite response organizations expected to respond in the event of an accident that contains the following information:

a. Facility description. A brief description of the licensee or applicant's facility and surroundings.

b. Types of accidents. An identification of each type of radioactive materials accident for which actions by licensee staff or offsite response organizations will be needed to protect members of the public.

c. Classification of accidents. A method for classifying and declaring an accident as alert or site area emergency.

d. Detection of accidents. Identification of the means for detecting each type of alert or site area emergency in a timely manner.

e. Mitigation of consequences. A brief description of the means and equipment that are available for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

f. Assessment of releases. A brief description of the methods and equipment available to assess releases of radioactive material.

g. Responsibilities. A brief description of the responsibilities of the licensee or applicant's personnel who will respond if an accident occurs, including identification of personnel

responsible for promptly notifying offsite response organizations, including the agency.

h. Plan maintenance. A brief description of the positions assigned and methods to develop, maintain and update the plan.

i. A list of offsite response organizations, description of their responsibilities and anticipated actions, and copy of formal commitments, if any.

j. Notification and coordination. A brief description of the means to promptly notify the offsite response organizations and request offsite assistance including medical assistance for the treatment of contaminated injured onsite workers. The notification and coordination shall include alternate provisions in case key personnel, parts of the facility, or some equipment are unavailable. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

k. Information to be communicated. A brief description of the types of information on facility status, radioactive releases and recommended protective actions, if necessary, to be given to offsite response organizations and the agency. A licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. A licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

l. Training. A brief description of the frequency, performance objectives and plan for training that the licensee or applicant will provide workers on how to respond to an emergency, including any special instructions and orientation tours that the licensee or applicant will offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific hazards and emergency procedures. The training shall also prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of drills, exercises and team training for such scenarios.

m. Drills and exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. The licensee or applicant shall invite offsite response organizations to participate in biennial exercises. The exercises shall use accident scenarios postulated as the most probable for the specific site and the scenarios may not be known to most exercise participants. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

n. Safe condition. A brief description of the means of restoring the facility and surroundings to a safe condition after an accident.

o. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-To-Know Act of 1986, Title III, P.L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

H. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part VII (12VAC5-481-1660 et seq.) of this chapter shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part III (12VAC5-481-380 et seq.) of this chapter for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 12VAC5-481-480 I.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an ANP as specified in 12VAC5-481-480 I 2.

4. Information identified in 12VAC5-481-480 I 1 c on the PET drugs to be noncommercially transferred to members of its consortium.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII (12VAC5-481-1660 et seq.).

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII (12VAC5-481-1660 et seq.) will be approved if:

a. The applicant satisfies the general requirements specified in 12VAC5-481-450;

b. The applicant submits evidence that the applicant is at least one of the following:

(1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(2) Registered or licensed with a state agency as a drug manufacturer;

(3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency.

c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10;

b. An individual that meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790, and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in 12VAC5-481-10, designated as an ANP if:

(1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or

d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710.

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3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:

- a. The individual's certification by a specialty board whose certification process has been recognized by the NRC with the written attestation signed by a preceptor as required by 12VAC5-481-1770;
- b. An NRC or another Agreement state license;
- c. NRC master materials licensee permit;
- d. The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or
- e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
- f. The Virginia Board of Pharmacy's license.

4. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

- a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
- b. Check each instrument for constancy and proper operation at the beginning of each day of use.

5. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

6. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination in accordance with 12VAC5-481-1930. The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 12VAC5-481-1930 A at the time of the generator elution in accordance with 12VAC5-481-2080 D.

12VAC5-481-451. Physical protection of Category 1 and Category 2 quantities of radioactive material.

A. Any licensee who possesses or uses an aggregated quantity of Category 1 or Category 2 radioactive material equal to or in excess of those in subdivision 1 of this subsection shall establish a physical protection program that meets all requirements detailed in this section.

1. Radionuclides of concern.

Radionuclide	Category 1 (TBq) ^{1,2}	Category 1 (Ci) ^{1,2}	Category 2 (TBq) ^{1,2}	Category 2 (Ci) ^{1,2}
Am-241	60	1,620	0.6	16.2
Am-241/Be	60	1,620	0.6	16.2
Cf-252	20	540	0.2	5.4
Cm-244	50	1,350	0.5	13.5
Co-60	30	810	0.3	8.1
Cs-137	100	2,700	1	27
Gd-153	1,000	27,000	10	270
Ir-192	80	2,160	0.8	21.6
Pm-147	40,000	1,080,000	400	10,800
Pu-238	60	1,620	0.6	16.2
Pu-239/Be	60	1,620	0.6	16.2
Ra-226	40	1,080	0.4	10.8
Se-75	200	5,400	2	54
Sr-90 (Y-90)	1,000	27,000	10	270
Tm-170	20,000	540,000	200	5,400
Yb-169	300	8,100	3	81
Combinations of radioactive materials listed above ³			See footnote 4 below	

¹The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the Category 1 or Category 2 threshold.

²The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , A (i,n), to the Category 1 or Category 2 threshold for radionuclide n , Q_n , listed for that radionuclide equals or exceeds one. $[(\text{aggregated source activity for radionuclide A}) / (\text{quantities of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) / (\text{quantities of concern for radionuclide B})] + \text{etc.} \dots \geq 1$.

2. A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of this section.

3. A licensee that possesses radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this section. The licensee shall implement the following requirements to secure the radioactive waste:

- a. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;
- b. Use a locked door or gate with monitored alarm at the access control point;
- c. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
- d. Immediately notify the local law-enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste.

B. Background investigations and access authorization program.

1. Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that possesses an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements in this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements in this subsection upon an amendment request of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold. Any licensee that has not previously implemented the increased control requirements of this section shall implement the provisions of this subsection before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. The licensee's access authorization program shall ensure that the individuals specified in subdivision 1 c of this subsection are trustworthy and reliable.

c. Licensees shall subject the following individuals to an access authorization program:

- (1) Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material; and
- (2) Reviewing officials.

d. Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals whose assigned job duties require unescorted access to Category 1 or Category 2 quantities of radioactive material.

e. Licensees need not subject the categories of individuals listed in subdivision 5 a of this subsection to the investigation elements of the access authorization program.

2. Access authorization program requirements.

a. Granting unescorted access authorization.

(1) Licensees shall implement the requirements of this subsection for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by subdivision C 2 c of this section before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Reviewing officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the agency via an appropriate means listed in 12VAC5-481-150. The fingerprints of the named reviewing official shall be taken by a law-enforcement agency, a federal or state agency that provides fingerprinting services to the public, or a commercial fingerprinting service authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with subdivision 3 c of this subsection.

(3) Reviewing officials shall be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive material.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

- (a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

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(b) The individual is subject to a category listed in subdivision 5 a of this subsection.

c. Informed consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent shall include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals who meet the requirements of subdivision 3 b of this subsection. A signed consent shall be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his consent, the licensee may not initiate elements of the background investigation that were not in progress at the time the individual withdrew his consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause of denial or termination of unescorted access authorization.

d. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subsection is sufficient cause for denial or termination of unescorted access.

e. Determination basis.

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all the information collected to meet the requirements of this subsection.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all the information collected to meet the requirements of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access information.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures shall include the provisions for the notification of individuals who are denied unescorted access. The procedures shall include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures shall contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. Right to correct and complete information.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this subsection with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification shall be maintained by the licensee for a period of one year from the date of the notification.

(2) If, after reviewing his criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law-enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 28 CFR 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division will make any change necessary in accordance with the

information supplied by that agency. Licensees shall provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of individuals approved for unescorted access authorization for three years after the list is superseded or replaced.

3. Background investigations.

a. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices containing the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation shall encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation shall include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection;

(2) Verification of true identity of the individual who is applying for unescorted access authorization. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document or maintain a photocopy of identifying documents on file in accordance with subdivision 6 of this subsection. Licensees shall certify in writing that the identification was properly reviewed and shall maintain the certification and all related documents for review upon inspection;

(3) Verification of employment history, including military history. Licensees shall verify the individual's

employment with each previous employer for the most recent seven years before the date of application;

(4) Verification that the individual participated in the education process during the claimed period;

(5) Completion of reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to, the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subsection shall be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) To the extent possible, obtain independent information to corroborate the information provided by the individual (e.g., seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide the information or indicates an inability or unwillingness to provide information within a timeframe deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation and attempt to obtain the information from an alternate source.

b. Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material in accordance with ~~12VAC5-481-451, "Increased controls and fingerprinting,"~~ fingerprint orders as effective on October 3, 2008, can continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement of subdivision 3 c of this subsection.

c. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection. The reinvestigations shall be completed within 10 years of the date on which these elements were last completed.

4. Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material.

a. General performance objective and requirements.

(1) Except for those individuals listed in subdivision 5 a of this subsection and those individuals grandfathered under subdivision 3 b of this subsection, each licensee subject to

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the provisions of this section shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. The licensee shall submit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his fingerprints will be used to secure a review of his criminal history record and shall inform him of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive material if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee based upon a background investigation conducted under this subsection, regulations or Fingerprint Orders from another Agreement state, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of subdivision 6 c of this subsection.

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for processing of fingerprint checks.

(1) For the purpose of complying with this subsection, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05-B32M T-8B20~~, Rockville, MD, 20852, one completed, legible standard fingerprint card (form FD-258, ORIMDNRCOOZ), electronic fingerprint scan, or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by email to forms.resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~<http://www.nrc.gov/site/help/e-submittals.html>~~ <https://www.nrc.gov/security/chp.html>.

(2) Fees for processing of fingerprint cards are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to the "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at (301) 492-3534~~ Division of Physical and Cyber Security Policy by emailing crimhist.resource@nrc.gov.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the ~~Electronic Submittals Licensee Criminal History Records Checks & Firearms Background Check information~~ page at <http://www.nrc.gov/site/help/e-submittals.html> <https://www.nrc.gov/security/chp.html> and see the link for the ~~Criminal History Program under Electronic Submission Systems~~ How do I determine how much to pay for the request?.

(3) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application for a criminal history records check.

5. Relief.

a. Fingerprinting, identification and criminal history records checks, and other elements of the background investigation required by this subsection are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive material:

(1) An employee of the NRC or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;

(2) A member of Congress;

(3) An employee of a member of Congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

(4) The governor of a state or his designated state employee representative;

(5) Federal, state, or local law-enforcement personnel;

(6) State radiation control program directors and state homeland security advisors or their designated employee representatives;

(7) State radiation program employees conducting security inspections on behalf of the NRC under an agreement executed under § 274i of the Atomic Energy Act (42 USC § 2021i);

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of Category 1 and Category 2 quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

(12) Any individual who has an active federal security clearance and provides the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for whom the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider shall be provided to the licensee. The licensee shall retain

the documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Fingerprinting and identification and criminal history records checks required by this subsection are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check, and the individual provides the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:

(1) National Agency Check;

(2) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

(3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

(4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;

(5) Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and

(6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

6. Protection of information.

a. Each licensee that obtains background information on an individual under this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

c. The personal information obtained on an individual from a background investigation may be provided to another licensee:

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(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in that individual's file; and

(2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

d. The licensee shall make background investigation records obtained under this subsection available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.

e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

7. Access authorization program review.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. The review shall be performed at least annually.

b. The results of the reviews, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the access authorization program; the cause of the conditions and, when appropriate, recommend corrective actions; and corrective actions taken. The licensee shall review the findings and take additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records shall be maintained for three years.

C. Physical protection requirements during use.

1. Security program.

a. Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements of this subsection upon an amendment request for modification of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material. Any licensee that has not previously implemented the requirements of this subsection shall

provide written notification to the agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

c. Each licensee's security program shall include the program features, as appropriate, described in subdivisions 2 through 8 of this subsection.

2. General security program requirements.

a. Security plan.

(1) Each licensee identified in subdivision 1 a of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subsection. The security plan shall, at a minimum, (i) describe the measures and strategies used to implement the requirements of this subsection and (ii) identify the security resources, equipment, and technology used to satisfy the requirements of this subsection.

(2) The security plan shall be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of agency requirements. The licensee shall ensure that (i) the revision has been reviewed and approved by the individual with overall responsibility for the security program and (ii) the affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

b. Implementing procedures.

(1) The licensee shall develop and maintain written procedures that document how the requirements of this subsection and the security plan will be met.

(2) The implementing procedures and revisions to these procedures shall be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure shall be retained for three years after the record is superseded.

c. Training.

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training shall include at a minimum, instruction on:

(a) The licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and the purpose and function of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of agency requirements;

(c) The responsibility of the licensee to report promptly to the local law-enforcement agency and the agency any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training shall be commensurate with the individual's potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

(3) Refresher training shall be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training shall include (i) review of the training requirements of this subsection and changes made to the security program since the last training; (ii) reports on all relevant security issues, problems, and lessons learned; (iii) relevant results of agency inspections; and (iv) relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records shall include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of information.

(1) Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and prevent the unauthorized disclosure of their security plan, implementing procedures, and the list of individuals who have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to and for proper

handling and protection against unauthorized disclosure of the security plan ~~and~~, implementing procedures, and the list of individuals who have been approved for unescorted access.

(3) Before granting an individual access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access, licensees shall:

(a) Evaluate an individual's need to know the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access; and

(b) If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, the licensee shall complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in subdivisions B 3 a (2) through (7) of this section.

(4) Licensees need not subject any individual to background investigation elements for protection of information if that individual is included in the categories of individuals listed in subdivisions B 5 a (1) through (12) of this section or is a security service provider employee, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in subdivisions B 3 a (2) though (7) of this subsection, has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access.

(6) Licensees ~~or~~ shall maintain a list of persons currently approved for access to the security plan implementing procedures, or the list of individuals who have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days after the determination, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access.

(7) When not in use, the licensee shall store its security plan ~~and~~, implementing procedures, and the list of individuals who have been approved for unescorted access in a manner to prevent unauthorized access. Information

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stored in nonremovable electronic form shall be password protected.

(8) The licensee shall retain as a record a copy of the information protection procedures and the list of individuals approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals who have been approved for unescorted access for three years after the document has been superseded.

3. Local law-enforcement agency (LLEA) coordination.

a. A licensee subject to this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA shall include:

(1) A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subsection; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

b. The licensee shall notify the agency within three business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation shall be kept for three years.

d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

4. Security zones.

a. Licensees shall ensure that all aggregated Category 1 or Category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

b. Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

c. Security zones shall, at a minimum, allow unescorted access only to approved individuals by:

(1) Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a

natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone;

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

d. For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

e. Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material shall be escorted by an approved individual when in a security zone.

5. Monitoring, detection, and assessment.

a. Monitoring and detection.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection shall be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(c) A monitored video surveillance system;

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designed individual located outside the security zone.

(3) A licensee subject to this subsection shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability shall provide:

(a) For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability shall be provided by electronic sensors linked to an alarm, continuous monitored video surveillance, or direct visual surveillance; and

- (b) For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.
 - b. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.
 - c. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessments system, licensees shall:
 - (1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and
 - (2) Provide an alternate communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmissions systems may not be subject to the same failure modes as the primary systems.
 - d. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.
6. Maintenance and testing.
- a. Each licensee subject to this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection shall be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no frequency suggested by the manufacturer or the frequency specified is greater than three months, the testing shall be performed at least quarterly, not to exceed three months.
 - b. The licensee shall maintain records on the maintenance and testing activities for three years.
7. Requirements for mobile devices. Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material shall:
- a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and
 - b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.
8. Security program review.
- a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. The review shall be conducted at least annually, not to exceed 12 months.
 - b. The results of the review, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the security program, the cause of the condition, corrective actions taken, and, when appropriate, recommend corrective actions. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.
 - c. The licensee shall maintain the review documentation for three years.
9. Reporting of events.
- a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency by telephone at 804-864-8150 during normal business hours and 804-674-2400 after hours. In no case shall the notification to the agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.
 - b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the agency by telephone 804-864-8150 during normal business hours and 804-674-2400 after hours.

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c. The initial telephonic notification shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include sufficient information for agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

D. Physical protection in transit.

1. Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material. A licensee transferring a Category 1 or Category 2 quantity of radioactive material to a licensee of the agency, the NRC, or another Agreement state shall meet the license verification provisions listed in this subdivision instead of those listed in 12VAC5-481-570.

a. Any licensee transferring Category 1 quantities of radioactive material to a licensee of the agency, the NRC, or another Agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring Category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another Agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

c. In an emergency where the licensee cannot reach the license-issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification shall include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment, the authorized address. The licensee shall keep a copy of the certification. The certification shall be confirmed by use of the NRC's license verification system or by contacting the license-issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for three years.

2. Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 a, 3 e, 4, 5 a (1), 5 b (1), 5 c, 6 a, 6 c, 6 e, 6 g, and 6 h of this subsection.

b. For shipments of Category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 b through 3 e, 5 a (2), 5 a (3), 5 b (2), 5 c, 6 b, 6 d, 6 f, 6 g, and 6 h of this subsection.

c. The shipping licensee shall be responsible for meeting the requirements of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subsection.

3. Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to discuss the state's intention to provide law-enforcement escorts and identify safe havens; and

(3) Document the preplanning and coordination activities.

b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

c. Each licensee that receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

d. Each licensee that transports or plans to transport a shipment of a Category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subdivision 3 b of this subsection, shall promptly notify the receiving licensee of the new no-later-than arrival time.

e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof as a record for three years.

4. As specified in subdivision 3 of this subsection, each licensee shall provide advance notification to the agency and the governor of a state, or the governor's designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of the state, before the transport or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification:

(1) The notification shall be made to the agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governor's designees is available on the NRC website at <https://scp.nrc.gov/special/designee.pdf>. The notification to the agency shall be in accordance with 12VAC5-481-150.

(2) A notification delivered by mail shall be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail shall reach the agency at least four days before the transport of the shipment commences and shall reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

b. Each advance notification of shipment of Category 1 quantities of radioactive material shall contain the following information, if available at the time of the notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival for the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the agency and the governor of the state or the governor's designee.

(2) A licensee shall promptly notify the agency and governor of the state or the governor's designee of any

changes to the information provided in accordance with this subdivision.

d. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the agency and the governor of each state or to the governor's designee previously notified. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

f. State officials, state employees, and other individuals, whether or not licensees of the agency, NRC, or another Agreement state, who receive schedule information of the kind specified in subdivision 4 b of this subsection shall protect that information against unauthorized disclosure as specified in subdivision C 2 d of this section.

5. Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment.

a. Shipments by road.

(1) Each licensee who transports or delivers to a carrier for transport in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, seven days a week and have the ability to communicate immediately, in an emergency, with the appropriate law-enforcement agencies;

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle, when an escort vehicle is used, and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center shall be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

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(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the U.S. Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(e) Develop written normal and contingency procedures to address (i) notifications to the communication center and law-enforcement agencies; (ii) communication protocols that shall include a strategy for the use of authentication codes and duress codes and provisions for refueling and other stops, detours, and locations where communication is expected to be temporarily lost; (iii) loss of communication; and (iv) responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. Shipments by rail.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location

of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

6. Reporting of events.

a. The shipping licensee shall notify the appropriate LLEA and the agency within one hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law-enforcement agency in the area of the shipment's last confirmed location. During the investigation required by this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

b. The shipping licensee shall notify the agency within four hours of its determination that a shipment of Category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located

and secure, the licensee shall immediately notify the agency.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of Category 1 radioactive material.

d. The shipping licensee shall notify the agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

e. The shipping licensee shall notify the agency and the LLEA as soon as possible upon recovery of any lost or missing Category 1 quantities of radioactive material.

f. The shipping licensee shall notify the agency as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

g. The initial telephonic notification required by subdivisions 6 a through 6 d of this subsection shall be followed within a period of 30 days by a written report submitted to the agency. A written report is not required for notifications on suspicious activities required by subdivisions 6 c and 6 d of this subsection. The report shall include the following information:

- (1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;
- (2) A description of the circumstances under which the loss or theft occurred;
- (3) A statement of disposition, or probable disposition, of the licensed material involved;
- (4) Actions that have been taken, or will be taken, to recover the material; and
- (5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

E. Records.

1. Each record required by this section shall be legible throughout the retention period specified. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The

record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

2. Licensees shall maintain the records that are required by this section for the period specified. If a retention period is not otherwise specified, these records shall be retained until the agency terminates the facility's license. All records related to this section may be destroyed upon agency termination of the facility license.

12VAC5-481-480. Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices that contain radioactive material.

A. Reserved.

B. Licensing the distribution of radioactive material in exempt quantities. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, DC 20555-0001.)

C. Licensing the manufacture or initial transfer of devices to persons generally licensed under 12VAC5-481-430 B.

1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 12VAC5-481-430 B or equivalent regulations of the NRC, or another Agreement state will be approved if:

a. The applicant satisfies the general requirements of 12VAC5-481-450;

b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(1) The device can be safely operated by persons not having training in radiological protection;

(2) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10% of the limits specified in 12VAC5-481-640; and

(3) Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it

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is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in 12VAC5-481-3580, Column IV;

c. Each device bears a durable, legible, clearly visible label or labels approved by the agency, which contain in a clearly identified and separate statement:

(1) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

(2) The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(3) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(a) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

_____Name of manufacturer or initial transferor

(b) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. (The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.)

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_____Name of manufacturer or initial transferor;

d. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, and the words, "Caution Radioactive Material," the radiation symbol described in 12VAC5-481-850, and the name of the manufacturer or initial distributor;

e. Each device meeting the criteria of 12VAC5-481-430 B 4 m bears a permanent (e.g., embossed, etched, stamped,

or engraved) label affixed to the source housing if separate, or the device if the source housing is not separable, that includes the words, "Caution Radioactive Material," and, if practicable, the radiation symbol described in 12VAC5-481-850; and

f. The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information that includes, but is not limited to:

- a. Primary containment or source capsule;
- b. Protection of primary containment;
- c. Method of sealing containment;
- d. Containment construction materials;
- e. Form of contained radioactive material;
- f. Maximum temperature withstood during prototype tests;
- g. Maximum pressure withstood during prototype tests;
- h. Maximum quantity of contained radioactive material;
- i. Radiotoxicity of contained radioactive material; and
- j. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under 12VAC5-481-430 B, or under equivalent regulations of the NRC, or another Agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in 12VAC5-481-640.

4. Each person licensed under this subsection to distribute devices to generally licensed persons shall:

a. Furnish a copy of the general license contained in 12VAC5-481-430 B to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 12VAC5-481-430 B;

b. Furnish a copy of the general license contained in the NRC's, or another Agreement state's, regulation equivalent to 12VAC5-481-430 B, or alternatively, furnish a copy of the general license contained in 12VAC5-481-430 B to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC, or another Agreement state. If a copy of the general license in 12VAC5-481-430 B is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, or another Agreement state, under requirements substantially the same as those in 12VAC5-481-430 B;

c. Report to the agency all transfers of such devices to persons for use under the general license in 12VAC5-481-430 B. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 12VAC5-481-430 B during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

d. Furnish reports to other agencies.

(1) Report to the NRC all transfers of such devices to persons for use under the NRC's general license in 10 CFR 31.5.

(2) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to 12VAC5-481-430 B.

(3) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be

submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(4) If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.

(5) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

e. Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 12VAC5-481-430 B, or equivalent regulations of the NRC or another Agreement state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of subdivision 4 of this subsection.

f. If a notification of bankruptcy has been made under 12VAC5-481-500 E or the license is to be terminated, each person licensed under this section shall provide, upon request, to the agency, the NRC and to any appropriate Agreement state, records of final disposition required under subdivision 4 e of this subsection.

g. The licensee shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section shall be maintained for a period of three years following the date of the recorded event.

D. Special requirements for the manufacture, initial transfer, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 12VAC5-481-430 D will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450.

2. The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

a. Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

b. Details of construction and design;

c. Details of the method of binding or containing the tritium or promethium-147;

d. Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

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- e. Quality assurance procedures to be followed that are sufficient to ensure compliance with subdivision 8 of this subsection; and
 - f. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the device.
3. Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.
4. The agency determines that:
- a. The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions likely to be encountered in normal use and handling of the device;
 - b. The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact with it by any person;
 - c. The device is so designed that it cannot easily be disassembled; and
 - d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 5 of this subsection.
5. The applicant shall subject at least five prototypes of the device to tests as follows:
- a. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.
 - b. The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 c of this subsection.
 - c. Device designs are rejected for which the following has been detected for any unit:
 - (1) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;
 - (2) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or
 - (3) Any other evidence of physical damage.
6. The device has been registered in the Sealed Source and Device Registry.

7. Labeling.

- a. A person licensed to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under 12VAC5-481-430 D, except as provided in subdivision 7 b of this subsection, shall affix to each device a label containing the radiation symbol prescribed by 12VAC5-481-850, such other information as may be required by the agency including disposal instructions when appropriate, and the following or a substantially similar statement that contains the information in the following statement:

The receipt, possession, use, and transfer of this device, Model* _____, Serial No.* _____, containing _____ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

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(Name of manufacturer, assembler, or initial transferor.)*

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

- b. If the agency determines that it is not feasible to affix a label to the device containing all the information called for in subdivision 7 a of this subsection, it may waive those requirements and require the following:

(1) A label is affixed to the device identifying:

- (i) The manufacturer, assembler, or initial transferor; and
- (ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor;

(ii) The type and quantity of radioactive material;

(iii) The model number;

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the NRC or of an Agreement state; and

(v) Such other information as may be required by the agency, including disposal instructions when appropriate.

8. Quality assurance; prohibition of transfer.

- a. Each person licensed under this subsection shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

b. Each person licensed under this subsection shall:

(1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in subdivision 8 c of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

c. The licensee shall subject each inspection lot to the following:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;

(ii) Levels of radiation in excess of 0.5 millirad (5 microgray) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under this subsection.

d. No person licensed under this subsection shall transfer to persons generally licensed under 12VAC5-481-430 D or under an equivalent general license of the NRC or other Agreement state:

(1) Any luminous safety device tested and found defective under any condition of a license issued under subdivisions 1 through 6 or this subdivision 8 of this subsection, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 b (2) of this subsection, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this subsection; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 b (2) and d (2)

(i) of this subsection and any other criteria that may be

required as a condition of the license issued under this subsection.

9. Transfer reports.

a. Each person licensed under this subsection shall file an annual report with the agency, which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under 12VAC5-481-430 D. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers have been made to persons generally licensed under 12VAC5-481-430 D during the reporting period, the report shall indicate so.

b. Each person licensed under this subsection shall report annually all transfers of devices to persons for use under a general license in the NRC or another Agreement state's regulations that are equivalent to 12VAC5-481-430 D to (i) the NRC at Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, by an appropriate method listed in 10 CFR 30.6(a) and (ii) the responsible Agreement state agency. The report shall state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to the NRC or particular Agreement state during the reporting period, this information shall be reported to the NRC and responsible Agreement state agency.

E. Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 12VAC5-481-430 F. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 12VAC5-481-430 F will be approved if:

1. The applicant satisfies the general requirement of 12VAC5-481-450.

2. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

a. Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

b. Details of construction and design;

c. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

d. Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or

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radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

e. Details of quality control procedures to be followed in manufacture of the source;

f. Description of labeling to be affixed to the source or the storage container for the source; and

g. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the source.

3. Each source will contain no more than 5 microcuries of americium-241 or radium-226.

4. The agency determines, with respect to any type of source containing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, that:

a. The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

b. The source has been subjected to and has satisfactorily passed appropriate tests required by subdivision 5 of this subsection.

5. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 to tests as follows:

a. The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

b. The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

c. The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 d of this subsection.

d. Source designs are rejected for which the following has been detected for any unit (i) removal of more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 from the source or (ii) any other evidence of physical damage.

6. Labeling of devices. Each person licensed under this subsection shall affix to each source or storage container for the source a label that shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar

statement which contains the information in the following statement:

"The receipt, possession, use, and transfer of this source, Model, Serial No., are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission (NRC) or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)"

7. Leak testing of each source. Each person licensed under this subsection shall perform a dry wipe test upon each source containing more than 0.1 microcurie (3.7 kilobecquerel) of americium-241 or radium-226 before transferring the source to a general licensee under 12VAC5-481-430 F or under equivalent regulations of the NRC or another Agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 by the methods described in this section, the source shall be rejected and shall not be transferred to a general licensee under 12VAC5-481-430 F, or equivalent regulations of the NRC or another Agreement state.

F. Reserved.

G. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 12VAC5-481-430 G will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450.

2. The radioactive material is to be prepared for distribution in prepackaged units of:

a. Carbon-14 in units not exceeding 370 kBq (10 μ Ci) each.

b. Cobalt-57 in units not exceeding 370 kBq (10 μ Ci) each.

c. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 μ Ci) each.

d. Iodine-125 in units not exceeding 370 kBq (10 μ Ci) each.

- e. Mock iodine-125 in units not exceeding 1.85 kBq (0.05 μ Ci) of iodine-129 and 185 Bq (0.005 μ Ci) of americium-241 each.
 - f. Iodine-131 in units not exceeding 370 kBq (10 μ Ci) each.
 - g. Iron-59 in units not exceeding 740 kBq (20 μ Ci) each.
 - h. Selenium-75 in units not exceeding 370 kBq (10 μ Ci) each.
3. Each prepackaged unit bears a durable, clearly visible label:
- a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 μ Ci) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 μ Ci) of hydrogen-3 (tritium); 740 kBq (20 μ Ci) of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (0.05 μ Ci) of iodine-129 and 185 Bq (0.005 μ Ci) of americium-241 each; and
 - b. Displaying the radiation caution symbol described in 12VAC5-481-850 and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."
4. One of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:
- a. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.
 _____ Name of manufacturer
 - b. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.
 _____ Name of manufacturer
5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the
- Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in 12VAC5-481-910.
- H. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 12VAC5-481-430 H will be approved if:
- 1. The applicant satisfies the general requirements of 12VAC5-481-450;
 - 2. The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:
 - a. Chemical and physical form and maximum quantity of strontium-90 in the device;
 - b. Details of construction and design of the source of radiation and its shielding;
 - c. Radiation profile of a prototype device;
 - d. Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;
 - e. Details of quality control procedures to be followed in manufacture of the device;
 - f. Description of labeling to be affixed to the device;
 - g. Instructions for handling and installation of the device;
 - h. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the safety of the device;
 - 3. Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;
 - 4. Each device will bear durable, legible labeling that includes the radiation caution symbol prescribed by 12VAC5-481-850, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited, and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;
 - 5. The agency determines that:
 - a. The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions that are likely to be encountered in normal use and handling of the device;

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- b. The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;
 - c. The device is so designed that it cannot be easily disassembled;
 - d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 6 of this subsection;
 - e. Quality control procedures have been established to satisfy the requirements of subdivision 8 of this subsection;
6. The applicant shall subject at least five prototypes of the device to tests as follows:
- a. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.
 - b. The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subdivision 6 c of this subsection.
 - c. Device designs are rejected for which the following has been detected for any unit:
 - (1) A leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device;
 - (2) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or
 - (3) Any other evidence of physical damage;
7. The device has been registered in the Sealed Source and Device Registry; and
8. Quality assurance; prohibition of transfer.
- a. Each person licensed under this subsection shall visually inspect each device and shall reject any that has an observable physical defect that could affect containment of the strontium-90.
 - b. Each person licensed under this subsection shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.
- c. Each person licensed under this subsection shall:
 - (1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and
 - (2) Subject inspection lots to acceptance sampling procedures by procedures specified in subdivision 8 d of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.
 - d. Each person licensed under this subsection shall subject each inspection lot to:
 - (1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.
 - (2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing using methods of inspection adequate to determine compliance with the following criteria for defective (i) a leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device and (ii) any other criteria specified in the license issued under this subsection.
 - e. No person licensed under this subsection shall transfer to persons generally licensed under 12VAC5-481-430 H, or under an equivalent general license of the NRC or another Agreement state:
 - (1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under this subsection unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or
 - (2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 c (2) of this subsection, unless:
 - (i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this subsection; and
 - (ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 c (2) and 8 e (2) (i) of this subsection and any other criteria as may be required as a condition of the license issued under this subsection.
- I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII (12VAC5-481-1660 et seq.) of this chapter.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter will be approved if:
 - a. The applicant satisfies the general requirements specified in 12VAC5-481-450;
 - b. The applicant submits evidence that the applicant is at least one of the following:
 - (1) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
 - (2) Registered or licensed with a state agency as a drug manufacturer;
 - (3) Licensed as a pharmacy by the Virginia Board of Pharmacy;
 - (4) Operating as a nuclear pharmacy within a federal medical institution; or
 - (5) A PET drug production facility registered with a state agency;
 - c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and
 - d. The applicant ~~satisfies~~ commits to the following labeling requirements:
 - (1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.
 - (2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.
2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:
 - a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10;
 - b. An individual who meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790, and the licensee has received an approved license amendment identifying this individual as an ANP;
 - c. A pharmacist, as defined in 12VAC5-481-10, designated as an ANP if:
 - (1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and
 - (2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or
 - d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710.
 3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:
 - a. The individual's certification by a specialty board whose certification process has been recognized by the NRC ~~with the written attestation signed by a preceptor as required by 12VAC5-481-1770~~ as specified in 12VAC5-481-1770;
 - b. An NRC or another Agreement state license;
 - c. NRC master materials licensee permit;
 - d. The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or
 - e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
 - f. The Virginia Board of Pharmacy's license.
 4. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:
 - a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10;
 - b. An individual who meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790, and the licensee has received an approved license amendment identifying this individual as an ANP;
 - c. A pharmacist, as defined in 12VAC5-481-10, designated as an ANP if:
 - (1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and
 - (2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or
 - d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710.

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- a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
- b. Check each instrument for constancy and proper operation at the beginning of each day of use.

5. A licensee shall satisfy the labeling requirements in subsection I 1 d of this section.

6. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

~~6.~~ 7. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination in accordance with 12VAC5-481-1930. The licensee shall record the results of each test and retain each record for three years after the record is made.

J. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter for the medical use of radioactive material or use as a calibration, transmission or reference source will be approved if:

1. The applicant satisfies the general requirements in 12VAC5-481-450;
2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - a. The radioactive material contained, its chemical and physical form, and amount;
 - b. Details of design and construction of the source or device;
 - c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
 - d. For devices containing radioactive material, the radiation profile of a prototype device;
 - e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
 - f. Procedures and standards for calibrating sources and devices;

g. Legend and methods for labeling sources and devices as to their radioactive content; and

h. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device provided, that instructions that are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the agency for distribution to persons licensed pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter for the medical use of radioactive material or under equivalent licenses of the NRC, or another Agreement state, provided that such labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;

4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source;

5. In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

- a. Primary containment or source capsule;
- b. Protection of primary containment;
- c. Method of sealing containment;
- d. Containment construction materials;
- e. Form of contained radioactive material;
- f. Maximum temperature withstood during prototype tests;
- g. Maximum pressure withstood during prototype tests;
- h. Maximum quantity of contained radioactive material;
- i. Radiotoxicity of contained radioactive material; and
- j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices; and

6. The device has been registered in the Sealed Source and Device Registry.

K. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 12VAC5-481-420 C or equivalent regulations of the NRC or another Agreement state will be approved if:

- a. The applicant satisfies the general requirements specified in 12VAC5-481-450;
- b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10% of the limits specified in 12VAC5-481-640; and
- c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The agency may deny any application for a specific license under this subsection if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to subdivision 1 of this subsection shall:

- a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
- b. Label or mark each unit to:
 - (1) Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
 - (2) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or another Agreement state;
- c. Assure that the depleted uranium before being installed in each product or device has been impressed with the

following legend clearly legible through any plating or other covering: "Depleted Uranium";

d. Do the following:

(1) Furnish a copy of the general license contained in 12VAC5-481-420 C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license contained in 12VAC5-481-420 C is transferred; or

(2) Furnish a copy of the general license contained in the NRC's or another Agreement state's regulation equivalent to 12VAC5-481-420 B and a copy of the NRC's or another Agreement state's certificate, or alternatively, furnish a copy of the general license contained in 12VAC5-481-420 C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license of the NRC or another Agreement state is transferred, with a note explaining that use of the product or device is regulated by the NRC or another Agreement state under requirements substantially the same as those in 12VAC5-481-420 C;

e. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 12VAC5-481-420 C. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 12VAC5-481-420 C during the reporting period, the report shall so indicate;

f. Do the following:

(1) Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in 10 CFR 40.25;

(2) For devices transferred to another Agreement state, report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to 12VAC5-481-420 C;

(3) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar

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quarter in which such product or device is transferred to the generally licensed person;

(4) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC; and

(5) If no transfers have been made to general licensees within another Agreement state during the reporting period, this information shall be reported to the responsible state agency upon the request of that agency; and keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 12VAC5-481-420 C or equivalent regulations of the NRC or another Agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

L. Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

12VAC5-481-590. Reciprocal recognition of licenses.

Licenses of radioactive, source, and special nuclear material in quantities not sufficient to form a critical mass.

1. Subject to these regulations, any person who holds a specific license from the NRC or another Agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within the Commonwealth for a period not in excess of 180 days during the one-year reciprocal approval period, provided that:

a. The licensing document does not limit the activity authorized by such document to specified installations or locations;

b. The out-of-state licensee notifies the agency ~~in writing~~ using Applications for Reciprocal Recognition of Out-of-State Radioactive Materials License and Reciprocity Notification forms at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year

following the receipt of the initial notification from a person engaging in activities under the general license provided in this subdivision;

c. The out-of-state licensee complies with all applicable regulations of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions that may be inconsistent with applicable regulations of the agency;

d. The out-of-state licensee supplies such other information as the agency may request;

e. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subdivision except by transfer to a person:

(1) Specifically licensed by the agency, the NRC or another Agreement state to receive such material, or

(2) Exempt from the requirements for a license for such material under 12VAC5-481-400 A; and

f. The out-of-state licensee submits the payment required by 12VAC5-490-40 to the agency.

2. Notwithstanding the provisions of subdivision 1 of this section, any person who holds a specific license issued by the NRC or another Agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 12VAC5-481-430 B within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

a. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or another Agreement state;

c. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

d. The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 12VAC5-481-430 B or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

3. The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or another Agreement state, or any

product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

12VAC5-481-1350. Personnel monitoring.

A. The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a ~~combination of~~ direct reading dosimeter, an operating alarming ratemeter, and ~~either a film badge, an optically stimulated luminescence (OSL) dosimeter or a thermoluminescent dosimeter (TLD)~~ a personnel dosimeter. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the ~~use~~ wearing of an alarming ratemeter is not required.

1. Pocket dosimeters must have a range from 0 to 2 mSv (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

2. Each ~~film badge, OSL or TLD~~ personnel dosimeter must be assigned to and worn by only one individual.

3. Film badges must be exchanged monthly ~~OSLs or TLDs must be exchanged~~, and all other dosimeters that require replacement must be exchanged at periods not to exceed three months. All personnel dosimeters must be evaluated at periods not to exceed three months or promptly after replacement, whichever is more frequent.

4. ~~After replacement, each film badge, OSL or TLD must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge, OSL or TLD in 14 calendar days, such circumstances must be documented and available for review by the agency.~~

B. Direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 12VAC5-481-1490.

C. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 12VAC5-481-1490. Acceptable dosimeters must read within plus or minus 20% of the true radiation exposure.

D. If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 mSv (200 mrem), the individual's ~~film badge, OSL or TLD~~ personnel dosimeter must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In

addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 12VAC5-481-1490.

E. ~~If a film badge, OSL or TLD~~ the personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement ~~film badge, OSL or TLD~~ personnel dosimeter meeting the requirements of subsection A of this section is provided and the exposure is calculated for the time period from issuance to loss or damage of the ~~film badge, OSL or TLD~~ personnel dosimeter. The results of the calculated exposure and the time period for which the ~~film badge, OSL or TLD~~ personnel dosimeter was lost or damaged must be included in the records maintained in accordance with 12VAC5-481-1490.

F. ~~Reports received from the film badge, OSL or TLD processor~~ Dosimetry results must be retained in accordance with 12VAC5-481-1490.

G. Each alarming ratemeter must:

1. Be checked to ensure that the alarm functions properly before using at the start of each shift;

2. Be set to give an alarm signal at a preset dose rate of 5 mSv (500 mrem) per hour with an accuracy of plus or minus 20% of the true radiation dose rate;

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with 12VAC5-481-1490.

12VAC5-481-1490. Records of personnel monitoring.

Each licensee or registrant shall maintain the following exposure records specified in 12VAC5-481-1350:

1. Direct reading dosimeter readings and yearly operability checks required by 12VAC5-481-1350 B and 12VAC5-481-1350 C for three years after the record is made;

2. Records of alarming ratemeter calibrations for three years after the record is made;

3. ~~Reports received from the film badge, OSL or TLD processor~~ Personnel dosimeter results until the agency terminates the license or registration; and

4. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged ~~film badges, OSL or TLD's,~~ personnel dosimeters until the agency terminates the license or registration.

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12VAC5-481-1690. Notifications.

A. Licensees shall provide the agency the following information for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an ophthalmic physicist, or an authorized medical physicist:

1. A copy of (i) the board certification, (ii) the written attestation signed by a preceptor, and (iii) the NRC or another Agreement state license;
2. The permit issued by a NRC master material licensee;
3. The permit issued by a broad scope licensee;
4. The permit issued by a NRC master material broad scope permittee; or
5. Documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC.
6. For individuals permitted to work within the 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:
 - a. Any additional case experience required in 12VAC5-481-1980 2 b (7) for an authorized user under 12VAC5-481-1950;
 - b. Any additional training required in 12VAC5-481-2040 A 4 for an authorized user under 12VAC5-481-2040 A; or
 - c. Any additional training required in 12VAC5-481-1760 A 3 for an authorized medical physicist.

B. A licensee shall notify the agency no later than 30 days after:

1. An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, an ophthalmic physicist, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
2. The licensee permits an authorized user or an individual qualified to be a radiation safety officer, under 12VAC5-481-1750 and 12VAC5-481-1790, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with 12VAC5-481-1700 C;
3. The licensee's mailing address changes;
4. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 12VAC5-481-500 B; or

5. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 12VAC5-481-1900 or 12VAC5-481-1920 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area.

C. The licensee shall send the documents required in this section to the appropriate address identified in 12VAC5-481-150.

12VAC5-481-1700. Authority and responsibilities for the radiation protection programs and changes.

A. In addition to the radiation protection program requirements of 12VAC5-481-630, the licensee's management or designee shall approve, in writing:

1. Requests for a license application, renewal, or amendment before submittal to the agency;
2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or an authorized medical physicist; and
3. Radiation protection program changes that do not require a license amendment and are permitted under subsection F of this section.

B. The licensee's management shall appoint a radiation safety officer (RSO) who agrees, in writing, to be responsible for implementing the radiation protection program. ~~This written document shall establish the authority, duties, and responsibilities of the RSO. Licensees, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee approved procedures and regulatory requirements. Licensees shall provide the RSO sufficient authority, organization freedom, time, resources, and management prerogative to:~~

- ~~1. Identify radiation safety problems;~~
- ~~2. Initiate, recommend, or provide corrective actions;~~
- ~~3. Stop unsafe operations; and~~
- ~~4. Verify implementation of corrective actions.~~

The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate RSO. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The RSO may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or

responsibilities for implementing the radiation protection program.

C. For up to 60 days each year, licensees may permit an authorized user or an individual qualified to be a RSO, under 12VAC5-481-1750 and 12VAC5-481-1790, to function as a temporary radiation safety officer, as provided in subsection G if the licensee takes the actions required in subsections B, E, G, and H of this section and notifies the agency in accordance with 12VAC5-481-1690 B.

D. Licensees may simultaneously appoint more than one temporary RSO in accordance with subsection C of this section, if needed to ensure that the temporary RSO satisfies the requirements to be a RSO for each of the different types of uses of radioactive material permitted by the licensee.

E. Licensees that are authorized for two or more different types of uses of radioactive material under Articles 6, 7, and 9 of this part, or two or more types of units under 12VAC5-481-2040 B, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. The RSC shall include an authorized user for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. The RSC may include other members the licensee considers appropriate.

F. A licensee may revise its radiation protection program without agency approval if:

1. The revision does not require a license amendment under 12VAC5-481-450 or 12VAC5-481-1680;
2. The revision is in compliance with this chapter and the license;
3. The revision has been reviewed and approved by the RSO and licensee management; and
4. The affected individuals are instructed on the revised program before the changes are implemented.

12VAC5-481-1720. Written directives.

A. A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries (μCi) (1.11 megabecquerels (MBq)), any therapeutic dose of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. The written directive shall contain the patient or human research subject's name and the following information:

1. For any administration of quantities greater than 30 μCi (1.11 MBq) of sodium iodide (I-131): the dosage;
2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide (I-131): the radioactive drug, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
4. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
5. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~
6. For permanent implant brachytherapy:
 - a. Before implantation: treatment site, the radionuclide, and the total source strength; and
 - b. After implantation but before the patient leaves the post-treatment recovery area: treatment site, number of sources implanted, total source strength implanted, and the date; or
7. For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:
 - a. Before implantation: treatment site, the radionuclide, and dose; and
 - b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) and date.

C. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.

12VAC5-481-1730. Procedures for administrations requiring a written directive.

For any administration requiring a written directive, licensees shall develop, implement, and maintain written directive procedures to provide high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive. A licensee shall retain a copy of the

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procedures required by this section in accordance with 12VAC5-481-2070. At a minimum, the procedures required by this section shall address the following items that are applicable to the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;
2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
3. Checking both manual and computer-generated dose calculations; ~~and~~
4. Verifying that all computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 12VAC5-481-2040 B, ~~and C~~ and 12VAC5-481-2060;

5. Determining if a medical event, as defined in 12VAC5-481-2080, has occurred; and

6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive unless a written justification of patient unavailability is documented.

12VAC5-481-1750. Training for radiation safety officer and associate radiation safety officer.

Except as provided in 12VAC5-481-1780, licensees shall require an individual fulfilling the responsibilities of the radiation safety officer (RSO) or an individual assigned duties and tasks as an associate radiation safety officer as provided in 12VAC5-481-1700 to be an individual who:

1. Is certified by a specialty board who has been recognized by the agency, the NRC, or an agreement state and who meets the requirements of subdivision 5 of this section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to (i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; (ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and (iii) pass an examination administered by diplomates of the specialty board that evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; has two years of full-time practical training or supervised experience in medical physics (i) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state or (ii) in clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980; and has passed an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

3. Has completed a structured educational program consisting of provisions, as follows:

a. 200 hours of classroom and laboratory training in the following areas:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Radiation biology; and
- (5) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, or another agreement state license or permit issued by ~~a~~ an NRC master material licensee that authorizes similar types of uses of radioactive material involving. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on an agency, NRC, or another agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

- (1) Shipping, receiving, and performing related radiation surveys;
- (2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- (3) Securing and controlling radioactive material;
- (4) Using administrative controls to avoid mistakes in the administration of radioactive material;
- (5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- (6) Using emergency procedures to control radioactive material; and

(7) Disposing of radioactive material; ~~or and~~
c. This individual must obtain a written attestation signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in subdivisions 3 a, 3 b, and 5 of this section and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or has an associate radiation safety officer for a medical use licensee; or

~~3-~~ 4. Meets the following qualifications:

a. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state under subdivision 1 of 12VAC5-481-1760 A-1 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO or an associate radiation safety officer and who meets the requirements in subdivisions 4 and subdivision 5 of this section; or

b. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist (i) identified on the an agency, NRC, or another agreement state license and; a permit issued by a NRC master material licensee; a permit issued by an agency, NRC, or another agreement state board scope licensee; or a permit issued by a NRC master material license board scope permittee; (ii) has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO or associate radiation safety officer responsibilities; and (iii) meets subdivisions 4 and subdivision 5 of this section; and or

c. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as a radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a NRC master material license. The individual must also meet the requirements in subdivision 5 of this section.

~~4-~~ 5. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, an associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval; and

~~5. Has obtained written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in subdivisions 1, 2, or 3; and 4 of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee.~~

12VAC5-481-1760. Training for an authorized medical physicist.

Except as provided in 12VAC5-481-1780, licensees shall require the authorized medical physicist (AMP) to be an individual who:

1. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements of subdivision 4 of this section. The name of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

b. Have two years of full-time practical training or supervised experience in medical physics (i) under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the agency, the NRC, or an agreement state; or (ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in 12VAC5-481-1780, 12VAC5-481-2018, or 12VAC5-481-2040; and

c. Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

2. Meets the following requirements:

a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, health physics, other physical science, engineering, or applied mathematics from an accredited college or university or an equivalent training program approved by the agency, the NRC, or another Agreement state and has completed one year of full-time training in medical physics and an additional year of full-time practical experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for

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which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and shall include:

- (1) Performing sealed source leak tests and inventories;
- (2) Performing decay corrections;
- (3) Performing full calibration and periodic spot-checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (4) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

3. Has training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types of use for which the individual is seeking authorization; and

4. Has obtained written attestation that the individual has satisfactorily completed the requirements of subdivisions ~~1~~ ~~or~~ 2; and 3 of this section; and ~~has achieved a level of competency sufficient to function independently as an authorized medical physicist~~ is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in 12VAC5-481-1760, 12VAC5-481-1780, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

12VAC5-481-1770. Training for an authorized nuclear pharmacist.

Except as provided in 12VAC5-481-1780, licensees shall require the authorized nuclear pharmacist (ANP) to be a pharmacist who:

1. Is certified by a specialty board whose certification process has been recognized by the NRC; ~~or, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:~~

- a. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education

(ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

b. Hold a current, active license to practice pharmacy;

c. Provide evidence of having acquired at least 4000 hours of training or experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

d. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research, and development; or

2. Meets the following requirements:

a. Has completed 700 hours in a structured educational program consisting:

(1) 200 hours of classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of byproduct material for medical use; and
- (e) Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

- (a) Shipping, receiving, and performing related radiation surveys;
- (b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;
- (c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (d) Using administrative controls to avoid medical events in the administration of radioactive material; and
- (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

3. Has obtained written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in subdivision ~~1~~ ~~or~~ 2 of this section and ~~has achieved a level of competency sufficient to function independently as an ANP~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

12VAC5-481-1780. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, and authorized user.

A. The following applies to individuals with experience as a radiation safety officer (RSO), teletherapy or medical physicist, authorized medical physicist (AMP), nuclear pharmacist, or authorized nuclear pharmacist (ANP):

1. ~~An individual identified as an RSO, AMP, or ANP on a specific an agency, NRC, or agreement state license or a permit issued by the agency, the NRC, or another agreement state; broad scope licensee or master material license permit; or by a master material license permittee of broad scope that authorizes medical use or the practice of nuclear pharmacy as a RSO, a teletherapy or medical physicist, AMP, a nuclear pharmacist, or an ANP on or before October 24, 2002~~ January 14, 2019, need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively, except the RSO and AMP identified in this subdivision must meet the training requirements in subdivision 5 of 12VAC5-481-1750 or subdivision 3 of 12VAC5-481-1760, as appropriate, for any material or uses for which they were not authorized prior to this date.

2. ~~An individual identified as an RSO, AMP, or ANP on a license or a permit issued by a the agency, NRC, or another agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively. certified by the American Board of Health Physics in Comprehensive Health Physics, American Board of Radiology, American Board of Nuclear Medicine, American Board of Science in Nuclear Medicine, Board of Pharmaceutical Specialties in Nuclear Pharmacy, American Board of Medical Physics in Radiation Oncology Physics, Royal College of Physicians and Surgeons of Canada in Nuclear Medicine, American Osteopathic Board of Radiology, or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 12VAC5-481-1750 to be~~ identified as an RSO or as an associate RSO on an agency, NRC, or another agreement state license or NRC master material permit for those materials and uses that these individuals performed on or before October 24, 2005. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 12VAC5-481-

1760 for those materials and uses that these individuals performed on or before October 24, 2005.

3. An RSO, AMP, or ANP, who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this subdivision, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this part.

B. The following applies to experienced authorized users (AU):

1. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another Agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other Agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee ~~on or before October 24, 2002~~ January 14, 2019, who perform only those medical uses for which they were authorized ~~on or before that date~~ need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part.

2. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another Agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other Agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee ~~who perform only those medical uses for which they were authorized between on or before October 24, 2002, and April 29, 2005~~ 2005, need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

a. For uses authorized under 12VAC5-481-1900 or 12VAC5-481-1920, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic

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radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

b. For uses authorized under 12VAC5-481-1950, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

c. For uses authorized under 12VAC5-481-2010 or 12VAC5-481-2040, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

d. For uses authorized under 12VAC5-481-2020, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both for medical uses at the locations and time period identified in this subdivision, qualifies as an AU for those materials and uses performed before these dates for purposes of this chapter.

C. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

12VAC5-481-1910. Training for uptake, dilution, and excretion studies.

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user of unsealed radioactive material for the uses authorized under 12VAC5-481-1900 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC ~~and who meets the requirements in subdivision 3 b of this section;~~ the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in subdivisions 3 a (1) through 3 a (2) (f) of this section; and

b. Pass an examination administered by diplomates of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

2. Who is an authorized user under 12VAC5-481-1940, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements; or

3. Who has:

a. Completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include the following:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience under the supervision of an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (f) Administering dosages of radioactive drugs to patients or human research subjects; and

b. ~~Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, 12VAC5 481 1780, 12VAC5 481 1940, or 12VAC5 481 1980, or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in subdivisions 1-a or subdivision 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 12VAC5 481 1900. is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 12VAC-481-1900. The attestation must be obtained from either:~~

(1) A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980 or equivalent NRC or other agreement state requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980 or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 3 a of this section.

12VAC5-481-1930. Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

A. Licensees may not administer to humans a radiopharmaceutical that contains:

- 1. More than 0.15 μ Ci of molybdenum-99 per mCi of technetium-99m (0.15 kBq of molybdenum-99 per MBq of technetium-99m); or
- 2. More than 0.02 μ Ci of strontium-82 per mCi of rubidium-82 chloride (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection) or more than 0.2 μ Ci of strontium-85 per mCi of rubidium-82 (0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection).

~~B. To demonstrate compliance with subsection A of this section, the licensee preparing the radioactive drug from the radionuclide generator shall:~~

- ~~1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium 99m generator;~~
- ~~2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems, not to exceed before the first patient use of the day for a strontium/rubidium 82 generator.~~

B. A licensee that uses molybdenum-99/technetium-99m for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subsection A of this section.

C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-82 to demonstrate compliance with subsection A of this section.

D. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-82 concentrations, the licensee shall retain a record of each measurement in accordance with 12VAC5-481-2070 K.

E. The licensee shall report any measurement that exceeds the limits in subsection A of this section at the time of generator elution in accordance with 12VAC5-481-2080 D.

12VAC5-481-1940. Training for imaging and localization studies.

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under 12VAC5-481-1920 to be a physician:

- 1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC ~~and who meets the requirements in subdivision 3 b of this section~~, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

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2. Who is an AU under 12VAC5-481-1980 and meets the requirements in subdivision 3 a (2) (g) of this section, or equivalent NRC or other Agreement state requirements; or

3. Who has:

a. Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include at a minimum:

(1) Classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g) of this section, or equivalent NRC or other Agreement state requirements. An authorized nuclear pharmacist who meets the requirements of 12VAC5-481-1770 or 12VAC5-481-1780 may provide the supervised work experience in subdivision 3 a (2) (g) of this section. Work experience must involve, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- (f) Administering dosages of radioactive drugs to patients or human research subjects; and
- (g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

b. ~~Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, 12VAC5 481 1780, or 12VAC5 481 1980 and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements,~~ that the individual has

~~satisfactorily completed the requirements in subdivisions 1 a or subdivision 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 12VAC5 481 1900 and 12VAC5 481 1920. is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 12VAC5-481-1900 and 12VAC5-481-1920. The attestation must be obtained from either:~~

(1) A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g) of this section, or equivalent NRC or other agreement state requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specific in subdivision 3 a of this section.

12VAC5-481-1950. Use of unsealed radioactive material for which a written directive is required.

Licensees may use any unsealed radioactive material identified in subdivision 2 b (7) of 12VAC5-481-1980 prepared for medical use and for which a written directive is required that is:

1. Obtained from a manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other Agreement state requirements or a PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or another agreement state requirements;
2. Excluding production of PET radionuclides, prepared by an ANP; a physician who is an authorized user (AU) and who meets the requirements specified in 12VAC5-481-1940 or 12VAC5-481-1980; or an individual under the supervision, as specified in 12VAC5-481-1710, of an ANP or the physician who is an AU;
3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or
4. Prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

12VAC5-481-1980. Training for use of unsealed radioactive material for which a written directive is required.

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under 12VAC5-481-1950 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state and who meets the requirements in subdivisions 2 b (7) and 3 of this section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

2. Who has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include:

a. Classroom and laboratory training in the following areas:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Chemistry of radioactive material for medical use; and
- (5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements. A supervising AU, who meets the requirements of this subdivision 2 shall also have experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status. The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- (6) (Reserved.)

(7) Administering dosages of radioactive drugs to patients or human research subjects ~~involving a minimum of three cases in each~~ from the three categories in this subdivision 2 b (7). Radioactive drugs containing radionuclides in categories not included in this subdivision are regulated under 12VAC5-481-2060. This work experience must involve a minimum of three cases in each of the following categories (experience with at least three cases in subdivision 2 b (7) (b) of this section also satisfies the requirements of subdivision 2 b (7) (a) of this section) for which the individual is requesting authorized user status.

~~These categories are oral~~ (a) Oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required;

~~oral~~ (b) Oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131;

~~parenteral~~

(c) Parenteral administration of any ~~beta emitter or a photon emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; or parenteral administration of any other radionuclide, for which a written directive is required.~~ radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in ~~either subdivisions 1 and subdivision 2 b (7) of this section or subdivision 2 of this section and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under 12VAC5-481-1950.~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The written attestation shall be obtained from either:

~~signed by a~~ a. A preceptor AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements. ~~The preceptor AU, who meets the requirements in subdivision 2 of this section shall have and has~~ experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements; has experience in administering dosages in the same dosage category as the individual requesting the authorized user status; and concurs with the attestation

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provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include the training and experience specified in subdivision 2 b of this section.

12VAC5-481-1990. Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq).

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification process includes all of the requirements of subdivision 3 of this section and has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Licensee Toolkit Web page; or
2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (a) and (b) of 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements; or
3. Who has:
 - a. Completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training shall include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of byproduct material for medical use; and
 - (5) Radiation biology; and
 - b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or another agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) (a) or subdivision 2 b (7) (b) of 12VAC5-481-1980. The work experience shall involve:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (5) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide (I-131); and

4. Obtained written attestation that the individual has satisfactorily completed the requirements in ~~subdivisions 1 and 3 b of this section or~~ subdivision 3 of this section and ~~has achieved a level of competency sufficient to function independently as an AU for oral administration of less than or equal to 33 milliCuries (1.22 gigabecquerels of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The attestation must be obtained from either:

~~The written attestation shall be signed by a preceptor AU who~~ a. A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirement in subdivision 2 of 12VAC5-481-1980 shall also have and has experience in administering dosages as specified in subdivision 2 b (7) (a) or (b) of 12VAC5-481-1980; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements, has experience in administering dosages as specified in 12VAC5-481-1980 2 b (7) (a) or (b), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 3 of this section.

12VAC5-481-2000. Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 mCi (1.22 GBq).

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification process includes all of the requirements in subdivision 3 of this section and has been recognized by the NRC; the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or
2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (b) of 12VAC5-481-1980 or equivalent NRC or other agreement state requirements; or
3. Who has:
 - a. Completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training shall include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
 - b. Work experience, under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, ~~12VAC5-481-1990~~, or equivalent NRC or other agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) (b) of 12VAC5-481-1980. The work experience shall involve:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(6) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide (I-131); and

c. Obtained written attestation that the individual has satisfactorily completed the requirements in ~~subdivisions 1 and 3 b of this section or~~ subdivision 3 of this section and ~~has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under 12VAC5-481-1950.~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The written attestation must be obtained by either:

~~shall be signed by a preceptor AU who~~ (1) A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, ~~12VAC5-481-1990~~, or equivalent NRC or other Agreement state requirements. A preceptor AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have and has experience in administering dosages as specified in subdivision 2 b (7) (b) of 12VAC5-481-1980; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements; has experience in administering dosages as specified in 12VAC5-481-1980 2 b (7) (b); and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience as specified in this subdivision 3.

12VAC5-481-2001. Training for the parenteral administration of unsealed radioactive material requiring a written directive.

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) for the parenteral administration requiring a written directive to be a physician:

1. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (c) of 12VAC5-481-1980 or equivalent NRC or other Agreement state requirements; or
2. Who is an AU under ~~12VAC5-481-2010~~ 12VAC5-481-2018, 12VAC5-481-2040, or equivalent NRC or other agreement state requirements and who meets the requirements in subdivision 4 of this section; or

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3. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state under 12VAC5-481-2018 or 12VAC5-481-2040 and who meets the requirements in subdivision 4 of this section; and

4. Who has:

a. Completed 80 hours of classroom and laboratory training applicable to parenteral administrations ~~for which a written directive is required of any beta emitter or any photon emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required.~~ The training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Chemistry of radioactive material for medical use; and
- (5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements in the parenteral administration ~~for which a written directive is required of any beta emitter or any photon emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ listed in 12VAC5-481-1980 2 b (7) (c). A supervising AU who meets the requirements in this section, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements shall have experience in administering dosages ~~as specified in subdivision 2 b (7) of 12VAC5-481-1980~~ in the same category as the individual requesting authorized user status. The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (6) Administering dosages to patients or human research subjects that include at least three cases ~~involving of the parenteral administration for which a written directive is required of any beta emitter or any photon emitting~~

~~radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required as specified in 12VAC5-481-1980 2 b (7) (c); and~~

5. Obtained a written attestation that the individual has satisfactorily completed the requirements in subdivision 2 or 3; and subdivision 4 b of this section or subdivision 4 of this section, and ~~has achieved a level of competency sufficient to function independently as an AU for the parenteral administration of unsealed radioactive material requiring a written directive~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation shall be obtained from either:

signed by a a. A preceptor AU who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirements in this section, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements shall have experience in administering dosages ~~as specified in subdivision 2 b (7) of 12VAC5-481-1980~~ in the same category as the individual requesting authorized user status; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements; has experience in administering dosages in the same dosage category as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council of Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 4 of this section.

12VAC5-481-2010. Use of sources for manual brachytherapy.

Licenses shall use only brachytherapy sources ~~for therapeutic medical uses:~~

1. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

12VAC5-481-2016. ~~Decay of strontium-90~~ Strontium-90 sources for ophthalmic treatments.

~~Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under 12VAC5-481-2015.~~

A. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection B of this section are performed by either:

1. An authorized medical physicist; or
2. An individual who:
 - a. Is identified as an ophthalmic physicist on a specific medical use license issued the agency, NRC, or another agreement state; permit issued by an agency, NRC, or another agreement state broad scope licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material broad scope medical use permittee;
 - b. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university;
 - c. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and
 - d. Has documented training in the following:
 - (1) The creation, modification, and completion of written directives;
 - (2) Procedures for administrations requiring a written directive; and
 - (3) Performing the calibration measurements of brachytherapy sources as detailed in 12VAC5-481-2015.

B. The individuals who are identified in subsection A of this section must:

1. Calculate the activity of each strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 12VAC5-481-2015; and
2. Assist the licensee in developing, implementing, and maintaining written procedures to provide a high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subsection A of this section will observe treatments, review the treatment methodology, calculate treatment time for prescribed dose,

and review records to verify that the administrations were in accordance with the written directive.

C. Licensees must return a record of the activity of each strontium-90 source in accordance with 12VAC5-481-2070 P.

12VAC5-481-2018. Training for use of manual brachytherapy sources.

Except as provided in 12VAC5-481-1780, licensees shall require an authorized user of a manual brachytherapy source for uses authorized under 12VAC5-481-2010 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

- a. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
- b. Pass an examination administered by diplomates of the specialty board that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

2. Who has:
 - a. Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
 - (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity; and
 - (d) Radiation biology; and
 - (2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements at a medical institution facility authorized to use radioactive material under 12VAC5-481-2010, involving:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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- (b) Checking survey meters for proper operation;
- (c) Preparing, implanting, and removing brachytherapy sources;
- (d) Maintaining running inventories of material on hand;
- (e) Using administrative controls to prevent a medical event involving the use of radioactive material;
- (f) Using emergency procedures to control radioactive material; and

b. Completed three years of supervised clinical experience in radiation oncology, under an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another Agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subdivision 2 a (2) of this section.

3. Who has obtained written attestation, ~~signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements,~~ that the individual has satisfactorily completed the requirements in this subdivision 2 of this section and has achieved a level of competency sufficient to function independently as an AU of manual brachytherapy sources for the medical uses authorized in 12VAC5-481-2010. This attestation must be obtained from either:

a. A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements; or

b. A residency program director who affirms in writing that the attestation represents the residency program faculty where at least one faculty member is an authorized user who meets the requirement in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specific in subsection 2 of this section.

12VAC5-481-2019. Training for ophthalmic use of strontium-90.

Except as provided in 12VAC5-481-1780, licensees shall require the AU of strontium-90 for ophthalmic radiotherapy to be a physician:

1. Who is an authorized user (AU) under 12VAC5-481-2018 or equivalent NRC or other Agreement state requirements; or

2. Who has:

a. Completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

b. Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

- (1) Examination of each individual to be treated;
- (2) Calculation of the dose to be administered;
- (3) Administration of the dose; and
- (4) Follow up and review of each individual's case history; and

c. Obtained written attestation, signed by a preceptor AU who meets the requirements in 12VAC5-481-1780, 12VAC5-481-2018, this section, or equivalent NRC or other Agreement state requirements, that the individual has satisfactorily completed the requirements in this subdivision 2 and ~~has achieved a level of competency sufficient to function independently as an AU of strontium-90 for ophthalmic use~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

12VAC5-481-2020. Use of sealed sources for diagnosis.

A. Licensees shall use only sealed sources that are not in medical devices for diagnostic medical uses as if the sealed sources are approved in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active

Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

12VAC5-481-2030. Training for use of sealed sources for diagnosis.

Except as provided by 12VAC5-481-1780, licensees shall require the authorized user of a diagnostic sealed source for use in a device authorized under 12VAC5-481-2020 to be a physician, dentist, or podiatrist who:

1. Is certified by a specialty board that whose certification process includes all of the requirements in subdivisions 3 and 4 of this section and whose certification has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or
2. Is an authorized user for uses listed under 12VAC5-481-1920 or equivalent NRC or other agreement state requirements; or
3. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:
 - a. Radiation physics and instrumentation;
 - b. Radiation protection;
 - c. Mathematics pertaining to the use and measurement of radioactivity; and
 - d. Radiation biology; and
- ~~3.~~ 4. Has completed training in the use of the device for the uses requested.

12VAC5-481-2040. Training requirements and use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A. Except as provided in 12VAC5-481-1780, licensees shall require an authorized user (AU) of a sealed source in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC, the agency, or an agreement state and who meets the requirements in subdivision 3 of this section. The names of board certifications that have been recognized by the agency, NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - a. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or

the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

b. Pass an examination administered by diplomates of the specialty board that tests knowledge and competence radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

2. Who has:

a. Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(1) 200 hours of classroom and laboratory training in the following areas: radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; and radiation biology; and

(2) 500 hours of work experience, under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another agreement state requirements at a medical institution that is authorized for subsections B and C of this section, involving: reviewing full calibration measurements and periodic spot-checks; preparing treatment plans and calculating treatment doses and times; using administrative controls to prevent a medical event involving the use of radioactive material; implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; checking and using survey meters; and selecting the proper dose and knowing how it is to be administered; and

b. Completed three years of supervised clinical experience in radiation therapy under an AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or another Agreement state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by this subdivision.

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in ~~(i) subdivision 1 or 2 of this subsection~~ subdivisions 2 a, 2 b, and (ii) subdivisions 3 and 4 of this subsection and has achieved a level of competency sufficient to function independently as an AU of each type of therapeutic medical unit for which the individual is requesting AU status. The written attestation shall be signed by either:

a. A preceptor AU who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or

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another agreement state requirements for an AU for each type of therapeutic medical unit for which the individual is requesting AU status; or

b. A residency program director who affirms in writing that the attestation of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements for the type of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivisions 2 a and 2 b of this subsection.

4. Who has received training in device operation, safety procedures, and clinical use for the types of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an AU or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

B. Licensees shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or
2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

C. Licensees shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. As approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

12VAC5-481-2043. Safety procedures and instructions, and precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A. Safety procedures and instructions.

1. Licensees shall:

- a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
- b. Permit only individuals approved by the authorized user (AU), the authorized medical physicist (AMP), or the RSO to be present in the treatment room during treatment with sources;
- c. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
- d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or remove the patient or human research subject from the radiation field with controls from the outside the treatment room. These procedures shall include:
 - (1) Instructions for responding to equipment failure and the names of the individuals responsible for implementing corrective actions;
 - (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - (3) The names and telephone numbers of the authorized user (AU), the authorized medical physicist (AMP), and the RSO to be contacted if the unit or the console operates abnormally.

2. A copy of the procedures required by subdivision 1 d of this subsection shall be physically located at the unit console.

3. Licensees shall post instructions at the unit console to inform the operator of:

- a. The location of the procedures required by subdivision 1 d of this subsection; and
- b. The names and telephone numbers of the AU, the AMP, and the RSO to be contacted if the unit or console operates abnormally.

4. Safety instruction and training.

- a. Prior to the first use of patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

b. Licensees shall provide instruction ~~and document~~ initially and at least annually to all individuals who operate the unit, as appropriate to the individual's assigned duties, in: ~~a. The~~ the procedures identified in subdivision 1 d of this subsection; and ~~b. The~~ the operating procedures for the unit.

5. Licensees shall ensure that operators, authorized users, and authorized medical physicists participate in drills of the emergency procedures initially and at least annually and document the exercise.

6. Licensees shall retain a record of individuals receiving instruction required by subdivision 4 of this subsection in accordance with 12VAC5-481-2070 L.

7. Licensees shall retain a copy of the procedures required by subdivisions 1 d and 4 b of this subsection in accordance with 12VAC5-481-2070 R.

B. Safety procedures for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. Licensees shall control access to the treatment room by a door at each entrance.

2. Licensees shall equip each entrance to the treatment room with an electrical interlock system that will:

- a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
- b. Cause the source to be shielded when an entrance door is opened; and
- c. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off console is reset at the console.

3. Licensees shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

4. Except for low-dose remote afterloader units, licensees shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

5. For licensed activities where sources are placed within the patient's or human research subject's body, licensees shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.

6. In addition to the requirements specified in subdivisions 1 through 5 of this subsection, licensees shall:

a. For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(1) An AMP and either an AU or a physician under the supervision of an AU who has been trained to the

operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the units; and

(2) An AMP and either an AU or an individual under the supervision of an AU who has been trained to remove the source applicators in the event of an emergency involving the unit to be immediately available during the continuation of all patient treatments involving the unit.

b. For high dose-rate remote afterloader units, require:

(1) An AU and an AMP to be physically present during the initiation of all patient treatments involving the unit; and

(2) An AMP and either an AU or a physician under the supervision of an AU who has been trained in the operation and emergency response for the unit to be physically present during continuation of all patient treatments involving the unit.

c. For gamma stereotactic radiosurgery units, require an AU and an AMP to be physically present throughout all patient treatments involving the unit.

d. Notify the RSO, or his designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

7. Licensees shall have applicable emergency response equipment available near each treatment room to respond to a source that:

- a. Remains in the unshielded position; or
- b. Lodges within the patient following completion of the treatment.

12VAC5-481-2048. ~~Five-year inspection~~ Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

A. Licensees shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement ~~or at intervals not to exceed five years, whichever comes first,~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

B. This inspection and servicing may only be performed by person specifically licensed to do so by the agency, the NRC, or another Agreement state.

C. Licensees shall keep a record of the inspection and servicing in accordance with 12VAC5-481-2070 X.

12VAC5-481-2070. Records.

A. Records of authority and responsibilities for radiation protection programs.

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1. Licensees shall retain a record of actions taken by the licensee's management in accordance with 12VAC5-481-1700 for five years. The record shall include a summary of the actions taken and a signature of licensee management.

2. Licensees shall retain a copy of both authority, duties, and responsibilities of the RSO as required by 12VAC5-481-1700 and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, as required by 12VAC5-481-1700, for the duration of the license. The records shall include the signature of the RSO and licensee management.

3. For each associate radiation safety officer, the licensee shall retain for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by licensee's management.

B. Records of radiation protection program changes. Licensees shall retain a record of each radiation protection program change made in accordance with 12VAC5-481-1700 F for five years. The record shall include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

C. Records of written directives. Licensees shall retain a copy of each written directive as required by 12VAC5-481-1720 for three years.

D. Records for procedures for administrations requiring written directive. Licensees shall retain a copy of the procedures required by 12VAC5-481-1730 for the duration of the license.

E. Records of dosages of unsealed radioactive material for medical use. Licensees shall maintain a record of dosage determinations required by 12VAC5-481-1820 for three years. The record shall contain the radiopharmaceutical; the patient's or human research subject's name or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 30 μCi (1.1 MBq); the date and time of dosage determination; and the name of the individual who determined the dosage.

F. Records of leak tests and inventory of sealed sources and brachytherapy sources.

1. Licensees shall retain records of leak tests required by 12VAC5-481-1840 for three years. The records shall include the model number, and the serial number, if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

2. Licensees shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 12VAC5-481-1840 for three years. The

inventory records shall contain the model number of each source, and serial number of each source if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

G. Records of surveys for ambient radiation exposure rate. Licensees shall retain a record of each survey required by 12VAC5-481-1860 for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

H. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. Licensees shall retain a record signed by the authorized user of the basis for authorizing the release of an individual in accordance with 12VAC5-481-1870 for three years after the date of release if the total effective dose equivalent is calculated by:

- a. Using the retained activity rather than the activity administered;
- b. Using an occupancy factor less than 0.25 at 1 meter;
- c. Using the biological or effective half-life; or
- d. Considering the shielding by tissue.

2. Licensees shall retain a record for three years after the date of release of the instruction required by 12VAC5-481-1870 that were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 mrem (5 mSv).

I. Records of mobile medical services.

1. Licensees shall retain a copy of each letter that permits the use of radioactive material at the client's address, as required by 12VAC5-481-1880. Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three years after the last provision of service.

2. Licensees shall retain the record of each survey required by 12VAC5-481-1880 for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

J. Records of decay-in-storage. Licensees shall maintain records of the disposal of licensed materials, as required by 12VAC5-481-1890 for three years. The record shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

K. Records of molybdenum-99, strontium-82 and strontium-85 concentrations. Licensee shall maintain a record of molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by 12VAC5-481-1930 for three years. The record shall include:

1. For each measured elution of technetium-99m, the ratio of measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m or kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m, the time and date of the measurement, and the name of the individual who made the measurement; or

2. For each measured elution of rubidium-82, the ratio of the measures expressed as microcurie of strontium-82 per millicurie of rubidium-82 or kilobecquerel of strontium-82 per megabecquerel of rubidium-82, microcurie of strontium-85 per millicurie of rubidium-82 or kilobecquerel of strontium-85 per megabecquerel of rubidium-82, the time and date of the measurement, and the name of the individual who made the measurement.

L. Records of safety instruction. Licensees shall maintain a record of safety instructions and training required by 12VAC5-481-1960 and 12VAC5-481-1970 and the operational and safety instructions required by 12VAC5-481-2013 for three years. Each record shall include a list of topics covered, the date of the instruction or training, the names of the attendees, and the names of the individuals who provided the instruction.

M. Records of surveys after source implant and removal. Licensees shall maintain a record of the surveys required by 12VAC5-481-2011 and 12VAC5-481-2041 for three years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

N. Records of brachytherapy source accountability.

1. Licensee shall maintain a record of brachytherapy source accountability required by 12VAC5-481-2012 for three years.

2. For temporary implants, the record shall include the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use and the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

3. For permanent implants, the record shall include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to

storage, and the number and activity of sources permanently implanted in the patient or human research subject.

O. Records of calibration measurements of brachytherapy sources. Licensees shall maintain a record of the calibrations of brachytherapy sources required by 12VAC5-481-2015 for three years after the last use of the source. The record shall include the date of the calibration; the manufacturer's name, model number and serial number for the source and the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

P. Records of decay of strontium-90 sources for ophthalmic treatments. Licensees shall maintain a record of the activity of a strontium-90 source required by 12VAC5-481-2016 for the life of the source. The record shall include the date and initial activity of the source as determined under 12VAC5-481-2016, and for each decay calculation, the date and the source activity as determined under 12VAC5-481-2016 and the signature of the authorized medical physicist.

Q. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the installation, adjustment, maintenance, and repair of remote afterloaders units, teletherapy units, and gamma stereotactic radiosurgery units as required by 12VAC5-481-2042 for three years. For each installation, adjustment, maintenance, and repair, the record shall include the date, description of the service, and names of the individuals who performed the work.

R. Records of safety procedures. Licensees shall retain a copy of the procedures required by 12VAC5-481-2043 until the licensee no longer possesses the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

S. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 12VAC5-481-2044 for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 12VAC5-481-2044; the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison.

T. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. Licensees shall maintain a record of the teletherapy unit, remote afterloader

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unit, and gamma stereotactic radiosurgery unit full calibrations required by 12VAC5-481-2045 for three years. The record shall include the date of calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit; the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the authorized medical physicist who performed the full calibration.

U. Records of periodic spot-checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

1. Licensees shall retain a record of each periodic spot-check for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units required by 12VAC5-481-2046 for three years. The record shall include:

a. For each teletherapy unit; the date of the spot-check, the manufacturer's name, model number, and serial number, source, and instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

b. For each remote afterloader unit: the date of the spot-check, the manufacturer's name, model and serial number for the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

c. For each gamma stereotactic radiosurgery unit: the date of the spot-check, the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating

the operability of radiation monitors; helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems; timer termination, treatment table retraction mechanism, and stereotactic frames and localizing device (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

2. Licensees shall retain a copy of the procedures required by 12VAC5-481-2046 A 2, 12VAC5-481-2046 B, and 12VAC5-481-2046 C 2 until the licensee no longer possesses the teletherapy unit, remote afterloader unit, or gamma stereotactic radiosurgery unit.

V. Records of additional technical requirements for mobile remote afterloader units. Licensees shall retain a record of each check for mobile remote afterloader units required by 12VAC5-481-2047 for three years. The record shall include the date of the check, the manufacturer's name, model number, and serial number of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces; source positioning accuracy; and the signature of the individual who performed the check.

W. Records of surveys of therapeutic treatment units. Licensees shall maintain a record of radiation surveys of treatment units made in accordance with 12VAC5-481-2041 for the duration of use of the unit. The record shall include the date of the measurements, the manufacturer's name, model number, and serial number of the treatment unit; source and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the test.

X. Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units. Licensees shall maintain a record of the ~~five-year inspections~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery required by 12VAC5-481-2048 for the duration of use of the unit. The record shall include the inspector's radioactive materials license number, the date of inspection, the manufacturer's name, model number, and serial number of both the treatment unit and source, a list of components inspected and serviced, the type of service, and the signature of the inspector.

12VAC5-481-2080. Reports.

A. Report and notification of a medical event.

1. Licensees shall report any event as a medical event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from

radioactive material, except permanent implant brachytherapy, results in:

a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

(1) The total dose delivered differs from the prescribed dose by 20% or more;

(2) The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

(3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

b. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(1) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(3) An administration of a dose or dosage to the wrong individual or human research subject;

(4) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(5) A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) ~~to an organ or tissue and 50%~~ or more of the dose expected ~~from to that site if the administration defined in had been given in accordance with the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)~~ prepared or revised before administration and 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material, excluding sources that were implanted in the correct site but migrated outside the treatment site, that result in the total source strength administered differing by 20% or more from the total source strength documented in the post-implantation portion of the written directive or the total source strength administered outside of the treatment site exceeding 20% of the total source strength documented in the post-implantation of the written directive or an administration involving any of the following: wrong radionuclide, the wrong individual or human research

subject, sealed sources implanted directly into a location discontinuous from the treatment site as documented in the post-implantation portion of the written directive, or a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

3. Licensees shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

3. 4. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.

4. 5. By an appropriate method listed in 12VAC5-481-150, licensees shall submit a written report to the agency within 15 days after discovery of the medical event.

a. The written report shall include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individuals who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

b. The report may not contain the individual's name or any other information that could lead to identification of the individual.

5. 6. Licensees shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. Licensees are not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, licensees shall notify the individual as soon as possible thereafter. Licensees may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subdivision, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, licensees shall inform the individual, or appropriate responsible relative or

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guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

7. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the individual who is the subject of the event; and

(2) ~~Social security number or other identification~~ Identification number, ~~or if one has been assigned no other identification number is available, the social security number,~~ of the individual who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

B. Report and notification of a dose to an embryo/fetus or a nursing child.

1. Licensees shall report any dose to an embryo/fetus that is greater than 500 mrem (5 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

2. Licensees shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

a. Is greater than 5 mSv (500 rem) total effective dose equivalent; or

b. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

3. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with subdivision 1 or 2 in this subsection.

4. By an appropriate method listed in 12VAC5-481-150, licensees shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subdivision 1 or 2 of this subsection.

a. The written report shall include

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

b. The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

5. Licensees shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as "mother," no later than 24 hours after discovery of an event that would require reporting under subdivisions 1 or 2 of this subsection, unless the referring physician personally informs the licensee either that the mother will be informed or that, based on medical judgment, telling the mother would be harmful. Licensees are not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, licensees shall make the appropriate notifications as soon as possible thereafter. Licensees may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subdivision, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, licensees shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) ~~Social security number or other identification~~ Identification number, ~~or if one has been assigned, no other identification number is available, the social security number~~ of the pregnant individual or the nursing child who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

C. Report of a leaking source.

1. Licensees shall file a report within five days if a leak test required by 12VAC5-481-1840 reveals the presence of 0.005 μCi (185 Bq) or more of removable contamination.
2. The report shall be filed with the agency by an appropriate method listed in 12VAC5-481-150. The written report shall include:
 - a. The model number and serial number, if assigned, of the leaking source;
 - b. The radionuclide and its estimated activity;
 - c. The results of the test;
 - d. The date of the test; and
 - e. The action taken.

D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

1. Licensees shall notify the agency and the distributor of the generator by telephone within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 12VAC5-481-1930 A at the time of generator elution. The telephone report to the agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.
2. By an appropriate method listed in 12VAC5-481-150, the licensee shall submit a written report to the agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report shall include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and assessment of failure in the licensee's equipment, procedure, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subdivision 1 of this subsection.

12VAC5-481-2850. Personnel monitoring.

A. Irradiator operators shall wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor ~~shall be accredited for the~~ must be capable of detecting high energy photons in the normal and accident dose ranges (see 12VAC5-481-750). Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be processed at least monthly, and other personnel dosimeters that require replacement shall be

~~processed~~ evaluated at least quarterly or promptly after replacement, whichever is more frequent.

B. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within plus or minus 30% of the true radiation dose.

12VAC5-481-3000. General license: NRC-approved packages.

A. A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC. This general license applies only to a licensee who has a quality assurance program approved by the agency as satisfying the provisions of 12VAC5-481-3130.

B. This general license applies only to a licensee who:

1. Has a copy of the license, CoC, or other approval by the NRC of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;
2. Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter;
3. Prior to the licensee's first use of the package, submits in writing to the NRC: ATTN: Document Control Desk, Director, Division of ~~Spent Fuel Storage and Transportation~~ Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval; and
4. Has a quality assurance program that complies with 12VAC5-481-3130.

C. The general license in subsection A of this section applies only when the package approval authorizes use of the package under this general license.

D. For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license is subject to the additional restrictions of 12VAC5-481-3010.

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12VAC5-481-3120. Advance notification of transport of nuclear waste.

A. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport.

B. Advance notification for transport of licensed material is required when:

1. The licensed material is required to be in Type B packaging for transportation;
2. The licensed material is being transported to or across state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and
3. The quantity of licensed material in a single package exceeds:
 - a. 3000 times the A₁ value of the radionuclides as specified in 12VAC5-481-3770;
 - b. 3000 times the A₂ value of the radionuclides as specified in 12VAC5-481-3770; or
 - c. 1000 terabecquerel (27,000 curies).

C. Each advance notification required by subsections A and B of this section shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);
3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
4. The seven-day period during which arrival of the shipment at state boundaries or tribal reservation boundaries is estimated to occur;
5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
6. A point of contact with a telephone number for current shipment information.

D. The notification required by subsections A and B of this section shall be made in writing to each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by any other means than mail shall reach each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee,

and the agency, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three years.

1. A list of names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

2. Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating tribes, including telephone and mailing addresses of tribal officials and tribal officials' designees, is available on the NRC website at: <https://scp.nrc.gov/special/designee.pdf>.

3. A list of the names and mailing addresses of the governors' designees and tribal officials' designees of participating tribes is available on request from the Director, Division of ~~Material~~ Materials Safety, Security, State, and Tribal ~~and~~ Rulemaking Program Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

E. The licensee shall notify the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency of any changes to schedule information provided pursuant to subsections A and B of this section. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency. The licensee shall maintain for three years a record of the name of the individual contacted.

F. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A copy of the notice shall be retained by the licensee for three years.

12VAC5-481-3290. Personnel monitoring.

A. No licensee shall permit any individual to act as a logging supervisor or a logging assistant unless each such individual wears ~~either a film badge, OSL or TLD personnel dosimeter at all times during the handling of licensed radioactive materials.~~ Each film badge, OSL or TLD personnel dosimeter shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSLs or TLDs all other personnel dosimeters that require replacement must be replaced at least quarterly. After replacement, each film badge, OSL or TLD must be promptly processed. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

B. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.

NOTICE: The following forms used in administering the regulation have been filed by the agency. Amended or added forms are reflected in the listing and are published following the listing. Online users of this issue of the Virginia Register of Regulations may also click on the name to access a form. The forms are also available from the agency contact or may be viewed at the Office of Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

FORMS (12VAC5-481)

Applications for a New Radioactive Material License

[Academic, Research and Development, and Other Licenses of Limited Scope, Revision 4 \(6/2018\)](#)

[Broad Scope, Revision 3 \(1/2016\)](#)

[Fixed Gauge Devices, Revision 4 \(6/2018\)](#)

[Industrial Radiography, Revision 4 \(6/2018\)](#)

[Irradiators – Part XII, Revision 2 \(6/2018\)](#)

[Medical Use, Revision 3 \(6/2018\)](#)

[Portable Gauges, Revision 3 \(6/2018\)](#)

[Radiopharmacy, Revision 2 \(6/2018\)](#)

[Sealed Sources, Revision 4 \(6/2018\)](#)

[Self-Shielded Irradiators, Revision 4 \(6/2018\)](#)

[Material in Well Logging, Tracer, and Field Flood Study, Revision 3 \(1/2016\)](#)

[XRF Devices, Revision 3 \(6/2018\)](#)

[Manufacturing and Distribution, Revision 3 \(6/2018\)](#)

Applications for Renewal of a Radioactive Material License

[Academic, Research and Development and Other Licenses of Limited Scope, Revision 4 \(6/2018\)](#)

[Broad Scope, Revision 3 \(1/2016\)](#)

[Fixed Gauge Devices, Revision 4 \(6/2018\)](#)

[Industrial Radiography, Revision 4 \(6/2018\)](#)

[Irradiators – Part XII, Revision 1 \(6/2018\)](#)

[Medical Use, Revision 3 \(6/2018\)](#)

[Portable Gauges, Revision 5 \(6/2018\)](#)

[Radiopharmacy, Revision 2 \(6/2018\)](#)

[Sealed Sources, Revision 4 \(6/2018\)](#)

[Self-Shielded Irradiators, Revision 4 \(6/2018\)](#)

[Material in Well Logging, Tracer, and Field Flood Study, Revision 3 \(1/2016\)](#)

[XRF Devices, Revision 5 \(6/2018\)](#)

[Manufacturing and Distribution, Revision 3 \(6/2018\)](#)

Training, Experience, and Preceptor Attestations

[A: Radiation Safety Officer for Medical Use, Revision 0 \(7/2016\)](#)

[B: Authorized User - Written Directive Not Required, Revision 0 \(7/2016\)](#)

[C: Unsealed Radioactive Material Requiring Written Directive, Revision 2, \(6/2014\)](#)

[D: Authorized User for Manual Brachytherapy Sources, Revision 0 \(7/2016\)](#)

[E: Authorized User of Remote Afterloader, Teletherapy, or Gamma Stereotactic Radiosurgery Units, Revision 0 \(7/2016\)](#)

[F: Authorized Medical Physicist, Revision 0 \(7/2016\)](#)

[G: Authorized Nuclear Pharmacist, Revision 0 \(7/2016\)](#)

Other Forms

[Certificate of Disposition of Materials, Revision 0 \(7/2016\)](#)

[Certificate - Use of Depleted Uranium under General License, Revision 0 \(7/2016\)](#)

[Cumulative Occupational Exposure History, Revision 1 \(1/2015\)](#)

[Fingerprint Record, Federal Bureau of Investigation, FD-258, \(rev. 9/2013\)](#)

[Notice to Employees, RH-F-12 \(1/2011\)](#)

[Occupational Exposure Record per Monitoring Period, Revision 1 \(1/2015\)](#)

[Registration Certificate - In Vitro Testing with Radioactive Material under General License, Revision 0 \(7/2016\)](#)

[Reciprocity Privileges Checklist, Revision 0 \(7/2016\)](#)

[Application for Reciprocal Recognition of Out-of-State Radioactive Materials License, Revision 0 \(2/2021\)](#)

[Reciprocity Notification, Revision 0 \(2/2021\)](#)

VA.R. Doc. No. R21-6434; Filed June 30, 2021, 4:01 p.m.



Regulations

TITLE 16. LABOR AND EMPLOYMENT

SAFETY AND HEALTH CODES BOARD

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 Safety and Health Codes Board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 16VAC25-90. Federal Identical General Industry Standards (adding 16VAC25-90-1910.502, 16VAC25-90-1910.505, 16VAC25-90-1910.509).

Statutory Authority: § 40.1-22 of the Code of Virginia.

Effective Date: August 2, 2021.

Agency Contact: Holly Trice, Attorney, Department of Labor and Industry, Main Street Centre, 600 East Main Street, Richmond, VA 23219, telephone (804) 786-2641, FAX (804) 786-8418, or email holly.trice@doli.virginia.gov.

Summary:

In an interim final rule, federal Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) to protect health care and health care support service workers from occupational exposure to COVID-19 in settings where people with COVID-19 are reasonably expected to be present. During the period of the emergency standard, covered health care employers must develop and implement a COVID-19 plan to identify and control COVID-19 hazards in the workplace. Covered employers must also implement other requirements to reduce transmission of COVID-19 in their workplaces related to (i) patient screening and management; (ii) standard and transmission-based precautions; (iii) personal protective equipment, including facemasks or respirators; (iv) controls for aerosol-generating procedures; (v) physical distancing of at least six feet, when feasible; (vi) physical barriers; (vii) cleaning and disinfection; (viii) ventilation; (ix) health screening and medical management; (x) training; (xi) anti-retaliation; (xii) recordkeeping; and (xiii) reporting. The standard requires employers to provide reasonable time and paid leave for employee vaccinations and any side effects of vaccination and encourages use of respirators in lieu of face masks by including a mini respiratory protection program that applies to such use. The standard exempts from coverage certain workplaces where all employees are fully vaccinated and individuals with possible COVID-19 are prohibited from entry, and it

exempts from some of the requirements of the standard fully vaccinated employees in well-defined areas where there is no reasonable expectation that individuals with COVID-19 will be present.

In this regulatory action, the Safety and Health Codes Board is adopting the federal ETS.

Note on Incorporation by Reference: Pursuant to § 2.2-4103 of the Code of Virginia, 29 CFR Part 1910 (Occupational Safety and Health Standards) is declared a document generally available to the public and appropriate for incorporation by reference. For this reason, this document will not be printed in the Virginia Register of Regulations. A copy of this document is available for inspection at the Department of Labor and Industry, Main Street Centre, 600 East Main Street, Richmond, Virginia 23219, and in the office of the Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

Statement of Final Agency Action: On June 29, 2021, the Safety and Health Codes Board adopted federal OSHA's interim final rule, Occupational Exposure to COVID-19, Emergency Temporary Standard, published in 86 FR 32376 through 86 FR 32628 on June 21, 2021, with an effective date of August 2, 2021.

Federal Terms and State Equivalents: When the regulations as set forth in the interim final rule for Occupational Safety and Health Standards are applied to the Commissioner of the Department of Labor and Industry or to Virginia employers, the following federal terms shall be considered to read as follows:

Federal Terms	VOSH Equivalent
29 CFR	VOSH Standard
Assistant Secretary	Commissioner of Labor and Industry
Agency	Department
June 21, 2021	August 2, 2021

VA.R. Doc. No. R21-6866; Filed July 9, 2021, 7:57 a.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF FUNERAL DIRECTORS AND EMBALMERS

Forms

REGISTRAR'S NOTICE: Forms used in administering the regulation have been 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, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

Titles of Regulations: 18VAC65-20. Regulations Governing the Practice of Funeral Services.

18VAC65-40. Regulations for the Funeral Service Internship Program.

Agency Contact: Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, FAX (804) 527-4434, or email elaine.yeatts@dhp.virginia.gov.

FORMS (18VAC65-20)

~~Continuing Education Provider Renewal Form (rev. 3/2018)~~

~~Checklist and Instructions for Funeral Service Licensee (rev. 7/2020)~~

~~Funeral Service License Reinstatement Application (rev. 7/2020)~~

~~[Checklist and Instructions for Funeral License \(rev. 7/2021\)](#)~~

~~[Funeral Service Licensee Reinstatement Application \(rev. 7/2021\)](#)~~

~~Request for Verification of a Virginia Funeral License (rev. 11/2019)~~

~~Checklist and Instructions for Courtesy Card Application (rev. 8/2020)~~

~~Checklist and Instructions for Surface Transportation and Removal Service Registration Application (rev. 7/2020)~~

~~Checklist and Instructions for Crematory Registration Application (rev. 7/2020)~~

~~Checklist and Instructions for Continuing Education Providers (rev. 7/2020)~~

~~[Checklist and Instructions for Courtesy Card Application \(rev. 7/2021\)](#)~~

~~[Checklist and Instructions for Surface Transportation and Removal Service Registration Application \(rev. 7/2021\)](#)~~

~~[Checklist and Instructions for Crematory Registration Application \(rev. 1/2021\)](#)~~

~~[Checklist and Instructions for Continuing Education Providers \(rev. 3/2021\)](#)~~

~~Instructions for Completing the Continuing Education Summary Form for The Virginia Board of Funeral Directors and Embalmers (rev. 8/2016)~~

~~Instructions for Continuing Education Providers Adding Additional Courses (rev. 3/2018)~~

~~[Instructions for Continuing Education Providers Adding Additional Courses \(rev. 3/2021\)](#)~~

~~Continuing Education (CE) Credit Form for Volunteer Practice (rev. 7/2020)~~

~~Continued Competency Activity and Assessment Form (rev. 7/2012)~~

~~Funeral Service New Establishment Application (rev. 7/2020)~~

~~Funeral Service Establishment/Branch Application (rev. 7/2020)~~

~~Funeral Service Establishment/Branch Change Application (rev. 7/2020)~~

~~Funeral Establishment or Branch Change of Manager Application (rev. 3/2018)~~

~~[Funeral Service New Establishment Application \(rev. 7/2021\)](#)~~

~~[Funeral Service Establishment/Branch Application \(rev. 7/2021\)](#)~~

~~[Funeral Service Branch Establishment Application \(rev. 7/2021\)](#)~~

~~[Funeral Service Establishment/Branch Change Application \(rev. 7/2021\)](#)~~

~~[Funeral Establishment or Branch Change of Manager Application \(rev. 7/2021\)](#)~~

~~Request for Reinspection due to Structural Change to Preparation Room (rev. 7/2020)~~

~~Waiver of Full Time Manager (rev. 7/2020)~~

~~Funeral Service Establishment Reinstatement Application (rev. 7/2020)~~

~~Courtesy Card Reinstatement Application (rev. 7/2020)~~

~~Waiver of Full-Time Manager (rev. 7/2021)~~

~~[Funeral Service Establishment Reinstatement Application \(rev. 7/2021\)](#)~~

~~[Courtesy Card Reinstatement Application \(rev. 7/2021\)](#)~~

~~Presentation Request Form (rev. 7/2020)~~

~~Name/Address Change Form (rev. 2/2016)~~

~~Appendix I. General Price List (rev. 10/2019)~~

~~Appendix II. Casket Price List, Outer Burial Container Price List (rev. 10/2019)~~

~~Appendix III. Itemized Statement of Funeral Goods and Services Selected (rev. 10/2019)~~

Regulations

FORMS (18VAC65-40)

Application for Funeral Service Internship Program, online form available at <https://www.license/dhp.virginia.gov/apply/>

[Funeral Supervisor Registration Application \(rev. 2/2021\)](#)

[Funeral Change of Supervisor Application \(rev. 2/2021\)](#)

[Funeral Supervisor Registration Application \(rev. 7/2021\)](#)

[Funeral Change of Supervisor Application \(rev. 7/2021\)](#)

[Checklist and Instructions for Registration for Funeral Service Internship Program \(rev. 7/2021\)](#)

[Checklist and Instructions for Registration for Funeral Directing Internship Program \(rev. 7/2021\)](#)

[Checklist and Instructions for Registration for Embalming Internship Program \(rev. 7/2021\)](#)

[First 1000 Hour Funeral Service Internship Report – Funeral Directing \(rev.1/2021\)](#)

[Second 1000 Hour Funeral Service Internship Report – Funeral Directing \(rev. 1/2021\)](#)

[Funeral Service Internship Report of Final Completion – Funeral Directing \(rev. 1/2021\)](#)

[First 1000 Hour Embalming Internship Report \(rev. 1/2021\)](#)

[Second 1000 Hour Embalming Internship Report \(rev. 1/2021\)](#)

[Embalming Internship Report of Final Completion \(rev. 1/2021\)](#)

[Funeral Intern Reinstatement Application \(rev. 7/2021\)](#)

VA.R. Doc. No. R21-6761; Filed July 4, 2021, 12:19 p.m.

BOARD OF MEDICINE

Final Regulation

REGISTRAR'S NOTICE: The Board of Medicine is claiming an exemption 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 or the appropriation act where no agency discretion is involved. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 18VAC85-160. **Regulations Governing the Licensure of Surgical Assistants and Registration of Surgical Technologists (amending 18VAC85-160-30, 18VAC85-160-40, 18VAC85-160-51).**

Statutory Authority: §§ 54.1-2400 and 54.1-2956.13 of the Code of Virginia.

Effective Date: September 1, 2021.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4558, FAX (804)527-4429, or email william.harp@dhp.virginia.gov.

Summary:

The amendments change the regulatory status of surgical technologists from registration to certification and update the certification requirements for surgical technologists in conformity with Chapter 230 of the 2021 Acts of Assembly, Special Session I.

Chapter 160

Regulations Governing the Licensure of Surgical Assistants and ~~Registration~~ Certification of Surgical Technologists

18VAC85-160-30. Current name and address.

Each licensee or ~~registrant certificate holder~~ shall furnish the board his current name and address of record. All notices required by law or by this chapter to be given by the board to any such licensee or ~~registrant certificate holder~~ shall be validly given when sent to the latest address of record provided or served to the licensee or ~~registrant certificate holder~~. Any change of name or address of record or public address, if different from the address of record, shall be furnished to the board within 30 days of such change.

18VAC85-160-40. Fees.

A. The following fees have been established by the board:

1. The fee for licensure as a surgical assistant or ~~registration certification~~ as a surgical technologist shall be \$75.
2. The fee for renewal of licensure or ~~registration certification~~ shall be \$70. Renewals shall be due in the birth month of the licensee or ~~registrant certificate holder~~ in each even-numbered year. For 2020, the renewal fee shall be \$54.
3. The additional fee for processing a late renewal application within one renewal cycle shall be \$25.
4. The handling fee for a returned check or a dishonored credit card or debit card shall be \$50.

B. Unless otherwise provided, fees established by the board are not refundable.

18VAC85-160-51. Requirements for ~~registration certification~~ as a surgical technologist.

A. An applicant for ~~registration certification~~ as a surgical technologist shall submit a completed application and a fee as prescribed in 18VAC85-160-40 on forms provided by the board.

B. An applicant for ~~registration certification~~ as a surgical technologist shall provide satisfactory evidence of:

1. A Successful completion of an accredited surgical technologist training program and a current credential as a certified surgical technologist from the National Board of

Surgical Technology and Surgical Assisting or its successor;
or

2. Successful completion of a ~~surgical technologist~~ training program for surgical technology during the applicant's service as a member of any branch of the armed forces of the United States.

V.A.R. Doc. No. R21-6800; Filed July 12, 2021, 3:03 p.m.

Final Regulation

REGISTRAR'S NOTICE: The Board of Medicine is claiming an exemption 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 or the appropriation act where no agency discretion is involved. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 18VAC85-170. **Regulations Governing the Practice of Genetic Counselors (amending 18VAC85-170-150).**

Statutory Authority: §§ 54.1-2400 and 54.1-2957.18 of the Code of Virginia.

Effective Date: September 1, 2021.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4558, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

Summary:

The amendment removes the provision relating to implementation of the conscience clause, which was repealed by the Chapter 240 of the 2021 Acts of Assembly, Special Session I.

18VAC85-170-150. Practitioner-patient communication; conscience clause; termination of relationship.

A. Communication with patients.

1. Except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately present information to a patient or his legally authorized representative in understandable terms and encourage participation in decisions regarding the patient's care.

2. A practitioner shall not deliberately withhold pertinent findings or information or make a false or misleading statement regarding the practitioner's skill or the efficacy or value of a medication, treatment, or procedure provided or directed by the practitioner in the treatment of any disease or condition.

3. When a genetic procedure is recommended, informed consent shall be obtained from the patient in accordance with the policies of the health care entity. Practitioners shall inform patients of the risks, benefits, and alternatives of the

recommended procedure that a reasonably prudent practitioner practicing genetic counseling in Virginia would tell a patient.

a. In the instance of a minor or a patient who is incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder, the legally authorized person available to give consent shall be informed and the consent documented.

b. An exception to the requirement for consent prior to performance of a genetic procedure may be made in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient.

c. For the purposes of this provision, "genetic procedure" means any diagnostic or therapeutic procedure performed on a patient that is not part of routine, general care and for which the usual practice within the health care entity is to document specific informed consent from the patient or surrogate decisionmaker prior to proceeding.

4. Practitioners shall adhere to requirements of § 32.1-162.18 of the Code of Virginia for obtaining informed consent from patients prior to involving them as subjects in human research with the exception of retrospective chart reviews.

B. Exercise of the conscience clause.

~~1. Notwithstanding provisions of subsection A of this section, a practitioner may exercise the conscience clause pursuant to requirements of § 54.1-2957.21 of the Code of Virginia. If a genetic counselor has deeply held moral or religious beliefs that may prevent him from participating in genetic counseling, he shall immediately inform a prospective patient with specificity about any associated limitations on counseling resulting therefrom, prior to the initiation of the patient-practitioner relationship and shall:~~

~~a. Offer to refer the patient to another licensed health care practitioner with a relevant scope of practice and direct the patient to the online directory of licensed genetic counselors maintained by the board;~~

~~b. Immediately notify any referring practitioner, if known, of this refusal to participate in genetic counseling for the patient; and~~

~~c. Alert the patient and the referring practitioner if the referral is time sensitive.~~

~~2. If, during the course of patient care, the genetic counselor encounters a situation in which his deeply held moral or religious beliefs would prevent him from participating in counseling, he shall immediately inform the patient with specificity about any associated limitations on counseling and shall:~~

~~a. Document the communication of such information in the patient record;~~

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b. Offer to refer the patient to another licensed health care practitioner with a relevant scope of practice and direct the patient to the online directory of licensed genetic counselors;

c. Immediately notify any referring practitioner, if known, of such refusal and referral of the patient; and

d. Alert the patient and the referring practitioner if the referral is time sensitive.

☞ **B.** Termination of the practitioner-patient relationship.

1. The practitioner or the patient may terminate the relationship. In either case, the practitioner shall make the patient record available, except in situations where denial of access is allowed by law.

2. A practitioner shall not terminate the relationship or make his services unavailable without documented notice to the patient that allows for a reasonable time to obtain the services of another practitioner.

VA.R. Doc. No. R21-6846; Filed July 13, 2021, 8:41 a.m.

BOARD OF LONG-TERM CARE ADMINISTRATORS

Forms

REGISTRAR'S NOTICE: Forms used in administering the regulation have been 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, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

Titles of Regulations: 18VAC95-20. Regulations Governing the Practice of Nursing Home Administrators.

18VAC95-30. Regulations Governing the Practice of Assisted Living Facility Administrators.

Agency Contact: Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, FAX (804) 527-4434, or email elaine.yeatts@dhp.virginia.gov.

FORMS (18VAC95-20)

Nursing Home Administrator Application - form available online only at <https://www.license.dhp.virginia.gov/apply/>

[Checklist and Instructions for Nursing Home Administrator Application for Initial Licensure \(rev. 7/2021\)](#)

[Checklist and Instructions for Nursing Home Administrator Application by Endorsement \(rev. 7/2021\)](#)

Nursing Home Administrator-in-Training Application, online form available at <https://www.license.dhp.virginia.gov/apply/>

[Checklist and Instructions for Nursing Home Administrator-in-Training \(rev. 7/2021\)](#)

[Nursing Home Administrator-in-Training Notice of Change of Status or Discontinuance \(rev. 7/2020\)](#)

Nursing Home Administrator Preceptor Application, online form available at <https://www.license.dhp.virginia.gov/apply/>

[Checklist and Instructions for Nursing Home Administrator Reinstatement Application \(rev. 7/2020\)](#)

[Checklist and Instructions for Nursing Home Administrator Preceptor Application \(rev. 7/2021\)](#)

[Checklist and Instructions for Nursing Home Administrator Reinstatement Application \(rev. 7/2021\)](#)

[Monthly Report of Nursing Home Administrator-in-Training \(rev. 7/2020\)](#)

[Nursing Home Administrator-in-Training Documentation of Completion Form \(rev. 7/2020\)](#)

[Proposed AIT Program Training Plan Domains of Practice \(rev. 7/2020\)](#)

[Continued Competency Activity and Assessment Form for Nursing Home Administrators \(rev. 10/2014\)](#)

[Continued Education \(CE\) Credit Form for Volunteer Practice \(rev. 7/2020\)](#)

FORMS (18VAC95-30)

Assisted Living Facility Administrator Application for Licensure - form available online only at https://www.dhp.virginia.gov/nha/nha_forms.htm#alfa

[Assisted Living Facility Administrators Education and Experience Matrix \(rev. 7/2020\)](#)

Assisted Living Facility Administrator Administrator-in-Training Application - form available online ~~only~~ at <https://www.license.dhp.virginia.gov/apply/>

[Monthly Report of Assisted Living Facility Administrator-in-Training \(rev. 7/2020\)](#)

[Assisted Living Facility Administrator-in-Training Documentation of Completion Form \(rev. 7/2020\)](#)

[Assisted Living Facility Administrator-in-Training Notice of Change of Status or Discontinuance \(rev. 7/2020\)](#)

Assisted Living Facility Administrator Preceptor Application - form only available online at https://www.dhp.virginia.gov/nha/nha_forms.htm#alfa

[Checklist and Instructions for Assisted Living Facility Administrator Preceptor Application \(rev. 7/2021\)](#)

[Proposed AIT Program Training Plan Domains of Practice \(rev. 7/2020\)](#)

~~Checklist and Instructions for Assisted Living Facility Administrator Reinstatement Application (rev. 7/2020)~~

~~Checklist and Instructions for Assisted Living Facility Administrator Preceptor Reinstatement Application (rev. 7/2020)~~

~~Checklist and Instructions for Acting Assisted Living Facility Administrator in Training (rev. 7/2020)~~

[Checklist and Instructions for Assisted Living Facility Administrator Reinstatement Application \(rev. 7/2021\)](#)

[Checklist and Instructions for Assisted Living Facility Administrator Preceptor Reinstatement Application \(rev. 7/2021\)](#)

[Checklist and Instructions for Acting Assisted Living Facility Administrator-in-Training \(rev. 7/2021\)](#)

[Continuing Competency Activity and Assessment Form for Assisted Living Facility Administrators \(rev. 9/2010\)](#)

[Continuing Education \(CE\) Credit Form for Volunteer Practice \(eff. 2/2018\)](#)

[Name/Address Change Form \(rev. 3/2019\)](#)

[Request for Verification of Virginia NHA or ALFA License \(eff. 3/2019\)](#)

[Continuing Education \(CE\) Credit Form for Volunteer Practice \(rev. 7/2020\)](#)

[Name/Address Change Form \(rev. 1/2021\)](#)

[Request for Verification of Virginia Long-Term Care Administrators License \(rev. 11/2019\)](#)

VA.R. Doc. No. R21-6859; Filed July 4, 2021, 12:21 p.m.

BOARD OF PHARMACY

Final Regulation

REGISTRAR'S NOTICE: The Board of Pharmacy is claiming an exemption from the Administrative Process Act in accordance with the second enactment of Chapter 205 and Chapters 227 and 228 of the 2021 Acts of Assembly, Special Session I, which exempts the actions of the board relating to the adoption of regulations necessary to implement the provisions of the acts; however, the board is required to provide an opportunity for public comment on any such regulations prior to their adoption.

Title of Regulation: 18VAC110-60. Regulations Governing Pharmaceutical Processors (amending 18VAC110-60-10 through 18VAC110-60-90, 18VAC110-60-110 through 18VAC110-60-330; adding 18VAC110-60-135, 18VAC110-60-136, 18VAC110-60-195, 18VAC110-60-215, 18VAC110-60-251, 18VAC110-60-321).

Statutory Authority: §§ 54.1-3442.6 and 54.1-3447 of the Code of Virginia.

Effective Date: September 1, 2021.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Summary:

Pursuant to Chapters 205 and 227 and 228 of the 2021 Acts of Assembly, Special Session I, the amendments (i) allow pharmaceutical processors to dispense botanical cannabis and establish testing, disposal, and security standards for botanical cannabis and a registration process for botanical cannabis products; (ii) eliminate limitation on the number of patients for whom a practitioner can write certification; (iii) eliminate the requirement that a pharmacist have oversight of the cultivation and processing areas of a pharmaceutical processor and establishment of requirements for a responsible party to oversee those areas; (iv) establish reasonable requirements for advertising of botanical cannabis and cannabis products; (v) allow the use of telemedicine; (vi) allow dispensing of botanical cannabis to a minor; (vii) allow registration of agents for patients certified to receive cannabis products; (viii) allow wholesale distribution of oils between processors; (ix) prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate; (x) provide for patients who are temporary residents to register to use cannabis products; (xi) set out standards for laboratories that provide testing to obtain a controlled substance registration; (xii) allow for sale of devices and inert sample products; and (xiii) replace the references to cannabis oil with cannabis products.

18VAC110-60-10. Definitions.

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"90-day supply" means the amount of cannabis ~~oil~~ products reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication through any means to directly induce any person to patronize a particular pharmaceutical processor or cannabis dispensing facility or to purchase particular approved cannabis products. Advertising includes marketing.

"Batch" means a quantity of (i) cannabis oil from a production lot or (ii) harvested botanical cannabis product that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

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"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabis ~~oil~~ products for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Dispensing error" means one or more of the following was discovered after the final verification by the pharmacist, regardless of whether the patient received the ~~oil~~ product:

1. Variation from the intended ~~oil~~ product to be dispensed, including:
 - a. Incorrect ~~oil~~ product;
 - b. Incorrect ~~oil~~ product strength;
 - c. Incorrect dosage form;
 - d. Incorrect patient; or
 - e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
 - a. Known therapeutic duplication;
 - b. Known drug-disease contraindications;
 - c. Known drug-drug interactions;
 - d. Incorrect drug dosage or duration of drug treatment;
 - e. Known drug-allergy interactions;
 - f. A clinically significant, avoidable delay in therapy; or
 - g. Any other significant, actual, or potential problem with a patient's drug therapy.
3. Delivery of ~~an oil~~ a cannabis product to the incorrect patient.
4. An act or omission relating to the dispensing of cannabis ~~oil~~ product that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis oil is sold to a registered patient, parent, ~~or~~ legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

"On duty" means that a pharmacist, the responsible party, or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"Perpetual inventory" means an ongoing system for recording quantities of cannabis oil received, dispensed, or otherwise distributed by a cannabis dispensing facility.

"PIC" means the pharmacist-in-charge whose name is on the pharmaceutical processor or cannabis dispensing facility application for a permit that has been issued and who shall have oversight of the processor's dispensing area or cannabis dispensing facility.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana for the creation of usable cannabis, botanical cannabis, or a cannabis product derived thereof, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by a combination of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Qualifying patient" means a Virginia resident who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabis ~~oil~~ products for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis ~~oil~~ products to such patient.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Responsible party" means the person designated on the pharmaceutical processor application who shall have oversight of the cultivation and production areas of the pharmaceutical processor.

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

Room or Phase	Temperature	Humidity
Mother room	65 - 75 85° F	50% - 60% 75%
Nursery phase	71 65 - 85° F	65% 50% - 75%
Vegetation phase	71 65 - 85° F	55% 50% - 65% 75%
Flower/harvest phase	71 65 - 85° F	55% 40% - 60% 75%
Drying/extract on rooms	< 75° F	55% 40% - 60% 75%

"Temporarily resides" means a person that does not maintain a principal place of residence within Virginia but resides in Virginia on a temporary basis as evidenced by documentation substantiating such temporary residence.

18VAC110-60-20. Fees.

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

1. Initial registration.	\$50
2. Annual renewal of registration.	\$50
3. Replacement of registration for a qualifying practitioner whose information has changed or whose original registration certificate has been lost, stolen, or destroyed.	\$50

C. Registration by a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

1. Initial registration of a patient.	\$50
2. Annual renewal of registration of a patient.	\$50
3. Initial registration of a parent or legal guardian.	\$25
4. Annual renewal of registration of a parent or guardian.	\$25
5. <u>Initial registration or annual renewal of a registered agent</u>	<u>\$25</u>
6. Replacement of registration for a qualifying patient, parent, or legal guardian, <u>or registered agent</u> whose original registration certificate has been lost, stolen, or destroyed.	\$25

D. Pharmaceutical processor permit.

1. Application.	\$10,000
2. Initial permit.	\$60,000
3. Annual renewal of permit.	\$10,000
4. Change of name of processor.	\$100
5. Change of PIC <u>or responsible party</u> or any other information provided on the permit application.	\$100
6. Change of ownership not requiring a criminal background check.	\$100
7. Change of ownership requiring a criminal background check.	\$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	\$1,000
9. Reinspection fee.	\$1,000
10. Registration of each cannabis oil product.	\$25

E. Cannabis dispensing facility permit.

1. <u>Initial permit.</u>	<u>\$5,000</u>
2. <u>Annual renewal of permit.</u>	<u>\$1,500</u>
3. <u>Change of name of dispensing facility.</u>	<u>\$100</u>
4. <u>Change of PIC or any other information provided on the permit application.</u>	<u>\$100</u>
5. <u>Change of ownership not requiring a criminal background check.</u>	<u>\$100</u>
6. <u>Change of ownership requiring a criminal background check.</u>	<u>\$250</u>
7. <u>Any acquisition, expansion, remodel, or change of location requiring an inspection.</u>	<u>\$1,000</u>
8. <u>Reinspection fee.</u>	<u>\$1,000</u>

~~E. F.~~ The handling fee for returned check or dishonored credit card or debit card shall be \$50.

18VAC110-60-30. Requirements for practitioner issuing a certification.

A. Prior to issuing a certification for cannabis ~~or~~ products for any diagnosed condition or disease, the practitioner shall meet the requirements of § 54.1-3408.3 of the Code of Virginia,

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shall submit an application and fee as prescribed in 18VAC110-60-20, and shall be registered with the board.

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition;

2. Diagnose the patient;

3. Be of the opinion that the potential benefits of cannabis ~~or~~ products would likely outweigh the health risks of such use to the qualifying patient;

4. Authorize on the written certification the use of botanical cannabis for a minor patient if the practitioner determines such use is consistent with the standard of care to dispense botanical cannabis to a minor. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing;

~~5.~~ 6. Explain proper administration and the potential risks and benefits of the cannabis ~~or~~ product to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

~~5.~~ 6. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabis ~~or~~ products for treating the diagnosed condition or disease;

~~6.~~ 7. Comply with generally accepted standards of medical practice, except to the extent such standards would counsel against certifying a qualifying patient for cannabis ~~or~~ products;

~~7.~~ 8. Maintain medical records in accordance with 18VAC85-20-26 for all patients for whom the practitioner has issued a certification; and

~~8.~~ 9. Access or direct the practitioner's delegate to access the Virginia Prescription Monitoring Program of the Department of Health Professions for the purpose of determining which, if any, covered substances have been dispensed to the patient.

C. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation, which may include the use of telemedicine, provided that the use of telemedicine:

1. Includes the delivery of patient care through real-time interactive audio-visual technology;

2. Conforms to the standard of care expected for in-person care; and

3. Transmits information in a manner that protects patient confidentiality.

~~Such telemedicine use shall be consistent with federal requirements for the prescribing of Schedules II through V controlled substances.~~

D. A practitioner shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a certification. Employees under the direct supervision of the practitioner may assist with preparing a certification, so long as the final certification is approved and signed by the practitioner before it is issued to the patient.

E. The practitioner shall provide instructions for the use of cannabis ~~or~~ products to the patient, parent, or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

~~F. A practitioner shall not issue certifications for cannabis oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.~~

~~G.~~ Upon request, a practitioner shall make a copy of medical records available to an agent of the Board of Medicine or Board of Pharmacy for the purpose of enabling the board to ensure compliance with the law and regulations or to investigate a possible violation.

18VAC110-60-40. Prohibited practices for practitioners.

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis ~~or~~ products;

2. Offer a discount or any other thing of value to a qualifying patient, parent, ~~or~~ guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis ~~or~~ product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis ~~or~~ products are dispensed or produced; or

4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor, a cannabis dispensing facility, or any other entity that may benefit from a qualifying patient's

acquisition, purchase, or use of cannabis ~~or~~ products, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabis ~~or~~ product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabis ~~or~~ other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. Registration of a patient, parent, ~~or~~ legal guardian, or registered agent.

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;
2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt or proof of temporary residency, if applicable, such as a current academic identification card from a Virginia institution of higher learning, rental agreement, utility bill, or attestation on a form prescribed by the board that contains information sufficient to document temporary residency in Virginia;
3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;
4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;
5. Payment of the appropriate fees; and
6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

B. A patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis products on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, birthdate, and registration number of each registered patient for whom the individual intends to act as a registered agent;

2. Proof of identity in the form of a copy of a government-issued identification card;

3. Payment of the applicable fee; and

4. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

~~B. C.~~ A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

~~C. D.~~ Patients, parents, ~~and~~ legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabis ~~or~~ products.

18VAC110-60-60. Denial of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent registration application.

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;
2. Does not provide acceptable proof of identity, residency or temporary residency, or age of the patient to the board;
3. Provides false, misleading, or incorrect information to the board;
4. Has had a qualifying registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent denied, suspended, or revoked by the board in the previous six months;
5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabis ~~or~~ products; or
6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-70. Reporting requirements for practitioners, patients, parents, ~~or~~ legal guardians, or registered agents.

A. A practitioner shall report to the board, on a form prescribed by the board, the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabis ~~or~~ products or the practitioner's inability to continue treating the patient. A practitioner shall report such death, change of status, or

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inability to continue treatment not more than 15 days after the practitioner becomes aware of such fact.

B. A patient, parent, or legal guardian who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change. The patient, parent, or legal guardian shall report changes that include a change in name, address, contact information, medical status of the patient, or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

~~D.~~ If a patient, parent, ~~or legal guardian, or registered agent~~ notifies the board of any change that results in information on ~~the registration of the patient, parent, or legal guardian's registration~~ guardian, or registered agent being inaccurate, the board shall issue a replacement registration. Upon receipt of a new registration, the qualifying patient, parent, ~~or legal guardian, or registered agent~~ shall destroy in a nonrecoverable manner the registration that was replaced.

~~D.~~ E. If a patient, parent, ~~or legal guardian, or registered agent~~ becomes aware of the loss, theft, or destruction of the registration of such patient, parent, ~~or legal guardian, or registered agent~~, the ~~patient, parent, or legal guardian~~ registrant shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

18VAC110-60-80. Proper storage and disposal of ~~cannabidiol oil or THC-A oil~~ cannabis products by patients, parents, ~~or legal guardians, or registered agents.~~

A. A registered patient, parent, ~~or legal guardian, or registered agent~~ shall exercise reasonable caution to transport and store cannabis ~~oil~~ products in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, ~~or legal guardian, or registered agent~~ shall dispose of all usable cannabis ~~oil~~ products in possession of the registered patient, parent, or legal guardian's possession ~~guardian, or registered agent~~ no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabis ~~oil~~ products. A registered patient, parent, ~~or legal guardian, or registered agent~~ shall complete such disposal by one of the following methods:

1. By removing the ~~oil~~ product from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.

2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, ~~or legal guardian, or registered agent~~ registration.

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, ~~or legal guardian, or registered agent)~~ under the following circumstances:

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;

2. The ~~patient, parent, or legal guardian~~ registrant provided false, misleading, or incorrect information to the board;

3. The ~~patient, parent, or legal guardian~~ registrant is no longer a resident of Virginia or is no longer temporarily residing in Virginia;

4. The ~~patient, parent, or legal guardian~~ registrant obtained more than a 90-day supply of cannabis ~~oil~~ products in a 90-day period;

5. The ~~patient, parent, or legal guardian~~ registrant provided or sold cannabis ~~oil~~ products to any person, including another ~~registered patient, parent, or legal guardian~~ registrant;

6. The ~~patient, parent, or legal guardian~~ registrant permitted another person to use the registration of the ~~patient, parent, or legal guardian~~ registrant, except as required for a registered agent to act on behalf of a patient;

7. The ~~patient, parent, or legal guardian~~ registrant tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the ~~patient, parent, or legal guardian~~ registrant;

8. The registration of the ~~patient, parent, or legal guardian~~ registrant was lost, stolen, or destroyed, and the ~~patient, parent, or legal guardian~~ registrant failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

9. The ~~patient, parent, or legal guardian~~ registrant failed to notify the board of a change in registration information or

notified the board of such change more than ~~14~~ 15 days after the change; or

10. The patient, parent, or legal guardian violated any federal or state law or regulation.

Part III

Application and Approval Process for Pharmaceutical Processors and Cannabis Dispensing Facilities

18VAC110-60-110. Application process for pharmaceutical processor permits.

A. The application process for permits shall occur in three stages: submission of initial application, award of conditional approval, and grant of a pharmaceutical processor permit.

B. Submission of initial application.

1. A pharmaceutical processor permit applicant shall submit the required application fee and form with the following information and documentation:

- a. The name and address of the applicant and the applicant's owners;
- b. The location within the health service area established by the State Board of Health for the pharmaceutical processor that is to be operated under such permit;
- c. Detailed information regarding the applicant's financial position indicating all assets, liabilities, income, and net worth to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis ~~or~~ products pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;
- d. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis ~~or~~ products;
- e. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of a permit;
- f. Information necessary for the board to conduct a criminal background check on the applicant;
- g. Information about any previous or current involvement in the medical cannabis ~~or~~ industry;
- h. Whether the applicant has ever applied for a permit or registration related to medical cannabis ~~or~~ in any state and, if so, the status of that application, permit, or registration, to include any disciplinary action taken by any state on the permit, the registration, or an associated license;

i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabis ~~or~~ products;

j. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;

k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the Cannabis plants and ~~or~~ products; (iii) the location of all areas that may contain Cannabis plants or cannabis ~~or~~ products; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress;

l. Documents related to any compassionate need program the pharmaceutical processor intends to offer;

m. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabis ~~or~~ products and to safely dispense such products; and

n. Such other documents and information required by the board to determine the applicant's suitability for permitting or to protect public health and safety.

2. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the permit selection process.

3. The board shall conduct criminal background checks on applicants and may verify information contained in each application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.

C. In the event the board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in a health service area, the board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

D. No person who has been convicted of a felony ~~or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 of~~ under the Code of Virginia or another jurisdiction within the last five years shall have ~~any form of ownership~~ 5.0% or greater ownership, be employed by, or act as an agent of a pharmaceutical processor.

18VAC110-60-120. Conditional approval.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant conditional approval on a competitive basis based on compliance with requirements set forth in 18VAC110-60-110.

Regulations

B. The board shall consider, but is not limited to, the following criteria in evaluating pharmaceutical processor permit applications:

1. The results of the criminal background checks required in 18VAC110-60-110 B 3 or any history of disciplinary action imposed by a state or federal regulatory agency;
2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school or daycare;
3. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants or the cannabis ~~or~~ products;
4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabis ~~or~~ products;
5. The extent to which the applicant or any of the applicant's pharmaceutical processor owners have a financial interest in another license, permit, registrant, or applicant; and
6. Any other reason provided by state or federal statute or regulation that is not inconsistent with the law and regulations regarding pharmaceutical processors.

C. The board may disqualify any applicant who:

1. Submits an incomplete, false, inaccurate, or misleading application;
2. Fails to submit an application by the published deadline;
3. Fails to pay all applicable fees; or
4. Fails to comply with all requirements for a pharmaceutical processor.

D. Following review, the board shall notify applicants of denial or conditional approval. The decision of the board not to grant conditional approval to an applicant shall be final.

E. If granted conditional approval, an applicant shall have one year from date of notification to complete all requirements for issuance of a permit, to include employment of a PIC, responsible party, and other personnel necessary for operation of a pharmaceutical processor, construction or remodeling of a facility, installation of equipment, and securing local zoning approval.

18VAC110-60-130. Granting of a pharmaceutical processor permit.

A. The board may issue a pharmaceutical processor permit when all requirements of the board have been met, to include:

1. Designation of a PIC and responsible party;
2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;

3. Evidence of utilization of an electronic tracking system; and

4. A satisfactory inspection of the facility conducted by the board or ~~its~~ the board's agents.

B. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

C. Before any permit is issued, the applicant shall attest to compliance with all state and local laws and ordinances. A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

E. A pharmaceutical processor shall be deemed to have commenced operation if Cannabis plants are under cultivation by the processor in accordance with the approved application.

F. In the event a permit is rescinded pursuant to this section, the board may award a pharmaceutical processor permit by selecting among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant who applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish in accordance with this section a notice of open applications for a pharmaceutical processor permit.

G. Once the permit is issued, ~~Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application a processor may begin cultivation of Cannabis, and the responsible party or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis.~~ Once Cannabis has been placed in the dispensing area of the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. ~~Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access.~~ The PIC responsible party shall ensure security measures are adequate to protect the cannabis in the cultivation and production area from diversion at all times, and the PIC shall have concurrent responsibility for preventing diversion from the dispensing area. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist or the responsible party shall continue to be on site on a daily basis.

18VAC110-60-135. Application for and granting of a permit for a cannabis dispensing facility.

A. Pursuant to § 54.1-3442.6 of the Code of Virginia, the board may issue up to five cannabis dispensing facility permits for each health service area. A permit may be issued to a facility that is owned, at least in part, by the pharmaceutical processor located in that health service area for the dispensing of cannabis products that has been cultivated and produced on the premises of a pharmaceutical processor. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for each cannabis dispensing facility permit shall be submitted to the board, along with the following information and documentation:

1. The name and address of the facility, which shall not be within 1,000 feet of a school or daycare;
2. The name and address of the facility's owners with 5.0% or greater ownership;
3. Name and signature of pharmacist-in-charge practicing at the facility;
4. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis products; and
5. Information necessary for the board to conduct a criminal background check on the facilities' owners with 5.0% or greater ownership.

C. Prior to issuing the permit, an inspection of the facility shall be performed by an agent of the board. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

D. A cannabis dispensing facility shall comply with all state and local laws and ordinances.

E. A cannabis dispensing facility permit shall not be issued to any person to operate from a private dwelling or residence.

F. No person who has been convicted of a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a cannabis dispensing facility.

G. If the cannabis dispensing facility is not operational within 90 days from the date the permit is issued, the board shall rescind the permit unless an extension is granted for good cause shown.

H. A cannabis dispensing facility shall be deemed to have commenced operation if it is in receipt of cannabis products from a pharmaceutical processor.

I. Once the facility is in possession of cannabis products, a pharmacist shall be on site at all times during the declared hours of operation.

18VAC110-60-136. Denial of a cannabis dispensing facility permit application.

A. The board may deny an application for a cannabis dispensing facility permit if the applicant:

1. Submits an incomplete, false, inaccurate, or misleading application;
2. Fails to pay all applicable fees; or
3. Fails to comply with all requirements for a cannabis dispensing facility.

B. If the board denies an application of cannabis dispensing facility permit, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-140. Notification of changes by pharmaceutical processor or cannabis dispensing facility.

A. Unless otherwise provided in law or regulation, the PIC ~~or the responsible party~~ designated on the application ~~to be in full and actual charge~~ of the pharmaceutical processor ~~or a cannabis dispensing facility~~ shall provide any notification or information that is required from a pharmaceutical processor ~~or a cannabis dispensing facility~~ with respect to their designated areas of oversight.

B. Prior to making any change to the pharmaceutical processor ~~or cannabis dispensing facility~~ name, the pharmaceutical processor ~~or cannabis dispensing facility~~ shall submit an application for such change to the board and pay the fee.

C. Any person wishing to engage in the acquisition of an existing pharmaceutical processor ~~or cannabis dispensing facility~~, change the location of an existing pharmaceutical processor ~~or cannabis dispensing facility~~, make structural changes to an existing pharmaceutical processor ~~or cannabis dispensing facility~~, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

1. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.
2. Cannabis, oil acquired from industrial hemp extract, or cannabis products shall not be moved to a new location until approval is granted by the inspector or board staff.

Regulations

18VAC110-60-150. Pharmaceutical processor or cannabis dispensing facility closings; going out of business; change of ownership.

A. At least 30 days prior to the date a pharmaceutical processor or cannabis dispensing facility closes, either temporarily or permanently, the owner shall:

1. Notify the board;
2. Send written notification to patients with current certification; and
3. Post a notice on the window or door of the pharmaceutical processor or cannabis dispensing facility.

B. The proposed disposition of all Cannabis, oil from industrial hemp, cannabis products, dispensing records, patient information records, and other required records, as applicable, shall be reported to the board. If the Cannabis, cannabis products, and records are to be transferred to another processor located in Virginia or to another cannabis dispensing facility in the same health service area, the owner shall inform the board and the patients and include on the public notice the name and address of the processor or cannabis dispensing facility to whom the Cannabis, cannabis products, and records are being transferred and the date of transfer.

C. Exceptions to the public notice shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmaceutical processor or cannabis dispensing facility is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as the owner knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

D. In the event of an exception to the notice, the PIC, responsible party, or owner shall provide notice as far in advance of closing as allowed by the circumstances.

E. At least 14 days prior to any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.
2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.
3. If a new owner's share constitutes 5.0% or greater of the total ownership, the new owner shall submit to

fingerprinting and the criminal history record search required by of § 54.1-3442.6 E of the Code of Virginia.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit or a cannabis dispensing facility.

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued; place such permit on probation; place conditions on such permit; or take other actions permitted by statute or regulation on the following grounds:

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabis or products that is authorized under state law and regulations;
2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;
3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabis or products, or other controlled substances;
4. Intentionally or through negligence obscuring, damaging, or defacing a permit or registration card;
5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, or legal guardian or registered agent, except as required for a registered agent to act on behalf of a patient;
6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor; or
7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown upon a written request from a pharmaceutical processor or cannabis dispensing facility. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production cannabis dispensing facility.

18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations.

A. A pharmacist with a current, unrestricted license issued by the board practicing at the location of the address on the pharmaceutical processor or cannabis dispensing facility application shall be in full and actual charge of the dispensing area of a pharmaceutical processor or of a cannabis dispensing facility and shall serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the dispensing area of the pharmaceutical processor or of a cannabis dispensing facility at all times during its hours of operation ~~or whenever the processor is being accessed~~.

C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application, shall have oversight of the cultivation and production areas, and shall possess:

1. A current, unrestricted license as a pharmacist issued by the board;
2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;
3. A certification recognized by the board; or
4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.

~~D.~~ E. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia ~~and who has had at least two years of experience practicing as a pharmacy technician~~ may perform the following duties under supervision of a pharmacist:

1. The entry of drug dispensing information and drug history into a data system or other recordkeeping system;
2. The preparation of labels for dispensing the ~~oil~~ cannabis product or patient information;
3. The removal of the ~~oil~~ cannabis product to be dispensed from inventory;
4. The measuring of the ~~oil~~ cannabis product to be dispensed;
5. The packaging and labeling of the ~~oil~~ cannabis product to be dispensed and the repackaging thereof;
6. The stocking or loading of devices used in the dispensing process;
7. The selling of the ~~oil~~ cannabis product to the registered patient, parent, ~~or~~ legal guardian or registered agent; and
8. The performance of any other task restricted to pharmacy technicians by the board's regulations.

~~D.~~ E. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, and extraction as authorized by the pharmaceutical processor, and duties associated with the dispensing of the ~~oil~~ products as authorized by the PIC or as otherwise authorized in law.

~~E.~~ A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a

~~degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.~~

~~F.~~ A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabis oil as authorized by the PIC.

~~G.~~ A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, and cannabis oil and shall ensure quality of the dispensed oils. Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC shall ensure security measures are adequate to protect the cannabis from diversion at all times.

~~F.~~ A pharmaceutical processor may employ individuals with less than two years of experience to perform cultivation-related duties under the supervision of an individual who has received a degree in a field related to the cultivation of plants or a certification recognized by the board or who has at least two years of experience cultivating plants.

~~G.~~ A pharmaceutical processor may employ individuals with less than two years of experience to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

~~H.~~ Except for certain employee access to secured areas designated for cultivation and authorized by the PIC pursuant to § 54.1-3442.6 of the Code of Virginia, at At no time shall the dispensing area of a pharmaceutical processor operate or be accessed without a pharmacist on duty. At no time shall the cultivation and production area operate or be accessed without an employee on duty who satisfies the requirements for providing direct supervision for the activities in the respective areas.

I. No person shall be employed by or serve as an agent of a pharmaceutical processor or cannabis dispensing facility without being at least 18 years of age.

J. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor or cannabis dispensing facility unless such license or registration has been reinstated and is current and unrestricted.

Regulations

18VAC110-60-180. Employee training.

A. All employees of a pharmaceutical processor or cannabis dispensing facility shall complete training prior to the employee commencing work at the pharmaceutical processor or cannabis dispensing facility. At a minimum, the training shall be in the following areas:

1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and cannabis ~~or~~ products;
2. Procedures and instructions for responding to an emergency;
3. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and
4. Developments in the field of the medical use of cannabis ~~or~~ products.

B. Prior to regular performance of assigned tasks, the employee shall also receive on-the-job training and other related education, which shall be commensurate with the tasks assigned to the employee.

C. The PIC and the responsible party shall assure the continued competency of all employees, in the respective areas for which they have oversight, through continuing in-service training that is provided at least annually, is designed to supplement initial training, and includes any guidance specified by the board.

D. The PIC and the responsible party shall be responsible for maintaining a written record documenting the initial and continuing training of all their respective employees that shall contain:

1. The name of the person receiving the training;
2. The dates of the training;
3. A general description of the topics covered;
4. The name of the person supervising the training; and
5. The signatures of the person receiving the training and the PIC or the responsible party.

E. When a change of pharmaceutical processor or cannabis dispensing facility PIC or responsible party occurs, the new PIC or responsible party shall review the training record and sign it, indicating that the new PIC or responsible party understands its contents.

F. A pharmaceutical processor or cannabis dispensing facility shall maintain the record documenting the employee training and make it available in accordance with regulations.

18VAC110-60-190. Pharmacy technicians; ratio; supervision and responsibility.

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor a cannabis dispensing facility designated for production or dispensing shall not exceed ~~four~~ six pharmacy technicians to one pharmacist.

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabis ~~or~~ products resulting from the actions of a pharmacy technician shall constitute grounds for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabis ~~or~~ product production or dispensing functions; and
2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent ~~or~~ legal guardian, or registered agent regarding (i) cannabis ~~or~~ products or other drugs either before or after cannabis ~~or~~ products have been dispensed or (ii) any medical information contained in a patient medication record;
2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabis ~~or~~ product or any other drug the patient may be taking;
3. Interpret the patient's clinical data or provide medical advice;
4. Determine whether a different formulation of cannabis ~~or~~ product should be substituted for the cannabis ~~or~~ product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or
5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

18VAC110-60-195. Responsibilities of the responsible party.

A person may only serve as the responsible party for one pharmaceutical processor at any one time. The responsible party shall be employed full time in a managerial position at the location of the processor and shall be actively engaged in daily operations of the processor during normal hours of operation.

B. The responsible party shall be aware of and knowledgeable about all policies and procedures pertaining to the operations of the pharmaceutical processor.

C. The responsible party shall ensure compliance with all security measures to protect the Cannabis within the cultivation and production areas from diversion at all times and ensure that cultivation and production is performed in a safe and compliant manner and free of adulteration and misbranding.

D. The responsible party shall be responsible for ensuring that:

1. All employees practicing in the cultivation and production areas are properly trained;
2. All record retention requirements are met;
3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and the cannabis products, within the cultivation and production area are met; and
4. Any other required filings or notifications regarding the cultivation and production areas are made on behalf of the processor as set forth in regulation.

E. When the responsible party ceases practice at a pharmaceutical processor or no longer wishes to be designated as the responsible party, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the responsible party.

F. The outgoing responsible party shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, or cannabis products on hand in the cultivation and production areas, on the date he ceases to be the responsible party unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A responsible party who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the responsible party. If the responsible party knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the responsible party that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new responsible party.

H. An application for a permit designating the new responsible party shall be filed with the required fee within 14 days of the original date of resignation or termination of the responsible party on a form provided by the board. It shall be unlawful for a pharmaceutical processor to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive

director for the board may grant an extension for up to an additional 14 days for good cause shown.

18VAC110-60-200. Responsibilities of the PIC.

A. No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy. The PIC of a pharmaceutical processor shall not serve as PIC of any other facility at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board. A person may serve simultaneously as the PIC for no more than two cannabis dispensing facilities located within the same health service area at any one time.

B. The PIC or the pharmacist on duty shall control all aspects of the practice in the dispensing area of the pharmaceutical processor or in a cannabis dispensing facility. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor or cannabis dispensing facility permit.

C. The PIC of a pharmaceutical processor ~~PIC~~ or cannabis dispensing facility shall be responsible for ensuring that:

1. Pharmacy technicians are registered and ~~all employees are~~ properly trained;
2. All record retention requirements pertaining to the dispensing area met;
3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and the cannabis ~~o~~ products are met;
4. The pharmaceutical processor or cannabis dispensing facility has appropriate pharmaceutical reference materials to ensure that cannabis ~~o~~ products can be properly dispensed;
5. The following items are conspicuously posted in the pharmaceutical processor or cannabis dispensing facility in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, ~~o~~ legal guardians, or registered agents:
 - a. Pharmaceutical processor permit or cannabis dispensing facility permit;
 - b. Licenses for all pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility; and
 - c. The price of all cannabis ~~o~~ products offered by the pharmaceutical processor or cannabis dispensing facility; and
6. Any other required filings or notifications are made on behalf of the dispensing area of the pharmaceutical processor or the dispensing facility as set forth in regulation.

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D. When the PIC ceases practice at a pharmaceutical processor or cannabis dispensing facility or no longer wishes to be designated as PIC, he shall immediately return the ~~pharmaceutical processor~~ permit to the board indicating the effective date on which he ceased to be the PIC.

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all ~~Cannabis, to include plants, extracts, or cannabis oil~~ products on hand in the dispensing area of the pharmaceutical processor or the dispensing facility on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmaceutical processor or cannabis dispensing facility to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

18VAC110-60-210. General provisions.

A. A pharmaceutical processor or cannabis dispensing facility shall only sell cannabis ~~oil~~ products in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, ~~or~~ legal guardian, or registered agent, the ~~oil~~ product may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

B. Only a pharmacist may dispense cannabis ~~oil~~ products to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board, or to a registered agent. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis ~~oil~~ products.

C. The PIC ~~or~~ pharmacist, responsible party, or person who is qualified to provide supervision in accordance with 18VAC110-60-170 on duty shall restrict access to the pharmaceutical processor or cannabis dispensing facility to:

1. A person whose responsibilities necessitate access to the pharmaceutical processor or cannabis dispensing facility and

then for only as long as necessary to perform the person's job duties; or

2. A person who is a registered patient, parent, ~~or~~ legal guardian or, registered agent, or a companion of the patient, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, or cannabis ~~oil~~ products are stored

D. All pharmacists and pharmacy technicians shall at all times while at the pharmaceutical processor or cannabis dispensing facility have their current license or registration available for inspection by the board or the board's agent.

E. While inside the pharmaceutical processor or cannabis dispensing facility, all ~~pharmaceutical processor~~ employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor or cannabis dispensing facility.

F. A pharmaceutical processor or cannabis dispensing facility shall be open for registered patients, parents, ~~or~~ legal guardians, or registered agents to purchase cannabis ~~oil~~ products for a minimum of 35 hours a week, except as otherwise authorized by the board.

G. A pharmaceutical processor or cannabis dispensing facility that closes the dispensing area during its normal hours of operation shall implement procedures to notify registered patients, parents, ~~and~~ legal guardians, and registered agents of when the pharmaceutical processor or cannabis dispensing facility will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the cultivation, production, or dispensing area of the pharmaceutical processor or if a cannabis dispensing facility is or will be closed during its normal hours of operation for longer than two business days, the pharmaceutical processor or cannabis dispensing facility shall immediately notify the board.

H. A pharmacist shall counsel registered patients, parents, ~~and~~ legal guardians, and registered agents, if applicable, regarding the use of cannabis ~~oil~~ products. Such counseling shall include information related to safe techniques for proper use and storage of cannabis ~~oil~~ products and for disposal of the ~~oils~~ products in a manner that renders them nonrecoverable.

I. The pharmaceutical processor or cannabis dispensing facility shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy that shall be available to the board or the board's agent upon request.

18VAC110-60-215. Advertising.

A. A pharmaceutical processor or cannabis dispensing facility shall not advertise (i) through any means unless at least 85% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time

outside of regular school hours for elementary and secondary schools.

B. Advertising must accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility responsible for its content and include a statement that cannabis products are for use by registered patients only. Any advertisement for cannabis products that is related to the benefits, safety, or efficacy, including therapeutic or medical claims, shall:

1. Be supported by substantial, current clinical evidence or data; and
2. Include information on side effects or risks associated with the use of cannabis.

C. Advertising shall not:

1. Be misleading, deceptive, or false or contain any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;
2. Contain a statement, design, illustration, picture, or representation that:
 - a. Encourages or represents the recreational use of cannabis;
 - b. Targets or is attractive to persons younger than 18 years of age, including a cartoon character, a mascot, or any other depiction or image that is commonly used to market products to minors;
 - c. Displays the use of cannabis, including the consumption, smoking, or vaping of cannabis;
 - d. Encourages or promotes cannabis for use as an intoxicant; or
 - e. Is obscene or indecent.

3. Display cannabis or cannabis product pricing except as allowed in 18VAC110-60-215 F.

4. Display cannabis products or images of products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place; and

5. Include coupons, giveaways of free cannabis products, or distribution of merchandise that displays anything other than the facility name and contact information.

D. A pharmaceutical processor or cannabis dispensing facility may list its business in public phone books, business directories, search engines, or other places where it is reasonable for a business to maintain an informational presence of its existence and a description of the nature of the business. A pharmaceutical processor or cannabis dispensing facility shall not engage in the use of pop-up digital advertisements.

E. Any website or social media site owned, managed, or operated by a pharmaceutical processor or cannabis dispensing facility shall employ a neutral age-screening mechanism that verifies that the user is at least 18 years of age, including by using an age-gate, age-screen, or age verification mechanism.

F. A pharmaceutical processor or cannabis dispensing facility may display the following information on its website or social media site:

1. Name and location of the processor or facility;
2. Contact information for the processor or facility;
3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;
4. Laboratory results;
5. Product information and pricing;
6. Directions to the processor or facility; and
7. Educational materials regarding the use of cannabis products that are supported by substantial, current clinical evidence or data.

G. Communication and engagement for educational purposes with registered practitioners, registered patients, parents, legal guardians, registered agents, other health care practitioners, and the general public, including the dissemination of information permitted by 18VAC110-60-215 F and educational materials regarding the use of cannabis products available from the pharmaceutical processor or cannabis dispensing facility, is allowed.

H. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility.

I. Signs placed on the property of a pharmaceutical processor or cannabis dispensing facility shall not:

1. Display imagery of cannabis or the use of cannabis or utilize long luminous gas-discharge tubes that contain rarefied neon or other gases;
2. Draw undue attention to the facility but may be designed to assist registered patients, parents, legal guardians, and registered agents to find the pharmaceutical processor or cannabis dispensing facility; or
3. Be illuminated during non-business hours.

J. All outdoor signage must be in compliance with local or state requirements.

K. A pharmaceutical processor or cannabis dispensing facility shall not advertise at any sporting event or use any billboard advertisements.

L. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand,

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transportation waiting area, train station, airport, or any similar transit-related location.

18VAC110-60-220. Pharmaceutical processor or cannabis dispensing facility prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis ~~oil~~ products in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;
2. Sell, deliver, transport, or distribute Cannabis, including cannabis ~~oil~~ products, to any other facility except for wholesale distribution between pharmaceutical processors and to a cannabis dispensing facility pursuant to 18VAC110-60-251;
3. Produce or manufacture cannabis ~~oil~~ products for use outside of Virginia; or
4. Provide cannabis ~~oil~~ products samples.

B. No cannabis dispensing facility shall:

1. Dispense cannabis products in any place except the approved facility at the address of record on the application for the cannabis dispensing facility permit;
2. Sell, deliver, transport, or distribute cannabis products to any other facility, except that it may distribute cannabis products back to the pharmaceutical processor from which it obtained the products or distribute cannabis oil products between cannabis dispensing facilities; or
3. Provide cannabis product samples.

~~C.~~ Except for certain employee access to secured areas designated for cultivation and production and authorized by the ~~PIC~~ responsible party pursuant to § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor or cannabis dispensing facility shall be open or in operation, and no person shall be in the dispensing area of a pharmaceutical processor or in a cannabis dispensing facility, unless a pharmacist is on the premises and directly supervising the activity within the dispensing area of the pharmaceutical processor or a cannabis dispensing facility. At all other times, the dispensing area of the pharmaceutical processor or the cannabis dispensing facility shall be closed and properly secured.

~~C.~~ D. No pharmaceutical processor or cannabis dispensing facility shall sell anything other than cannabis ~~oil~~ products ~~from the pharmaceutical processor~~ except for devices for administration of dispensed products or hemp-based CBD products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280 D 2 and D 3.

~~D.~~ A pharmaceutical processor shall not advertise cannabis oil products, except it may post the following information on websites:

- ~~1. Name and location of the processor;~~
- ~~2. Contact information for the processor;~~
- ~~3. Hours and days the pharmaceutical processor is open for dispensing cannabis oil products;~~
- ~~4. Laboratory results;~~
- ~~5. Product information and pricing; and~~
- ~~6. Directions to the processor facility.~~

E. No cannabis ~~oil~~ products shall be consumed on the premises of a pharmaceutical processor or cannabis dispensing facility, except for emergency administration to a registered patient. Such administration shall be recorded and a file maintained for a period of two years.

F. No person except a pharmaceutical processor or cannabis dispensing facility employee or a registered patient, parent, ~~or~~ legal guardian, registered agent, or a companion of a patient shall be allowed on the premises of a processor or facility with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis or cannabis ~~oil~~ products samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor or cannabis dispensing facility employee prior to entering the ~~pharmaceutical~~ processor or facility.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility.
2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility and shall return the visitor identification badge to ~~a pharmaceutical processor~~ an employee upon exiting the pharmaceutical processor or facility.
3. All visitors shall log in and out. The pharmaceutical processor or cannabis dispensing facility shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.
4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor or cannabis dispensing facility to obtain a waiver from the board, the processor or facility shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor or cannabis

dispensing facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

H. No cannabis ~~oil~~ products shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor or cannabis dispensing facility, except that a registered parent ~~or~~ legal guardian, or registered agent or an agent of the processor or cannabis dispensing facility may deliver cannabis ~~oil~~ products to the registered patient or in accordance with 18VAC110-60-310 A.

I. Notwithstanding the requirements of subsection F of this section, an agent of the board or local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor or cannabis dispensing facility if necessary to perform their governmental duties.

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis ~~oil~~ products, at the facility. The responsible party shall ensure all required inventories are performed in the cultivation and production areas, and the PIC shall ensure all required inventories are performed in the dispensing area. The ~~inventory~~ inventories shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, ~~or~~ pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. If a facility commences business with no Cannabis or cannabis products on hand, the pharmacist or responsible party shall record this fact as the initial inventory; and

2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis ~~oil~~ products, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

B. Upon commencing business, each pharmaceutical processor ~~and production facility~~ shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, and cannabis ~~oil~~ products in stock, that shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist ~~or~~ pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. ~~The record of all cannabis oil sold, dispensed, or otherwise disposed of shall show the date of sale; the name of the pharmaceutical processor; the registered patient, parent, or legal guardian to whom the cannabis oil was~~

~~sold; the address of such person; and the kind and quantity of cannabis oil sold.~~

C. Upon commencing business, each cannabis dispensing facility shall maintain a perpetual inventory of all cannabis products received and dispensed that accurately indicates the physical count of each cannabis product on hand at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each cannabis product at least monthly with a written explanation for any difference between the physical count and the theoretical count.

~~D.~~ The record of all cannabis ~~oil~~ products sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and address of the registered patient, parent, ~~or~~ legal guardian, or registered agent to whom the cannabis ~~oil~~ product was sold; the kind and quantity of cannabis ~~oil~~ product sold or disposed of; and the method of disposal.

~~D.~~ E. A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, and cannabis ~~oil~~ products on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC or responsible party may choose, so long as it is not more than one year following the prior year's inventory.

~~E.~~ F. All inventories, procedures, and other documents required by this section shall be maintained on the premises and made available to the board or its agent.

~~F.~~ G. Inventory records shall be maintained for three years from the date the inventory was taken.

~~G.~~ H. Whenever any sample or record is removed by a person authorized to enforce state or federal law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabis ~~oil~~ products for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall:

~~1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days;~~

~~2. Not not maintain cannabis ~~oil~~ product in excess of the quantity required for normal, efficient operation;~~

B. At no time shall a cannabis dispensing facility maintain cannabis products in excess of the quantity required for normal, efficient operation.

C. Items a pharmaceutical processor shall properly secure include Cannabis plants, seeds, parts of plants, extracts, and cannabis products. A cannabis dispensing facility shall

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properly secure cannabis products. To secure these items a pharmaceutical processor and a cannabis dispensing facility shall:

- ~~3.~~ 1. Maintain all Cannabis plants, seeds, parts of plants, extracts, and cannabis ~~or~~ products in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;
- ~~4.~~ 2. Store all cut parts of Cannabis plants, extracts, or cannabis ~~or~~ products in an approved safe or approved vault within the pharmaceutical processor or cannabis dispensing facility and not sell cannabis ~~or~~ products when the pharmaceutical processor or cannabis dispensing facility is closed;
- ~~5.~~ 3. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabis ~~or~~ products securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, or cannabis ~~or~~ products;
- ~~6.~~ 4. Keep all locks and security equipment in good working order;
- ~~7.~~ 5. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the dispensing area to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility;
- ~~6.~~ Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the cultivation and production areas to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing in the processor or persons supervising cultivation-related or production-related activities at the processor; and
- ~~8.~~ 7. Not allow keys to be left in the locks or accessible to ~~non-pharmacists~~ persons not authorized by the PIC or responsible party.

D. Employees, other than a pharmacist or person supervising cultivation-related or production-related activities at the processor, but so designated by the PIC or responsible party, may have the ability to unlock a secured area to gain entrance to perform required job duties, but only during hours of operation of the processor or dispensing facility. At no time shall these employees have access to the security system.

~~B.~~ E. The pharmaceutical processor or cannabis dispensing facility shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, or cannabis ~~or~~ products. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor or cannabis dispensing facility. The

installation and the device shall be based on accepted alarm industry standards and subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other generally accepted and suitable device;
2. The device shall be monitored in accordance with accepted industry standards, be maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational;
3. The device shall fully protect the entire processor or facility and shall be capable of detecting breaking by any means when activated;
4. The device shall include a duress alarm, a panic alarm, and an automatic voice dialer; and
5. Access to the alarm system for the dispensing area of the processor or cannabis dispensing facility shall be restricted to the pharmacists working at the pharmaceutical processor or cannabis dispensing facility, and the system shall be activated whenever the ~~pharmaceutical processor or facility~~ is closed for business. Access to the alarm system in areas of a pharmaceutical processor that designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor.

~~C.~~ F. A pharmaceutical processor or cannabis dispensing facility shall keep the outside perimeter of the premises ~~well-~~ well lit. A processor or facility shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, or cannabis ~~or~~ products and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

1. The processor or facility shall direct cameras at all approved safes, approved vaults, dispensing areas, or cannabis ~~or~~ products sales areas, and any other area where Cannabis plants, seeds, extracts, or cannabis ~~or~~ products are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor or facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;
2. The video system shall have:
 - a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor or facility within five minutes of the failure, either by telephone, email, or text message;
 - b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image, live or recorded;

c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

d. The ability to remain operational during a power outage;

3. All video recordings shall allow for the exporting of still images in an industry standard image format. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmaceutical processor or cannabis dispensing facility shall erase all recordings prior to disposal or sale of the facility; and

4. The processor or facility shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor or facility is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor or facility shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor or cannabis dispensing facility PIC that it is not necessary to retain the recording.

~~D.~~ G. The processor or facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every six months.

~~E.~~ H. A pharmaceutical processor or cannabis dispensing facility shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor or facility shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor or facility. The pharmaceutical processor or cannabis dispensing facility shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

~~F.~~ I. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, or cannabis ~~oil~~ products has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

18VAC110-60-250. Requirements for the storage and handling of Cannabis or cannabis ~~oil~~ products.

A. A pharmaceutical processor or cannabis dispensing facility shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature, and humidity as defined in 18VAC110-60-10 and space, equipment, and security conditions for the cultivation of Cannabis and the production and dispensing of cannabis ~~oil~~ products;

2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabis ~~oil~~ products, that ~~is~~ are outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, or cannabis ~~oil~~ products are destroyed;

3. Be maintained in a clean, sanitary, and orderly condition; and

4. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. A pharmaceutical processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabis ~~oil~~ products. These shall include policies and procedures that:

1. Restrict movement between compartments;

2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;

3. Require pocketless clothing for all ~~production facility~~ employees working in an area containing Cannabis plants, seeds, and extracts, including cannabis oil and cannabis products; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, and cannabis ~~oil~~ products.

C. A cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper dispensing of cannabis products, including a requirement for pocketless clothing for all facility employees working in an area containing cannabis products.

D. The PIC and responsible party of a pharmaceutical processor or the PIC of a cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including the seeds, parts of plants, extracts, and the cannabis ~~oil~~ products, as applicable. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories.

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Pharmaceutical processors and cannabis dispensing facilities shall include in their written policies and procedures a process for the following:

1. Handling mandatory and voluntary recalls of cannabis ~~oil~~ products. The process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor or cannabis dispensing facility to (i) remove defective or potentially defective cannabis ~~oil~~ products from the market or (ii) promote public health and safety by replacing existing cannabis ~~oil~~ products with improved products or packaging;
2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;
3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, and cannabis ~~oil~~ products, is segregated from all other Cannabis, seeds, parts of plants, extracts, and cannabis ~~oil~~ products and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, and cannabis ~~oil~~ product disposition; and
4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, and cannabis ~~oil~~ products are used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

~~D. E.~~ The pharmaceutical processor shall store all Cannabis, including seeds, parts of plants, extracts, and cannabis ~~oil~~ products, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss; shall make Cannabis, including the seeds, parts of plants, extracts, and cannabis ~~oil~~ products accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist, responsible party, or other person authorized by the responsible party to supervise cultivation and production at the processor shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, and cannabis ~~oil~~ products, inside an area or building that affords adequate security.

F. The cannabis dispensing facility shall store all cannabis products in such a manner as to prevent diversion, theft, or loss; shall make cannabis products accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the cannabis products to their secure location at the completion of the dispensing or at end of the scheduled business day.

18VAC110-60-251. Wholesale distribution of cannabis oil products.

A. Cannabis oil, cannabis products, botanical cannabis, and usable cannabis from a batch that have passed the tests required in 18VAC110-60-300 G and H and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility.

B. Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between cannabis dispensing facilities.

C. A pharmaceutical processor or cannabis dispensing facility wholesale distributing the products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor or cannabis dispensing facility distributing the product and the processor or cannabis dispensing facility receiving the product, (iii) the kind and quantity of product being distributed, and (iv) the batch and lot identifying information to include harvest date, testing date, processing or manufacturing date, and expiration date. The record of the transaction shall be maintained by the distributing pharmaceutical processor or cannabis dispensing facility with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or facility receiving the product in its records of receipt. Such records shall be maintained by each processor or facility for three years in compliance with 18VAC110-60-260.

D. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared upon request to registered patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

E. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall store and handle products and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

F. If a pharmaceutical processor or cannabis dispensing facility wholesale distributing products uses an electronic system for the storage and retrieval of records related to distributing products, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

18VAC110-60-260. Recordkeeping requirements.

A. If a pharmaceutical processor or cannabis dispensing facility uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabis ~~oil~~ products, as applicable, the pharmaceutical processor or cannabis dispensing facility shall use a system that:

1. Guarantees the confidentiality of the information contained in the system;
2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist or responsible party; and
3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

B. All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of three years and shall be made available to the board upon request.

18VAC110-60-270. Reportable events; security.

A. Upon becoming aware of (i) diversion, theft, loss, or discrepancies identified during inventory; (ii) unauthorized destruction of any cannabis ~~oil~~ products; or (iii) any loss or unauthorized alteration of records related to cannabis ~~oil~~ products or qualifying patients, a pharmacist or responsible party, pharmaceutical processor, or cannabis dispensing facility shall immediately notify appropriate law-enforcement authorities and the board.

B. A pharmacist or responsible party, pharmaceutical processor, or cannabis dispensing facility shall provide the notice required by subsection A of this section to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabis ~~oil~~ product diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist or responsible party, processor, or facility shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacist or responsible party, pharmaceutical processor, or cannabis dispensing facility shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:

1. An alarm activation or other event that requires a response by public safety personnel;
2. A breach of security;
3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. Corrective measures taken if any.

D. A pharmacist ~~or responsible party~~, pharmaceutical processor, or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony ~~or any offense referenced in § 54.1-3442.6 of the Code of Virginia~~.

Part VI

Cultivation, Production, and Dispensing of Cannabis ~~Oil~~ Products**18VAC110-60-280. Cultivation and production of cannabis ~~oil~~ products.**

A. No cannabis ~~oil~~ products shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

B. Cultivation methods for Cannabis plants and extraction methods used to produce the cannabis ~~oil~~ products shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, or cannabis ~~oil~~ products not in compliance with this section shall be deemed adulterated.

D. A pharmaceutical processor may acquire oil from industrial hemp extract for the purpose of formulating such oil extract with cannabis plant extract into allowable dosages of cannabis oil provided:

1. The pharmaceutical processor acquires the oil from industrial hemp extract processed in Virginia and in compliance with state or federal law from a registered industrial hemp dealer or processor;
2. The oil from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements applicable to cannabis plant extract as verified by testing performed by a laboratory located in Virginia and in compliance with state law; and
3. The industrial hemp dealer or processor provides such third-party testing results to the pharmaceutical processor before oil from industrial hemp is acquired.

E. A pharmaceutical processor acquiring oil from industrial hemp extract shall ensure receipt of a record of the transaction that shows the date of distribution, the names and addresses of the registered industrial hemp dealer or processor distributing the product and the pharmaceutical processor receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be maintained by the pharmaceutical processor with its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years.

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F. A pharmaceutical processor shall maintain policies and procedures for the proper storage and handling of oil from industrial hemp extract, to include a process for executing or responding to mandatory and voluntary recalls in a manner that complies with 18VAC110-60-250.

G. No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate.

18VAC110-60-285. Registration of products.

A. A pharmaceutical processor shall assign a brand name to each product of cannabis ~~oil~~. The pharmaceutical processor shall register each brand name with the board on a form prescribed by the board prior to any dispensing and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);
2. Tetrahydrocannabinol acid (THC-A);
3. Cannabidiols (CBD); and
4. Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 90% to 110%.

C. The board shall not register any brand name that:

1. Is identical to or confusingly similar to the name of an existing commercially available product;
2. Is identical to or confusingly similar to the name of an unlawful product or substance;
3. Is confusingly similar to the name of a previously approved cannabis oil product brand name;
4. Is obscene or indecent;
5. May encourage the use of marijuana or cannabis ~~oil~~ products for recreational purposes;
6. May encourage the use of cannabis ~~oil~~ products for a disease or condition other than the disease or condition the practitioner intended to treat;
7. Is customarily associated with persons younger than the age of 18; or
8. Is related to the benefits, safety, or efficacy of the cannabis ~~oil~~ product unless supported by substantial evidence or substantial clinical data.

18VAC110-60-290. Labeling of batch of cannabis ~~oil~~ products.

A. Cannabis ~~oil~~ products produced as a batch shall not be adulterated.

B. Cannabis ~~oil~~ products produced as a batch shall be:

1. Processed, packaged, and labeled according to the U.S. Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 CFR Part 111; and

2. Labeled with:

- a. The name and address of the pharmaceutical processor;
- b. The brand name of the cannabis ~~oil~~ product that was registered with the board pursuant to 18VAC110-20-285;
- c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;
- d. The date of testing and packaging;
- e. The expiration date ~~based on~~, which shall be six months or less from the date of packaging, unless supported by stability testing;
- f. The quantity of cannabis ~~oil~~ products contained in the batch;
- g. A terpenes profile and a list of all active ingredients, including:
 - (1) Tetrahydrocannabinol (THC);
 - (2) Tetrahydrocannabinol acid (THC-A);
 - (3) Cannabidiol (CBD); and
 - (4) Cannabidiolic acid (CBDA); ~~and~~

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

h. A For cannabis oil products, pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis; and

i. For botanical cannabis products, a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, pesticide chemical residue analysis, water activity, and moisture content, and the potency.

18VAC110-60-300. Laboratory requirements; testing.

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis ~~oil~~ products unless such laboratory:

1. Is independent from all other persons involved in the cannabis ~~oil~~ industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist,

pharmaceutical processor, cannabis dispensing facility, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis ~~oil~~ products; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the ISO/IEC 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration method utilized to perform a cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use nonaccredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use nonaccredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize nonaccredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within 24 hours. The laboratory shall immediately stop handling, testing, or analyzing Cannabis for pharmaceutical processors.

5. Complies with a transportation protocol for transporting Cannabis or cannabis products to or from itself or to or from pharmaceutical processors.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, ~~and~~ pesticide chemical residue, and, for botanical cannabis, the water activity and moisture content; and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

C. A pharmaceutical processor shall make a sample available from each harvest batch of botanical cannabis product to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, water activity, and moisture content and (ii) conduct an active ingredient analysis and terpenes profile. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The same must be representative of the entire batch to include selection from various points in the batch lot and be of sufficient sample size to allow for analysis of all required tests.

D. ~~From the time that a batch of cannabis ~~oil~~ product has been homogenized for sample sampled for testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.~~

~~E.~~ E. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis ~~oil~~ product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

~~F.~~ F. The processor shall require the laboratory to immediately return or properly dispose of any cannabis ~~oil~~

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products and materials upon the completion of any testing, use, or research.

~~F. G.~~ If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, ~~or~~ pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, ~~the pharmaceutical processor shall dispose of the entire batch from which the sample was taken~~ batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

1. For purposes of the microbiological test, a cannabis oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

- a. Tetrahydrocannabinol (THC);
- b. Tetrahydrocannabinol acid (THC-A);

- c. Cannabidiols (CBD); and
- d. Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.

~~6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopoeia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.~~

H. If a sample of botanical cannabis product does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity, or moisture content test based on the standards set forth in this subsection, the batch may be remediated. Once remediated, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity, and moisture content, and an active ingredient analysis and terpenes profile shall be conducted. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all testing standards set forth in subsection G of this section.

1. For purposes of the microbiological test, a botanical cannabis product sample shall be deemed to have passed if it satisfies the standards set forth in the most current American Herbal Pharmacopoeia Cannabis Inflorescence Standards of Identity, Analysis, and Quality Control.

2. For purposes of the mycotoxin test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

Test Specification	
<u>Aflatoxin B1</u>	<u><20 ug/kg of Substance</u>
<u>Aflatoxin B2</u>	<u><20 ug/kg of Substance</u>
<u>Aflatoxin G1</u>	<u><20 ug/kg of Substance</u>
<u>Aflatoxin G2</u>	<u><20 ug/kg of Substance</u>
<u>Ochratoxin A</u>	<u><20 ug/kg of Substance</u>

3. For purposes of the heavy metal test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

<u>Metal</u>	<u>Limits - parts per million (ppm)</u>
<u>Arsenic</u>	<u><10 ppm</u>
<u>Cadmium</u>	<u><4.1 ppm</u>
<u>Lead</u>	<u><10 ppm</u>
<u>Mercury</u>	<u><2 ppm</u>

4. For purposes of the pesticide chemical residue test, a sample of botanical cannabis product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food (40 CFR Part 180).

5. For purposes of the active ingredient analysis, a sample of the botanical cannabis product shall be tested for:

- a. Total tetrahydrocannabinol (THC); and
- b. Total cannabidiol (CBD).

6. For the purposes of water activity and moisture content for botanical cannabis, the product shall be deemed to have passed if the water activity rate does not exceed 0.65Aw and the moisture content does not exceed 15%.

I. If a sample of cannabis ~~oil~~ product passes the required tests listed in ~~18VAC110-60-300 subsections G and H microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test of this section~~, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products, except stability testing shall not be required for cannabis products if the pharmaceutical processor assigns an expiration date of six months or less from the date of packaging.

J. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the ~~microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test~~ required tests listed in subsections G and H of this section at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

K. Each pharmaceutical processor or cannabis dispensing facility shall have such laboratory results available upon request to registered patients, parents ~~or~~ legal guardians ~~and~~, registered agents, registered practitioners who have certified qualifying patients, the board, or an agent of the board.

18VAC110-60-310. Dispensing of cannabis ~~oil~~ products.

A. A pharmacist in good faith may dispense cannabis ~~oil~~ products to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of cannabis ~~oil~~ products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view in person or by audiovisual means a current photo identification of the patient, parent, ~~or~~ legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis ~~oil~~ products to the registered patient.

2. ~~The A~~ pharmacist or pharmacy technician employed by the processor or cannabis dispensing facility shall make ~~and maintain for three years~~ a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible and shall maintain it on site or by electronic means for two years.

3. Prior to any subsequent dispensing, the pharmacist, ~~or pharmacy technician, or delivery agent~~ shall ~~view~~ verify that the current written certification and on file has not expired. An employee or delivery agent shall view a current photo identification and current registration of the patient, parent, or legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the pharmaceutical processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis ~~oil~~ product. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis ~~oil~~ products at any time except that no registered patient, parent, ~~or~~ legal guardian, or registered agent shall receive more than a 90-day supply of cannabis ~~oil~~ products for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. However, no more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. In determining the appropriate amount of cannabis product to be dispensed to a patient, a pharmacist shall consider all cannabis products dispensed and adjust the amount dispensed accordingly.

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall

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affix a label to the container of ~~each~~ cannabis product that contains:

1. A serial number assigned to the dispensing of the ~~each~~ product;
2. The brand name of cannabis ~~each~~ product that was registered with the board pursuant to 18VAC110-60-285 and its strength;
3. The serial number assigned to the ~~each~~ product during production;
4. The date of dispensing the cannabis ~~each~~ product;
5. The quantity of cannabis ~~each~~ products dispensed;
6. A terpenes profile and a list of all active ingredients, including:
 - a. Tetrahydrocannabinol (THC);
 - b. Tetrahydrocannabinol acid (THC-A);
 - c. Cannabidiol (CBD); and
 - d. Cannabidiolic acid (CBDA);

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, ~~and~~ pesticide chemical residue analysis, and for botanical cannabis, the water activity and moisture content analysis;
8. The name and registration number of the registered patient;
9. The name and registration number of the certifying practitioner;
10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;
11. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;
- ~~12.~~ 13. The name or initials of the dispensing pharmacist;
- ~~12.~~ 13. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;
- ~~13.~~ 14. Any necessary cautionary statement; and
- ~~14.~~ 15. A prominently printed expiration date based on stability testing and the pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. A pharmaceutical processor shall not label cannabis ~~each~~ products as "organic" unless the Cannabis plants have been organically grown and the cannabis oil products have been produced, processed, manufactured, and certified to be

consistent with organic standards in compliance with 7 CFR Part 205.

E. The cannabis ~~each~~ products shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

F. No person except a pharmacist or a pharmacy technician operating under the direct supervision of a pharmacist shall alter, deface, or remove any label so affixed.

G. A pharmacist shall be responsible for verifying the accuracy of the dispensed ~~each~~ product in all respects prior to dispensing and shall document that each verification has been performed.

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis ~~each~~ products in treating the registered patient's diagnosed condition or disease or the symptoms thereof. If the authorization for botanical cannabis for a minor is communicated verbally or in writing to the pharmacist at the time of dispensing, the pharmacist shall also document such authorization. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis ~~each~~ products to a registered patient, parent, ~~or~~ legal guardian, or registered agent if the pharmacist suspects that dispensing cannabis ~~each~~ products to the registered patient, parent, ~~or~~ legal guardian, or registered agent may have negative health or safety consequences for the registered patient or the public.

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor or cannabis dispensing facility shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor or cannabis dispensing facility shall distribute the written policies and procedures to all pharmaceutical processor or cannabis dispensing facility employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor or cannabis dispensing facility. The policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall

describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor or cannabis dispensing facility shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor or cannabis dispensing facility PIC shall:

1. Inform pharmaceutical processor or cannabis dispensing facility employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor or facility employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;

3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and

4. Create a record of every quality assurance review. This record shall contain at least the following:

- a. The date of the quality assurance review and the names and titles of the persons performing the review;
- b. The pertinent data and other information relating to the dispensing error reviewed;
- c. Documentation of contact with the registered patient, parent, ~~or~~ legal guardian, or registered agent, where applicable, and the practitioner who certified the patient;
- d. The findings and determinations generated by the quality assurance review; and
- e. Recommended changes to pharmaceutical processor or cannabis dispensing facility policy, procedure, systems, or processes if any.

C. A pharmaceutical processor or cannabis dispensing facility shall maintain for three years a copy of the pharmaceutical processor's or cannabis dispensing facility's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

18VAC110-60-321. Devices, hemp-based CBD products, and inert product samples.

A. A pharmaceutical processor or cannabis dispensing facility may have for sale on-site devices intended for the administration of dispensed cannabis products and hemp based CBD products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280 D 2 and D 3.

B. The pharmaceutical processor or cannabis dispensing facility may use and distribute inert product samples that do not contain any active cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility without the need for a written certification. Such inert product samples may not be sold or further distributed.

18VAC110-60-330. Disposal of cannabis ~~oil~~ products.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated green waste, extracts, and cannabis products, as applicable. Green waste includes Cannabis plants, including seeds, and parts of plants, extracts, or cannabis oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabis oil nonrecoverable. Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render the mixture inactive and unrecognizable. Once rendered unrecognizable, green waste shall be considered agricultural waste and may be disposed of accordingly.

B. The destruction and disposal of green waste, extracts, and cannabis oil, as applicable, shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor a pharmacist and at least one other employee of the pharmaceutical processor or cannabis dispensing facility, respectively, and shall be conducted under video surveillance. The persons destroying and disposing of the green waste, extracts, or cannabis ~~oil~~ products shall maintain and make available a separate record of each ~~such~~ occurrence of destruction and disposal indicating:

- 1. The date and time of destruction and disposal;
- 2. The manner of destruction and disposal;
- 3. The name and quantity of cannabis ~~oil~~ product and green waste destroyed and disposed of; and
- 4. The signatures of the persons destroying and disposing of the green waste, extracts, or cannabis ~~oil~~ products.

C. The record of destruction and disposal shall be maintained at the pharmaceutical processor or cannabis dispensing facility for three years from the date of destruction and disposal.

VA.R. Doc. No. R21-6755; Filed July 12, 2021, 1:47 p.m.

BOARD OF PHYSICAL THERAPY

Forms

REGISTRAR'S NOTICE: Forms used in administering the regulation have been 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, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

Regulations

Title of Regulation: 18VAC112-20. Regulations Governing the Practice of Physical Therapy.

Agency Contact: Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, FAX (804) 527-4434, or email elaine.yeatts@dhp.virginia.gov.

FORMS (18VAC112-20)

Application for Licensure by Examination to Practice Physical Therapy as a Physical Therapist or Physical Therapist Assistant - form available online ~~only~~ at https://www.dhp.virginia.gov/PhysicalTherapy/physther_for.ms.htm

[Application for Licensure by Examination to Practice Physical Therapy \(rev. 7/2021\)](#)

Application for Licensure by Endorsement to Practice Physical Therapy as a Physical Therapist or Physical Therapist Assistant - form available online ~~only~~ at https://www.dhp.virginia.gov/PhysicalTherapy/physther_for.ms.htm

~~Application for Reinstatement to Practice Physical Therapy (rev. 4/2021)~~

~~Application for Reinstatement After Disciplinary Action (rev. 7/2020)~~

[Application for Licensure by Endorsement to Practice Physical Therapy \(rev. 7/2021\)](#)

[Application for Reinstatement to Practice Physical Therapy \(rev. 7/2021\)](#)

[Application for Reinstatement after Disciplinary Action \(rev. 7/2021\)](#)

Checklist and Instructions for Application for Licensure by Endorsement to Practice Physical Therapy (rev. 4/2021)

Checklist and Instructions for Application for Licensure by Endorsement to Practice Physical Therapy (Graduate of a Non-Approved Program) (rev. 4/2021)

Checklist and Instructions for Application for Licensure by Examination to Practice Physical Therapy (rev. 7/2020)

Checklist and Instructions for Application for Licensure by Examination to Practice Physical Therapy (Graduate of a Non-Approved Program) (rev. 7/2020)

Instructions: Reinstatement of Licensure to Practice as a Physical Therapist or Physical Therapist Assistant (rev. 4/2021)

Trainee Application - Statement of Authorization (rev. 7/2020)

Trainee Application - Statement of Authorization (Graduates of a Non-Approved PT or PTA Program Who Need to

Complete a Full Time 1,000 Hours of Traineeship) (rev. 7/2020)

Trainee Application - Statement of Authorization (320-hour Traineeship) (rev. 7/2020)

320 Hour Traineeship Completion Form (rev. 7/2020)

Educational Authorization Form (rev. 7/2020)

Continued Competency Activity and Assessment Form (rev. 1/2015)

Continuing Education (CE) Credit Form for Volunteer Practice (rev. 7/2020)

~~Application for Direct Access Certification (rev. 6/2020)~~

[Application for Direct Access Certification \(rev. 7/2021\)](#)

Instructions - Direct Access Certification by Experience (rev. 11/2020)

Instructions - Direct Access Certification by Transitional Doctorate (rev. 11/2020)

~~Direct Access Patient Attestation and Medical Release Form (eff. 5/2018)~~

[Direct Access Patient Attestation and Medical Release Form \(rev. 7/2021\)](#)

Name/Address Change Form (rev. 7/2020)

Request for Verification of a Virginia Physical Therapy License (rev. 7/2020)

VA.R. Doc. No. R21-6858; Filed July 4, 2021, 12:24 p.m.



TITLE 20. PUBLIC UTILITIES AND TELECOMMUNICATIONS

STATE CORPORATION COMMISSION

Forms

REGISTRAR'S NOTICE: Forms used in administering the regulation have been 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, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

Title of Regulation: 20VAC5-342. Rules Governing Multi-Family Shared Solar Program.

Agency Contact: C. Austin Skeens, Attorney, Office of General Counsel, Public Utility Regulation, State Corporation

Commission, P.O. Box 1197, Richmond, VA 23218, telephone
(804) 371-9140, or email austin.skeens@scc.virginia.gov.

FORMS (20VAC5-342)

[Standard Consumer Disclosure Form](#)

V.A.R. Doc. No. R21-6874; Filed July 13, 2021, 2:57 p.m.

GUIDANCE DOCUMENTS

PUBLIC COMMENT OPPORTUNITY

Pursuant to § 2.2-4002.1 of the Code of Virginia, a certified guidance document is subject to a 30-day public comment period after publication in the Virginia Register of Regulations and prior to the guidance document's effective date. During the public comment period, comments may be made through the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) or sent to the agency contact. Under subsection C of § 2.2-4002.1, the effective date of the guidance document may be delayed for an additional period. The guidance document may also be withdrawn.

The following guidance documents have been submitted for publication by the listed agencies for a public comment period. Online users of this issue of the Virginia Register of Regulations may click on the name of a guidance document to access it. Guidance documents are also available on the Virginia Regulatory Town Hall (<http://www.townhall.virginia.gov>) or from the agency contact or may be viewed at the Office of the Registrar of Regulations, 900 East Main Street, Richmond, Virginia 23219.

STATE BOARD OF EDUCATION

Title of Document: [Draft Guidance for Unscheduled Remote Learning Days.](#)

Public Comment Deadline: September 1, 2021.

Effective Date: September 2, 2021.

Agency Contact: Michael Bolling, Assistant Superintendent for Learning and Innovation, Department of Education, 101 North 14th Street, Richmond, VA 23219, telephone (804) 225-2034, or email michael.bolling@doe.virginia.gov.

* * *

Title of Document: [Transfer of Rights for Students with Disabilities upon Reaching the Age of Majority in Virginia.](#)

Public Comment Deadline: September 1, 2021.

Effective Date: September 2, 2021.

Agency Contact: Samantha Hollins, Assistant Superintendent for Special Education and Student Services, Department of Education, 101 North 14th Street, Richmond, VA 23219, telephone (804) 786-8079, or email samantha.hollins@doe.virginia.gov.

VIRGINIA SOIL AND WATER CONSERVATION BOARD

Title of Document: [2022 Grant Manual for the Virginia Dam Safety, Flood Prevention, and Protection Assistance Fund.](#)

Public Comment Deadline: September 1, 2021.

Effective Date: September 2, 2021.

Agency Contact: Lisa McGee, Policy and Planning Director, Department of Conservation and Recreation, 600 East Main Street, 24th Floor, Richmond, VA 23219, telephone (804)786-4378, or email lisa.mcgee@dcr.virginia.gov.

GENERAL NOTICES

STATE CORPORATION COMMISSION

AT RICHMOND, JULY 9, 2021

COMMONWEALTH OF VIRGINIA, *ex rel.*

STATE CORPORATION COMMISSION

CASE NO. BFI-2021-00007

Ex Parte: In the matter of Adopting
Regulations Governing Qualified
Education Loan Servicers under Chapter 26
of Title 6.2 of the Code of Virginia

ORDER REQUESTING ADDITIONAL COMMENTS

On March 9, 2021, the State Corporation Commission (Commission) entered an Order to Take Notice of a proposal by the Bureau of Financial Institutions (Bureau) to adopt regulations governing qualified education loan servicers, to be set forth in Chapter 220 of Title 10 of the Virginia Administrative Code.

The Bureau submitted the proposed regulations pursuant to Chapters 1198 and 1250 of the 2020 Virginia Acts of Assembly, which amends the Code of Virginia (Code) by adding Chapter 26 of Title 6.2 (§ 6.2-2600 *et seq.*) of the Code (Chapter 26). Chapter 26 establishes a licensing and regulatory framework for qualified education loan servicers effective on July 1, 2021. The regulations implement the provisions of Chapter 26 by, among other things, establishing the amount required for the surety bond, annual reporting requirements, the procedure for documenting eligibility for automatic issuance of a license, the application and renewal process, the annual fee schedule, and procedures for submitting information to the Bureau.

The Order to Take Notice and proposed regulations were published in the Virginia Register of Regulations on March 29, 2021, posted on the Commission's website, and sent to certain interested persons. All interested persons were afforded the opportunity to file written comments or request a hearing on or before April 16, 2021. Comments on the proposed regulations were filed by Virginia21; the New Virginia Majority; the Virginia Poverty Law Center; National Association of Student Loan Administrators (NASLA); Progress Virginia Education Fund; and Student Loan Servicing Alliance (SLSA). The Commission did not receive any requests for a hearing.

The Bureau considered the comments filed and responded to them in its Response to Comments (Response), which the Bureau filed with the Clerk of the Commission on May 17, 2021.

NOW THE COMMISSION, upon consideration of this matter, finds that additional pleadings on the federal preemption and intergovernmental immunity issues are warranted. As the

Bureau explains: (1) NASLA asserts application of Chapter 26 and the proposed regulations to Federal Guarantors is preempted by federal law, and the doctrine of intergovernmental immunity bars direct state regulation of federal contractors such as federal guarantors; and (2) SLSA asserts federal student loans are preempted from any licensing regime.

The Commission notes, however, that neither the Bureau, nor any of the commenters, other than NASLA and SLSA, have substantively addressed the legal issues of federal preemption or intergovernmental immunity raised by NASLA and SLSA. Before ruling on these legal questions, the Commission requests the Bureau, NASLA, SLSA, and any interested person desiring so (including others that previously filed comments), to file comments further addressing these issues of federal preemption and intergovernmental immunity.

Specifically, any such comments shall be due on or before August 16, 2021, and (not by way of exclusion) such commenters are requested to address the following questions:

(1) Identify specifically any part(s) of the statute and/or regulations that are federally preempted. For each such part identified, explain in detail which theory of preemption applies and all reasons why the statute and/or regulation are preempted, with citations to applicable law, including caselaw. Please also address whether each part(s) identified are severable from the remainder of the statute.

(2) Identify specifically any part(s) of the statute and/or regulations that violate the doctrine of intergovernmental immunity. For each part identified, explain in detail why the statute and/or regulation violates the doctrine of intergovernmental immunity, with citations to applicable law, including caselaw. Please also address whether the part(s) identified are severable from the remainder of the statute.

(3) If no such part(s) of the statute and/or regulations are identified in question (1) above, explain in detail why the statute and/or regulations are not federally preempted, with citations to applicable law, including caselaw.

(4) If no such part(s) of the statute and/or regulations are identified in question (2) above, explain in detail why the statute and/or regulations do not violate the doctrine of intergovernmental immunity, with citations to applicable law, including caselaw.

(5) Address *Student Loan Servicing Alliance v. District of Columbia*, 351 F.Supp.3d 26 (2018) and its applicability to this case, Chapter 26 of Title 6.2 of the Code, and the proposed regulations pursuant thereto in Virginia.

Accordingly, IT IS SO ORDERED, and this matter is CONTINUED.

A COPY of this Order shall be sent by the Clerk of the Commission to the Commission's Office of General Counsel

General Notices

and to the Commissioner of Financial Institutions, who shall send by e-mail or U.S. mail a copy of this Order to all those who commented in this matter and to the Commonwealth of Virginia's Office of the Attorney General.

¹Comments submitted by SLSA were filed on April 19, 2021, after the deadline imposed by the Order to Take Notice. However, the Commission will make a limited exception in this instance due in part to the fact that the Bureau indicated it considered and responded to all comments received and finding that such does not result in any undue prejudice.

AT RICHMOND, JUNE 29, 2021

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. PUR-2020-00124

Ex Parte: In the matter of establishing regulations for a multi-family shared solar program pursuant to § 56-585.1:12 of the Code of Virginia

ORDER

On December 23, 2020, the State Corporation Commission ("Commission") issued its Order Adopting Rules in this docket to govern multi-family shared solar programs to be offered by Virginia Electric and Power Company d/b/a Dominion Energy Virginia ("Dominion") and Kentucky Utilities Company d/b/a Old Dominion Power Company ("KU-ODP"). Among other things, the Order Adopting Rules noted that § 56-585.1:12 E 6 of the Code of Virginia ("Code") requires that the Commission adopt a standardized disclosure form to be provided to each prospective customer before subscribing to a multi-family shared solar facility. The Commission directed the low-income working group established in Case No. PUR-2020-00125 to develop the disclosure form(s) to be adopted by the Commission for the multi-family shared solar program.¹

The Order Adopting Rules also provided that, pursuant to Code § 56-585.1:12 D, the Commission would by separate order calculate and publish the applicable bill credit rate for multi-family shared solar customers.² On April 10, 2021, the Coalition for Community Solar Access ("CCSA"), together with the Chesapeake Solar and Storage Association ("CHESSA"), moved the Commission to enter an order clarifying the applicable bill credit rate for the multi-family shared solar program³ and the shared solar program⁴ ("CCSA-CHESSA Motion"). CCSA and CHESSA requested that the Commission enter an order: (1) adopting 2021 applicable bill credit rates for each customer class (residential, commercial, and industrial) for the multi-family shared solar program based on the most recent posted U.S. Energy Information Agency ("EIA") data; and (2) confirming that the same EIA data and calculation methodology will be

used to determine the applicable bill credit rates for both the multi-family shared solar program and shared solar program.

On May 18, 2021, Dominion and KU-ODP filed responses to the CCSA-CHESSA Motion. Dominion stated that it did not disagree with using EIA data to calculate the Multi-Family Shared Solar bill credit rate but argued that "before the statutory formula can be applied, taxes must be removed from the revenue total, because these tax payments are passed through to the respective governmental entities to whom they belong, and are not Company revenue."⁵ KU-ODP objected to the use of EIA data because (1) this data is not timely – the most recent available EIA data is from 2019 – and (2) the EIA data is not jurisdictionalized but rather includes data for customers not subject to the Commission's jurisdiction.⁶ Instead, KU-ODP proposed that the Commission base the bill credit rate on information derived from KU-ODP's Form 1, which is filed annually with the Federal Energy Regulatory Commission ("FERC") and provided to the Commission in March of each year.⁷ On June 2, 2021, CCSA and CHESSA filed a reply to KU-ODP's and Dominion's responses. CCSA and CHESSA did not object to KU-ODP's proposal to use FERC Form 1 data but opposed Dominion's proposal to exclude taxes from the EIA data.⁸

NOW THE COMMISSION, having considered this matter, is of the opinion and finds as follows.

Bill Credit Rate

Code § 56-585.1:12 D provides that:

[t]he Commission shall annually calculate the applicable bill credit rate as the effective retail rate of the customer's rate class, which shall be inclusive of all supply charges, delivery charges, demand charges, fixed charges, and any applicable riders or other charges to the customer. This rate shall be expressed in dollars or cents per kilowatt-hour.

While the Commission determined in the Order Adopting Rules that it would calculate a bill credit using publicly available data, the Order Adopting Rules did not establish a methodology for this calculation. Under the specific circumstances of this case, we find that either the data published by the EIA or the FERC Form 1 data filed with the Commission would be publicly available data by which we could calculate a bill credit rate. We agree with KU-ODP that, because the FERC Form 1 is more timely and provides data by jurisdiction, and because both Dominion and KU-ODP submit Virginia-specific FERC Form 1 information to the Commission each March, using the FERC Form 1 data to calculate the bill credit rate is preferable.⁹ Using this data, we will set the initial bill credit rate for the multifamily shared solar program to 11.765 cents per kilowatt-hour ("¢/kWh") for Dominion and 11.328 ¢/kWh for KU-ODP.¹⁰

Consumer Disclosure Form

Code § 56-585.1:12 E provides implementation details for the multi-family shared solar program, and requires that the program "[r]easonably allow for the transferability and portability of subscriptions, including allowing a subscriber to retain a subscription in a shared solar facility if the subscriber moves within the same utility territory."¹¹ The Code also requires that the Commission "[a]dopt standardized consumer disclosure forms."¹²

The stakeholder group established in Case No. PUR-2020-00125 discussed standardized disclosure forms for both the shared solar program established by Code § 56-594.3 and the multi-family shared solar program established by Code § 56-585.1:12. In the Low Income Stakeholder Working Group Report on the Virginia Shared Solar and Multi-Family Shared Solar Programs (2020-2021) ("Working Group Report") filed as part of the Commission Staff Update on April 22, 2021, in Case No. PUR-2020-00125, the Working Group Report stated that the stakeholder group largely agreed as to the language for the consumer disclosure form, but that "[i]t is unclear whether the transferred subscription must 1) remain associated with the original subscriber and not involve a new customer; and/or 2) whether the 'new address' must also be in a multifamily residence."¹³ The Commission finds that the plain language of the statute requires that a customer seeking to transfer a multi-family shared solar subscription to a new residence must be relocating to a new multi-family residence within the service territory of the same utility. Any transfer of a subscription to a new customer would only be permitted if the new customer meets the applicable requirements established by the utility.

Pursuant to Code § 56-585.1:12 E 6, we will adopt the consumer disclosure form provided in the Working Group Report, which is attached to this Order Adopting Rules.

Accordingly, IT IS ORDERED THAT:

- (1) The initial multi-family shared solar bill credit rate for Dominion shall be 11.765 ¢/kWh.
- (2) The initial bill credit rate for KU-ODP shall be 11.328 ¢/kWh.
- (3) On or before September 1, 2021, Dominion and KU-ODP shall file with the Clerk of the Commission, in this docket, one (1) original document containing any revised tariff provisions necessary to implement the regulations adopted in this proceeding, including the initial bill credit rate adopted herein, and shall also file a copy of the document containing the revised tariff provisions with the Commission's Division of Public Utility Regulation. The Clerk of the Commission need not distribute copies but shall make such filings available for public inspection in the Clerk's Office and post them on the Commission's website at: scc.virginia.gov/pages/Case-Information.

(4) The Standard Consumer Disclosure Form attached hereto as Attachment A is adopted.

(5) This case is continued.

A COPY hereof shall be sent electronically by the Clerk of the Commission to all persons on the official Service List in this matter. The Service List is available from the Clerk of the Commission.

¹Order Adopting Rules at 7-8. Case No. PUR-2020-00125 addresses regulations for the non-multi-family shared solar program being developed pursuant to Code § 56-594.3. See, Commonwealth of Virginia, ex rel: State Corporation Commission, Ex Parte: In the matter of establishing regulations for a shared solar program pursuant to § 56-594.3 of the Code of Virginia, Case No. PUR-2020-00125, Doc. Con. Ctr. No. 201230214, Order Adopting Rules (Dec. 23, 2020).

²Order Adopting Rules at 9.

³See 20 VAC 5-342-10 et seq.

⁴See 20 VAC 5-340-10 et seq.

⁵Dominion Response at 3.

⁶KU-ODP Response at 3.

⁷Id. KU-ODP asserted that as part of the FERC Form 1 filing, KU-ODP could "provide jurisdictionalized revenues and sales data by rate class and a calculation of the applicable bill credit rate for the multi-family shared solar program." Id.

⁸CCSA-CHESSA Reply at 4-6.

⁹In addition, use of FERC Form 1 data would obviate the need to remove taxes from the data before calculating the bill credit rate, as Dominion argues would be necessary if the EIA data were used.

¹⁰As the multi-family shared solar program is open only to residential customers, we will not establish a bill credit rate for non-residential rate classes. Dominion's FERC Form 1 for Virginia customers reports residential sales of 29,714,750,000 kWh and residential revenues of \$3,495,913,849. KU-ODP's FERC Form 1 for Virginia customers reports residential sales of 338,170,246 kWh and residential revenues of \$38,306,897.

¹¹Code § 56-585.1:12 E 4.

¹²Code § 56-585.1:12 E 6.

¹³Commission Staff Update, Doc. Con. Ctr. No. 210430117 at 9, filed in Case No. PUR-2020-00125. See supra n.1. We direct the Commission Staff to file a copy of the April 22, 2021 Commission Staff Update in Case No. PUR-2020-00124, and to file any future working group reports or updates in both Case Nos. PUR-2020-00124 and PUR-2020-00125.

STATE WATER CONTROL BOARD

Proposed Enforcement Action for BleachTech LLC

The State Water Control Board proposes to issue a consent special order to BleachTech LLC for alleged violation of the State Water Control Law at 2020 Bessemer Road, Petersburg, Virginia. A description of the proposed action is available at the Department of Environmental Quality office listed or online at www.deq.virginia.gov. The staff contact will accept comments by email or postal mail from August 2, 2021, to September 1, 2021.

General Notices

Contact Information: Jeff Reynolds, Department of Environmental Quality, Piedmont Regional Office (Enforcement), 4949-A Cox Road, Glen Allen, VA 23060, or email jefferson.reynolds@deq.virginia.gov.

Proposed Consent Order for Huguenot Woods LLC

An enforcement action has been proposed for Huguenot Woods LLC for Canterbury Farms Subdivision located at the intersection of Huguenot Trail and Manakintown Ferry Road, Powhatan, Virginia. The board proposes to issue a consent order to address noncompliance with State Water Control Law and regulations. A description of the proposed action is available at the Department of Environmental Quality office listed or a copy can be obtained upon request. Frank Lupini will accept requests and comments by email at frank.lupini@deq.virginia.gov or postal mail at Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, from August 2, 2021, to September 2, 2021.

Public Comment Period and Public Meeting - Polychlorinated Biphenyls (PCB) Water Quality Study for Lewis Creek

Description of technical advisory committee and public meetings: The Virginia Department of Environmental Quality (DEQ) will host the 3rd Technical Advisory Committee Meeting and final public meeting for the Lewis Creek polychlorinated biphenyls (PCB) total maximum daily load (TMDL) Project on Wednesday, August 18, 2021. The technical advisory committee (TAC) meeting will be held from 5:30 p.m. until 6 p.m. at the Montgomery Hall Park Rotary Pavilion, 1000 Montgomery Hall Avenue, Staunton, VA 24401. The final public meeting will be held from 6 p.m. until 7:30 p.m. at the same location. There is limited seating available at the pavilion, so it is suggested that attendees bring a chair to the meeting. In the case of inclement weather, both meetings will be held at the same time and location on Wednesday, September 1, 2021. TAC consists of representatives from local governments, local landowners, and conservation groups in the watershed. TAC meetings are open to the public, and interested citizens are welcome to observe and ask questions at the meeting. All are welcome at the public meeting.

Purpose of notice: DEQ and its contractors will discuss the results of the PCBs water quality study known as a TMDL for Lewis Creek. The additional TAC discussion prior to the public meeting will focus on the draft report that has been completed for the study. The TMDL draft document will also be presented and discussed at the public meeting. The draft report will be posted on the DEQ PCB TMDL webpage at <https://www.deq.virginia.gov/water/water-quality/tmdl-development/tmdls-under-development/pcb-tmdls> prior to the public meeting. A 30-day public comment period will follow the meeting and expire on September 17, 2021.

Description of study: A portion of Lewis Creek, located in Augusta County and the city of Staunton, is listed as impaired for PCBs based on a Virginia Department of Health fish consumption advisory and violations of Virginia's Water Quality Standards. The PCB impairment begins approximately 0.65 miles upstream of the Route 262 bridge crossing and extends 12.53 miles downstream to Lewis Creek's confluence with Middle River. A TMDL has been completed for the Lewis Creek watershed in order to address all sources contributing to the impaired segment. A TMDL is the total amount of a pollutant a water body can contain and still meet water quality standards. Virginia agencies have worked cooperatively with local partners to identify sources of PCBs in Lewis Creek, and to recommend reductions needed from these sources to meet the TMDL. The results of the TMDL study for Lewis Creek will be presented at the public meeting and the draft report will be reviewed at the technical advisory committee meeting.

How to comment and participate: The meetings of the TMDL process are open to the public and all interested parties are welcome. A technical advisory committee was formed to assist in the development of this TMDL. Written comments will be accepted through September 17, 2021, and should include the name, address, and telephone number of the person submitting the comments. For more information or to submit comments, please contact Mark Richards, Department of Environmental Quality, Office of Watershed Programs, telephone (804) 698-4392, email mark.richards@deq.virginia.gov, or Nesha McRae, Department of Environmental Quality, Valley Regional Office, telephone (540) 574-7850, email nesha.mcrae@deq.virginia.gov. To submit comments via postal mail, please use the address provided.

Contact Information: Mark Richards, Office of Watershed Programs, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4392, FAX (804) 698-4178, or email mark.richards@deq.virginia.gov.

Proposed Enforcement Action for Middle Mile Infrastructure LLC

An enforcement action has been proposed for Middle Mile Infrastructure LLC for violations of the State Water Control Law at in-line amplifier sites along the MMI Atlantic Coast Long Haul Fiber Optic Installation Project in Campbell County, Carroll County, Fauquier County, Floyd County, Franklin County, Giles County, Madison County, and Nelson County, Virginia. A description of the proposed action is available at the office listed or online at <https://www.deq.virginia.gov/permits-regulations/public-notices/enforcement-orders>. Comments will be accepted by the contact person from August 2, 2021, through September 1, 2021.

Contact Information: Kristen Sadtler, Enforcement Manager, Department of Environmental Quality, 1111 East Main Street,

Richmond, VA 23219, telephone (804) 698-4149, FAX 804-698-4178, or email kristen.sadtler@deq.virginia.gov.

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, Pocahontas Building, 900 East Main Street, 8th Floor, Richmond, VA 23219; *Telephone:* (804) 698-1810; *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 <https://commonwealthcalendar.virginia.gov>.

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/cumulatab.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.

ERRATA

VIRGINIA RACING COMMISSION

Title of Regulation: **11VAC10-100. Horses.**

Publication: 37:24 VA.R. 3643 July 19, 2021.

Correction to Final Regulation:

Page 3643, after "Title of Regulation: **11VAC10-100. Horses (amending 11VAC10-100-30).**" on the next line, insert "Statutory Authority: § 59.1-369 of the Code of Virginia."

VA.R. Doc. No. R21-6797; Filed July 14, 2021

COMMON INTEREST COMMUNITY BOARD

Title of Regulation: **18VAC48-60. Common Interest Community Board Management Information Fund Regulations.**

Publication: 37:24 VA.R. 3722-3724 July 19, 2021.

Correction to Final Regulation:

Page 3724, 18VAC48-60-60, table column 1, row 7, replace "5001%2B" with "5001+"

VA.R. Doc. No. R19-5532; Filed July 19, 2021, 9:24 a.m.