SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

February 11, 2021

( ) ACTION/DECISION
(X) INFORMATION

I. TITLE: Healthcare Quality Administrative and Consent Orders.

II. SUBJECT: Healthcare Quality Administrative Orders and Consent Orders for the period of December 1, 2020 through December 31, 2020.

III. FACTS: For the period of December 1, 2020 through December 31, 2020, Healthcare Quality reports two (2) Consent Orders totaling $6,000 in assessed monetary penalties and eighty-three (83) Notices of Violation and Civil Penalty totaling $25,650 in assessed monetary penalties. No Administrative Orders were executed during the reporting period.

Name of Bureau	Facility, Service, Provider, or Equipment Type	Notices of Violation and Civil Penalty	Administrative Orders	Consent Orders	Assessed Penalties
Bureau of Facilities Oversight	Community Residential Care Facility	68	0	2	$27,700
	Nursing Home	15	0	0	$3,950
TOTAL		**83**	**0**	**2**	**$31,650**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

HEALTHCARE QUALITY ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

February 11, 2021

Bureau of Facilities Oversight

1. Facilities in Violation of Public Health Order No. COVID-19-5

Violations: The Department found that the sixty-eight (68) community residential care facilities (CRCFs) and fifteen (15) nursing homes listed below failed to submit a weekly visitation report to the Department by the mandatory deadline. Failure to submit the report by the deadline is in violation of the Department's October 7, 2020, Public Health Order that requires all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report on their visitation status.

Enforcement Action: In December 2020, the Department issued Notices of Violation and Civil Penalty against sixty-eight (68) community residential care facilities (CRCFs) and fifteen (15) nursing homes. All of the facilities listed below were required to pay the full amount of their accumulated penalties within twenty (20) days of the dated notices.

Facility Name	Facility Type	Civil Penalty	Payment Received
A'lelia Residential Care	CRCF	$350	No
Ashley Gardens Alzheimer's Special Care Center	CRCF	$250	Yes
Ashley River Plantation	CRCF	$250	No
Atria Mount Pleasant	CRCF	$250	Yes
Black Drive's Community Residence	CRCF	$250	Yes
Bloom at Hilton Head	CRCF	$250	Yes
Briana's Residential Care Facility	CRCF	$250	Yes
Bridge Assisted Living at Life Care Center of Charleston	CRCF	$250	Yes
Brookdale Ebenezer Road	CRCF	$250	Yes
Brookwood Community Residence	CRCF	$250	Yes
Cantrell's Residential Care Facility	CRCF	$350	Yes
Carlisle Place	CRCF	$250	No
Carolina Gardens at Harbison	CRCF	$250	No
Carolina Gardens at Rock Hill	CRCF	$350	Yes
Carson's Community Care	CRCF	$250	Yes
Carter-May Home	CRCF	$250	Yes
Casual Community Care Home	CRCF	$450	No
Charles M Ingram Sr Community Residence	CRCF	$250	Yes
Chesterfield Community Residence	CRCF	$250	Yes
Dominion Senior Living at Patrick Square	CRCF	$250	Yes
Easley Place North-A Continuum of Care Community	CRCF	$350	Yes
Easley Place-A Continuum of Care Community	CRCF	$350	No
Evelyn's Residential Care Facility	CRCF	$250	Yes

Faith Hope and Charity Retirement	CRCF	$350	Yes
Flanagan Community Care Home	CRCF	$450	No
Flora's Residential Care Facility II	CRCF	$250	Yes
Generations of Monetta	CRCF	$250	Yes
Hampton Street Community Residence	CRCF	$350	Yes
Harmony House Residential Care	CRCF	$350	No
Helms-Gordon Residential Care Home	CRCF	$1,000	No
Herriott's Residential Care Facility	CRCF	$250	Yes
Hills of Cumberland Village	CRCF	$250	Yes
Ida Lane I	CRCF	$250	Yes
Ida Lane II	CRCF	$250	Yes
Maples of Honea Path	CRCF	$250	Yes
Merrill Gardens at Carolina Park	CRCF	$250	Yes
Midway Residential Care Facility #1	CRCF	$350	No
Midway Residential Care Facility #1A	CRCF	$350	No
Midway Residential Care Facility #2	CRCF	$350	No
Midway Residential Care Facility #3	CRCF	$350	No
Midway Residential Care Facility #4	CRCF	$350	No
Midway Residential Care Facility #5	CRCF	$350	No
Oakridge Community Care Home #2	CRCF	$350	Yes
Pacifica Senior Living Skylyn	CRCF	$250	Yes
Pageland Care Facility	CRCF	$250	Yes
Palmettos of Garden City	CRCF	$250	Yes
Park Circle Home I	CRCF	$250	Yes
Park Circle Home II	CRCF	$450	Yes
Renaissance	CRCF	$250	No
Residences at Park Place	CRCF	$250	Yes
Resting Place #1	CRCF	$350	Yes
Riley's Residential Care Home	CRCF	$250	Yes
Sherman Residential Care	CRCF	$350	Yes
Somerby of Mount Pleasant	CRCF	$250	No
Sunny Pines Boarding Home	CRCF	$250	Yes
Varnville Community Residence	CRCF	$350	Yes
Village Community Care Home-Unit A	CRCF	$350	Yes
Village Community Care Home-Unit B	CRCF	$350	Yes
Village Community Care Home-Unit C	CRCF	$350	Yes
Village Community Care Home-Unit D	CRCF	$350	Yes
Village Inn Community Care Home	CRCF	$350	No
Wellmore of Tega Cay	CRCF	$250	Yes
Wesley Court Assisted Living Community	CRCF	$450	Yes
Westside Residential Home	CRCF	$250	Yes
Wildewood Downs Assisted Living Community	CRCF	$800	Yes
Wright's Residential Care #2 A & B	CRCF	$350	Yes
Wright's Residential Care Facility 1	CRCF	$350	Yes

Zeigler Street Community Residence	CRCF	$350	Yes
Grand Strand Rehab and Nursing Center	Nursing Home	$250	Yes
Life Care Center of Columbia	Nursing Home	$250	No
Lodge at Wellmore	Nursing Home	$250	Yes
Magnolia Manor-Inman	Nursing Home	$250	Yes
Magnolia Manor - Spartanburg	Nursing Home	$250	No
Martha Franks Baptist Retirement Community	Nursing Home	$250	Yes
Morrell Nursing Center	Nursing Home	$250	Yes
Presbyterian Communities of South Carolina-Foothills	Nursing Home	$250	No
PruittHealth-Rock Hill	Nursing Home	$250	No
PruittHealth-North Augusta	Nursing Home	$250	Yes
Simpsonville Rehabilitation and Healthcare Center	Nursing Home	$250	Yes
Skylyn Nursing and Rehabilitation Center	Nursing Home	$250	Yes
White Oak Manor Spartanburg	Nursing Home	$350	Yes
White Oak of Rock Hill	Nursing Home	$250	Yes
Woodruff Manor	Nursing Home	$350	Yes

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Community Residential Care Facility	493	22,150

2. Carriage House Senior Living of Florence – Florence, SC

Inspections and Investigations: The Department conducted an infection control focused inspection in September 2020 and found the facility to have numerous regulatory violations.

Violations: The Department found the facility failed to comply with Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, as well as multiple Centers for Disease Control and Prevention's (CDC) COVID-19 guidelines, in hygiene and preventing the spread of an infectious virus. These violations include, and are not limited, to: Insufficient and improper use of PPE by staff, improper disposal of hazardous substances, no signs regarding infection control prevention in common areas, and a lack of social distancing between staff and residents.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of five thousand dollars ($5,000) against the facility. The facility was required to pay the full amount of the penalty within thirty (30) days of executing the Consent Order.

Remedial Action: The facility has made the required payment.

Prior Enforcement Actions: None in the past five years.

3. Bowles Community Care Home – McClellanville, SC

Inspections and Investigations: The Department notified the facility on several occasions beginning in July 2020 that the facility was required to submit a license renewal application and the license renewal fee in order to renew their license. The Department found that the facility repeatedly violated regulatory requirements by letting their license expire.

Violations: The Department found the facility failed to comply with Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, by continuously failing to submit the renewal application and fees within the specified timeframe. The facility repeatedly failed to timely submit a renewal application and pay the required fees.

Enforcement Action: The parties agreed to resolve the matter with a consent order after the Department notified the facility that their license was expired and no longer valid. In December 2020, the parties executed a consent order imposing a civil monetary penalty of one thousand dollars ($1,000) against the facility. The facility was required to pay the full amount of the penalty within thirty (30) days of executing the Consent Order. The Department will reissue the facility's renewal license upon receipt of the full monetary penalty.

Remedial Action: The facility has made the required payment. The Department has reissued the facility's license.

Prior Enforcement Actions: None in the past five years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
February 11, 2021

_____ACTION/DECISION

__X__INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.

2. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period December 1, 2020, through December 31, 2020.

3. **FACTS:** For the reporting period of December 1, 2020, through December 31, 2020, the Office of Environmental Affairs issued twenty-three (23) Consent Orders with total assessed civil penalties in the amount of one hundred seventy-one thousand, one hundred fifty-six dollars and nine cents ($171,156.09). Also, eight (8) Administrative Orders with total assessed civil penalties in the amount of sixty-one thousand, nine hundred nineteen dollars ($61,919.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	4	$61,919.00	1	$2,000.00
Aboveground Tanks	0	0	0	0
Solid Waste	0	0	0	0
Hazardous Waste	0	0	1	$6,800.00
Infectious Waste	0	0	0	0
Mining	0	0	0	0
SUBTOTAL	**4**	**$61,919.00**	**2**	**$8,800.00**
Water				
Recreational Water	0	0	6	$4,320.00
Drinking Water	0	0	3	$1,900.00
Water Pollution	0	0	6	$7,736.09
Dam Safety	0	0	0	0
SUBTOTAL	**0**	**0**	**15**	**$13,956.09**
Air Quality				
SUBTOTAL	**0**	**0**	**3**	**$146,600.00**
Environmental Health Services				
Food Safety	0	0	1	$800.00
Onsite Wastewater	4	0	2	$1,000.00
SUBTOTAL	**4**	**0**	**3**	**$1,800.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**8**	**$61,919.00**	**23**	**$171,156.09**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
February 11, 2021

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 19-0155-UST
Order Date: December 8, 2020
Individual/Entity: **Quick Pantry of Orangeburg, LLC**
Facility: Quick Pantry 2
Location: 8640 Old State Road
Holly Hill, SC 29059
Mailing Address: 2182 Magnolia Street
Orangeburg, SC 291158
County: Orangeburg
Previous Orders: None
Permit/ID Number: 13185
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.40(a) and 280.43(d) (2012 and Supp. 2019).

Summary: Quick Pantry of Orangeburg, LLC (Individual/Entity) is the owner of underground storage tanks (USTs) located in Orangeburg County, South Carolina. The Department conducted an inspection on April 22, 2019. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide an adequate release detection method and failed to conduct automatic tank gauging properly.

Action: The Individual/Entity is required to: submit either current, passing automatic tank gauge records for the 8,000-gallon regular and 6,000-gallon diesel USTs or proof that the 8,000-gallon regular and 6,000-gallon diesel USTs have an adequate release detection method in place by February 13, 2021. The Department has assessed a total civil penalty in the amount of four thousand, six hundred fifteen dollars ($4,615.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, six hundred fifteen dollars **($4,615.00)** by February 12, 2021.

Updates: None.

2) Order Type and Number: Administrative Order 20-0202-UST
Order Date: December 8, 2020
Individual/Entity: **Estate of Albert Rollings, Sr.**
Facility: City Service
Location: 204 South Main Street
Jefferson, SC 29718

Mailing Address: P.O. Box 485
Jefferson, SC 29718
County: Chesterfield
Previous Orders: None
Permit/ID Number: 02300
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.70(c), 280.93(a), and 280.110(c) (2012 and Supp. 2019).

Summary: Estate of Albert Rollings, Sr. (Individual/Entity) is the owner of underground storage tanks (USTs) located in Chesterfield County, South Carolina. The Department conducted file reviews on September 30, 2019, and August 10, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to permanently close a UST system that has been temporarily out of service for greater than twelve (12) months and does not meet current corrosion protection standards; failed to demonstrate financial responsibility for an UST system; failed to submit evidence of financial assurance to the Department upon request; and failed to pay annual UST registration fees.

Action: The Individual/Entity is required to: pay outstanding annual tank registration fees and associated late fees for fiscal years 2016, 2017, 2018, 2019, 2020, and 2021 in the amount of six thousand, two hundred ninety-two dollars ($6,292.00); submit a completed Certificate of Financial Responsibility and provide evidence of financial assurance; submit a completed Tank and Sludge Disposal form by February 14, 2021; within forty-five (45) days of this submission, submit proof the USTs have been permanently closed; and submit a UST Closure and Assessment Report sixty (60) days after permanently closing the USTs. The Department has assessed a total civil penalty in the amount of seventeen thousand, two hundred fifty dollars ($17,250.00). The Individual/Entity shall pay a civil penalty in the amount of seventeen thousand, two hundred fifty dollars **($17,250.00)** by February 12, 2021.

Updates: None.

3) Order Type and Number: Administrative Order 20-0207-UST
Order Date: December 8, 2020
Individual/Entity: **Donald Kenneth Graham**
Facility: Sam's Grocery & Grill
Location: 1969 South Highway 501
Marion, SC 29571
Mailing Address: 546 Shannon Road
Marion, SC 29571
County: Marion
Previous Orders: None
Permit/ID Number: 06208
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.70(c), 280.93(a), and 280.110(c) (2012 and Supp. 2019).

Summary: Donald Kenneth Graham (Individual/Entity) is the owner of underground storage tanks (USTs) located in Marion County, South Carolina. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to permanently close a UST system that has been temporarily out of service for greater than twelve (12) months and does not meet current corrosion protection standards; failed to demonstrate financial responsibility for an UST system; failed to submit evidence of financial assurance to the Department upon request; and failed to pay annual UST registration fees.

Action: The Individual/Entity is required to: pay outstanding annual tank registration fees and associated late fees for fiscal years 2016, 2018, 2019, 2020, and 2021 in the amount of six thousand, thirty-eight dollars ($6,038.00); submit a completed Certificate of Financial Responsibility and evidence of financial assurance; submit a completed Tank and Sludge Disposal form by February 5, 2021, and within forty-five (45) days of this submission, proof that the USTs have been permanently closed; and submit a UST Closure and Assessment Report sixty (60) days after permanently closing the USTs. The Department has assessed a total civil penalty in the amount of twenty-three thousand, five hundred and fifty-four dollars ($23,554.00). The Individual/Entity shall pay a civil penalty in the amount of twenty-three thousand, five hundred fifty-four dollars **($23,554.00)** by February 5, 2021.

Updates: None.

4) Order Type and Number: Administrative Order 19-0113-UST
Order Date: December 15, 2020
Individual/Entity: **Sunshine Foods**
Facility: Sunshine Food Store 2
Location: 1266 Remount Road
North Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 01354
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.30(a), 280.31(a), 280.34(c), 280.40(a), 280.40(a)(2), 280.41(b)(1)(i)(B), 280.44(a), 280.50, 280.93(a), and 280.110(c) (2012 and Supp. 2019).

Summary: Sunshine Foods (Individual/Entity) is the owner of underground storage tanks (USTs) located in Charleston County, South Carolina. The Department conducted both an inspection and file review in March 2019. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to ensure releases due to spilling or overfilling do not occur; failed to maintain and operate corrosion protection equipment continuously; failed to provide records to the Department upon request; failed to provide an adequate release detection method for a UST system; failed to properly install, calibrate, operate, and maintain release detection equipment; failed to conduct an annual line tightness test on pressurized lines of a UST system; failed to conduct an annual test of automatic line leak detectors; failed to report a

suspected release within twenty-four (24) hours; failed to demonstrate financial responsibility for an UST system; failed to submit evidence of financial assurance to the Department upon request; and failed to pay annual UST registration fees.

Action: The Individual/Entity is required to: submit either the most recent twelve (12) months of automatic tank gauge records for all USTs or tank tightness test results for all USTs; submit line tightness test results for both the 12,000-gallon regular and 8,000-gallon regular non-ethanol USTs; submit line leak detector function check results for all USTs; submit proof that unprotected metal components in all UST dispenser sumps are isolated from soil and/or water and proof that nay removed soil and/or water has been disposed of properly; submit hydrostatic test results for all spill buckets; pay outstanding annual tank registration fees and associated late fees for fiscal year 2020 in the amount of two thousand, four hundred twenty dollars ($2,420.00); and submit a completed Certificate of Financial Responsibility and evidence of financial assurance by February19, 2021. The Department has assessed a total civil penalty in the amount of sixteen thousand, five hundred dollars ($16,500.00). The Individual/Entity shall pay a civil penalty in the amount of sixteen thousand, five hundred dollars **($16,500.00)** by February 19, 2021.

Updates: None.

5)

Order Type and Number:	Consent Order 20-0243-UST
Order Date:	December 8, 2020
Individual/Entity:	**Samer Express, LLC**
Facility:	Glenn Road Convenience Store
Location:	295 Glenn Road West Columbia, SC 29172
Mailing Address:	Same
County:	Lexington
Previous Orders:	20-0046-UST ($1,000.00)
Permit/ID Number:	19853
Violations Cited:	The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.20(c)(1)(ii) (2012 & Supp 2019).

Summary: Samer Express, LLC (Individual/Entity) owns and operates underground storage tanks in Lexington County, South Carolina. An inspection and Notice of Violation was issued on October 12, 2020. the Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of two thousand dollars **($2,000.00)** by January 22, 2021.

Updates: The Individual/Entity has paid the civil penalty.

Hazardous Waste Enforcement

6) Order Type and Number: Consent Order 20-14-HW

Order Date:	December 30, 2020
Individual/Entity:	**Schaeffler Group USA, Inc.**
Facility:	Schaeffler Group USA, Inc.
Location:	301 Hwy 1 South Cheraw, SC 29520
Mailing Address:	Same
County:	Chesterfield
Previous Orders:	None
Permit/ID Number:	SCD 049 128 598
Violations Cited:	The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2019).

Summary: Schaeffler Group USA, Inc. (Individual/Entity) is a manufacturing facility located in Chesterfield County, South Carolina. The Department conducted an inspection on August 19, 2020. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to mark or label its containers with an indication of the hazards of the contents; failed to contact the transporter and or the owner or operator of the designated facility to determine the status of the hazardous waste; failed to submit an Exception Report to the Agency when it did not receive a copy of the manifest with the handwritten signature from the designated facility; failed to describe in the Contingency Plan the actions facility personnel would take during an emergency; failed to include in the Contingency Plan a list of all emergency equipment at the facility and its location along with a brief outline of its capabilities; failed to submit a copy of the contingency plan and all revisions to all local emergency responders; failed to submit a quick reference guide of the contingency plan to the local emergency responders; failed to maintain universal waste batteries and universal waste lamps in a manner to prevent a release and to keep such containers closed; failed to immediately clean up broken pieces of universal waste lamps; failed to clearly label or mark universal waste batteries or a container of batteries with one of the following phrases: "Universal Waste – Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies)"; and failed to clearly label or mark universal waste lamps or a container of lamps with one with one of the following phrases: "Universal Waste- Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)."

Action: The Individual/Entity is required to: submit an updated Contingency Plan for the facility by January 29, 2021. The Department assessed a total civil penalty in the amount of six thousand eight hundred dollars ($6,800.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand eight hundred dollars **($6,800.00)** by January 29, 2021.

Updates: None.

BUREAU OF WATER

Recreational Waters Enforcement

7) Order Type and Number: Consent Order 20-136-RW
Order Date: December 11, 2020
Individual/Entity: **City of Darlington**
Facility: Darlington City Pool
Location: 101 Gary Street
Darlington, SC 29532
Mailing Address: P.O. Box 57
Darlington, SC 29540
County: Darlington
Previous Orders: None
Permit/ID Number: 16-014-2
Violations Cited: S.C. Code Ann. Regs. 61-51.J.22

Summary: The City of Darlington (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Darlington County, South Carolina. The Department issued a Notice of Alleged Violation on November 12, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove a kiddie pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: submit to the Department for review and approval, a plan detailing the procedure and materials to be used to properly fill in or remove the kiddie pool within fifteen days of execution date of the Order; and, complete the procedure in accordance with the plan and contact the Department to schedule an inspection to verify the completed work within ninety days of the Department's approval of the plan. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four hundred dollars **($400.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity submitted a plan to fill in the kiddie pool and the plan was approved on January 4, 2021.

8) Order Type and Number: Consent Order 20-137-RW
Order Date: December 17, 2020
Individual/Entity: **Beach Club at Montego Inn Homeowners Association, Inc.**
Facility: Montego Inn Beach Club
Location: 1307 South Ocean Boulevard
Myrtle Beach, SC
Mailing Address: Same
County: Horry
Previous Orders: 18-147-RW ($680.00)
Permit/ID Number: 26-H76-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Beach Club at Montego Inn Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 9, 2020, and July 16, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the drinking water fountain was not operating properly; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring rope was broken; the emergency notification device was not operational; and, the bound and numbered log book was not available for Department review during the first inspection and was not maintained on a daily basis during the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

Updates: The Individual/Entity has paid the civil penalty. This Order has been closed.

9)

Order Type and Number:	Consent Order 20-138-RW
Order Date:	December 17, 2020
Individual/Entity:	**Blue Atlantic Columbia, LLC**
Facility:	The Station at Five Points
Location:	2025 Gervais Street Columbia, SC 29201
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1160B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Blue Atlantic Columbia, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 10, 2020, and July 13, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool floor, walls, deck, and waterline tiles were not clean; there was algae on the pool floor; there was standing water on the pool deck; the pool furniture was not at least four feet from the edge of the pool; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the life ring rope was deteriorated; there were no "Shallow Water – No Diving Allowed" signs posted; the current pool operator of record information was not posted to public; and, the bound and numbered log book was not maintained at least three times per week by the current pool operator of record and was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Updates: The Individual/Entity has paid the civil penalty. This Order has been closed.

10) Order Type and Number: Consent Order 20-139-RW
Order Date: December 17, 2020
Individual/Entity: **Kilnsea Village Apartments, LLC**
Facility: Kilnsea Village Apartments
Location: 9690 Dorchester Road
North Charleston, SC 29405
Mailing Address: 201 North Elm Street
Greensboro, NC 27401
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1212B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Kilnsea Village Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 16, 2020, and July 27, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the drinking water fountain was not operating; the foot rinse shower was not operating; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the pool rules sign did not have all of the required rules; and, the cyanuric acid levels were not recorded in the bound and numbered log book a minimum of once per week.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Updates: The Individual/Entity has paid the civil penalty. This Order has been closed.

11) Order Type and Number: Consent Order 20-142-RW
Order Date: December 21, 2020
Individual/Entity: **Longpoint Property Owners Association, Inc.**
Facility: Long Point
Location: 251 Needlerush Parkway @ Mt Royal
Mount Pleasant, SC 29464
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-406-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Longpoint Property Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 8, 2020, and August 5, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; skimmers were missing weirs; skimmer baskets were floating; the chlorine level was not within the acceptable range of water quality standards; and, the lettering on the "Shallow Water – No Diving Allowed" and the "No Lifeguard On Duty – Swim At Your Own Risk" signs was not the appropriate size.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Updates: The Individual/Entity has paid the civil penalty. This Order has been closed.

12)

Order Type and Number:	Consent Order 20-141-RW
Order Date:	December 22, 2020
Individual/Entity:	**Wahoo Aquatic Club, Inc.**
Facility:	Live to Play
Location:	1513 Mathis Ferry Road Mount Pleasant, SC 29464
Mailing Address:	164 Market Street, Suite 307 Charleston, SC 29401
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1196B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Wahoo Aquatic Club, Inc. (Individual/Entity) manages and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 29, 2020, and July 8, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; there was debris in the skimmer baskets; the shepherd's crook was not properly mounted in its designated location; the emergency notification device was not operational; only one "Shallow Water – No Diving Allowed" sign was posted; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Updates: The Individual/Entity has paid the civil penalty. This Order has been closed.

Drinking Water Enforcement

13) Order Type and Number: Consent Order 20-029-DW
Order Date: December 11, 2020
Individual/Entity: **Ellenburg Campground, LLC**
Facility: Coltsfoot Circle & Tuckaway Lane
Location: 1 Coltsfoot Circle
Sunset, SC 29685
Mailing Address: 435 Riggins Bridge Road
Liberty, SC 29657
County: Pickens
Previous Orders: None
Permit/ID Number: 3970680 & 3970805
Violations Cited: S.C. Code Ann. Regs. 61-58.7 & 61-58.8.B

Summary: Ellenburg Campground, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of two (2) public water systems (PWSs) located in Pickens County, South Carolina. The Department conducted an inspection on September 8, 2020, and the PWSs were rated unsatisfactory for failure to properly operate and maintain, and failure to provide a copy of a complete Emergency Preparedness Plan. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the vents at the wells were not elbowed downward and were not at least eighteen inches above the well house floors; the sample taps at the wells were threaded; there were gaps in the sanitary seals at the wells; there was electrical wiring that was not in conduit; the storage capacity and number of taps was not the originally permitted amount; the system map was not updated; the Emergency Preparedness Plan was not complete; and, the procedures manual was not complete.

Action: The Individual/Entity is required to: replace the vents and sample taps at the wells, seal the gaps in the sanitary seals, and place the electrical wiring in conduit by November 30, 2020; submit to the Department applications to obtain construction permits to address the storage capacity deficiency by February 1, 2021; complete the work in accordance with the construction permits and contact the Department to request inspections and obtain written approvals to operate within thirty days of the date of the issuance of the construction permits; and submit an updated system map, a complete Emergency Preparedness Plan, and a complete procedures manual for the PWSs within thirty days of obtaining the written approvals to operate. The Department has assessed a total civil penalty in the amount of eleven thousand dollars ($11,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, one hundred dollars **($1,100.00)** and pay a stipulated penalty in the amount of nine thousand, nine hundred dollars ($9,900.00) should any requirement of the Order not be met.

Updates: The Individual/Entity has completed all the requirements that were due by November 30, 2020. The Individual/Entity has paid the assessed civil penalty.

14) Order Type and Number: Consent Order 20-030-DW
Order Date: December 17, 2020
Individual/Entity: **Town of Clio**
Facility: Town of Clio
Location: 101 Calhoun Street

	Clio, SC 29525
Mailing Address:	P.O. Box 487
	Clio, SC 29525
County:	Marlboro
Previous Orders:	None
Permit/ID Number:	34WS050
Violations Cited:	S.C. Code Ann. Regs. 61-113.H.2

Summary: The Town of Clio (Individual/Entity) owns and is responsible for obtaining the proper permit for a groundwater withdrawal system located in Marlboro County, South Carolina. On August 14, 2020, a violation was issued as a result of Department review of groundwater withdrawal permitting records. The Individual/Entity has violated the Groundwater Use and Reporting Regulation as follows: failed to submit a completed application to the Department to renew its groundwater withdrawal permit at least ninety days prior to the expiration date.

Action: The Individual/Entity is required to: submit to the Department for review and approval a completed application for the renewal of its groundwater withdrawal permit by January 17, 2021. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Updates: The civil penalty is to be paid in four monthly installments due January 15, 2021, February 15, 2021, March 15, 2021, and April 15, 2021.

15)

Order Type and Number:	Consent Order 20-031-DW
Order Date:	December 17, 2020
Individual/Entity:	**Hewitt Oaks, LLC**
Facility:	Hewitt Oaks
Location:	203 Stillwell Road
	Bluffton, SC 29910
Mailing Address:	Same
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	0770935
Violations Cited:	S.C. Code Ann. Regs. 61-58.17.K(1)(a)

Summary: Hewitt Oaks, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Beaufort County, South Carolina. On October 5, 2020, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level (MCL) for E. coli.

Action: The Individual/Entity is required to: submit an investigative report and a corrective action plan to address the causes of the total coliform present results at the PWS by January 17, 2021. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated** penalty in the amount of four thousand dollars (**$4,000.00**) should any requirement of the Order not be met.

Updates: None

Water Pollution Enforcement

16) Order Type and Number: Consent Order 20-046-W
Order Date: December 3, 2020
Individual/Entity: **City of West Columbia**
Facility: West Columbia Water Treatment Plant
Location: 406 Sunset Boulevard
West Columbia, SC 29169
Mailing Address: P.O. Box 4044
West Columbia, SC 29169
County: Lexington
Previous Orders: None
Permit/ID Number: SCG646005
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), Water Pollution Control Permits, 3 S.C. Code Ann Regs. 61-9.122.21(d) (2011), and NPDES Permit SCG646005

Summary: City of West Columbia (Individual/Entity) owns and is responsible for the proper operation and maintenance of a water treatment plant (WTP) in Lexington County, South Carolina. On August 11, 2020, a Notice of Violation was issued as a result of its failure to reapply for permit coverage within one hundred eighty (180) days prior to the existing NPDES Permit's expiration date. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to submit an application for renewal of the NPDES Permit at least one hundred eighty (180) days before the existing permit expires.

Action: The Individual/Entity is required to continue operating the WTP in accordance with the most recent NPDES permit until a new permit becomes effective. The Department has assessed a total civil penalty in the amount of seven hundred dollars ($700.00). The Individual/Entity shall pay a civil penalty in the amount of seven hundred dollars **($700.00)** by January 2, 2021.

Updates: The Individual/Entity has paid the civil penalty. The Department received an administratively complete application on October 1, 2020.

17) Order Type and Number: Consent Order 20-047-W
Order Date: December 3, 2020
Individual/Entity: **City of Walhalla**
Facility: Walhalla Water Treatment Plant
Location: Old Walhalla Highway and Melton Road
Walhalla, SC 29691
Mailing Address: P.O. Box 1099
Walhalla, SC 29691
County: Oconee

Previous Orders: None
Permit/ID Number: SCG646084
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), Water Pollution Control Permits, 3 S.C. Code Ann Regs. 61-9.122.21(d) (2011), and NPDES Permit SCG646084.

Summary: City of Walhalla (Individual/Entity) owns and is responsible for the proper operation and maintenance of a water treatment plant (WTP) in Oconee County, South Carolina. On August 12, 2020, a Notice of Violation was issued as a result of its failure to reapply for permit coverage within one hundred eighty (180) days prior to the existing NPDES permit's expiration date. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to submit an application for renewal of the NPDES Permit at least one hundred eighty (180) days before the existing permit expires.

Action: The Individual/Entity is required to continue operating the WTP in accordance with the most recent NPDES Permit until a new permit becomes effective and submit an administratively complete application for permit renewal by December 18, 2020. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)** by January 2, 2021.

Updates: The Individual/Entity has paid the civil penalty. The Department also received an administratively complete permit renewal application on December 18, 2020.

18) Order Type and Number: Consent Order 20-048-W
Order Date: December 8, 2020
Individual/Entity: **Town of Lynchburg**
Facility: Lynchburg Water Treatment Plant
Location: Off U.S. 76 East
Lynchburg, SC 29080
Mailing Address: P.O. Box 147
Lynchburg, SC 29080
County: Lee
Previous Orders: None
Permit/ID Number: SCG646035
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), Water Pollution Control Permits, 3 S.C. Code Ann Regs. 61-9.122.21(d) (2011), and NPDES Permit SCG646035

Summary: Town of Lynchburg (Individual/Entity) owns and is responsible for the proper operation and maintenance of a water treatment plant (WTP) in Lee County, South Carolina. On August 19, 2020, a Notice of Violation was issued as a result of its failure to reapply for permit coverage within one hundred eighty (180) days prior to the existing NPDES Permit's expiration date. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to submit an application for renewal for the NPDES permit at least one hundred eighty (180) days before the existing permit expires.

Action: The Individual/Entity is required to continue operating the WTP in accordance with the most recent NPDES Permit until a new permit becomes effective. The

Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)** by January 7, 2021.

Updates: The Individual/Entity has paid the civil penalty. The Department also received an administratively complete permit renewal application on August 12, 2020.

19) Order Type and Number: Consent Order 20-049-W
Order Date: December 17, 2020
Individual/Entity: **SC Dept. of Parks, Recreation, & Tourism**
Facility: SCPRT/Oconee State Park
Location: 624 State Park Road, Mountain Rest Oconee, SC
Mailing Address: 1205 Pendleton Street, Suite 251 Columbia, SC
County: Oconee
Previous Orders: None
Permit/ID Number: SCG570014
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), and Water Pollution Control Permits Regulation, S.C. Code Ann. Regs. 61-9.122.41(a) (2011), and NPDES Permit SCG570014

Summary: The South Carolina Department of Parks, Recreation, & Tourism (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility in Oconee County, South Carolina. On February 12, 2020, the Department issued a Notice of Violation for failure to submit required monitoring reports. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to meet the required frequency of analysis (did not sample) for biochemical oxygen demand (BOD), total suspended solids (TSS), ammonia-nitrogen, total residual chlorine (TRC), E.coli, BOD percent removal, and suspended solids (SS) percent removal for the October 2019 and November 2019 monthly monitoring periods.

Action: The Individual/Entity is required to submit to the Department a Contingency Plan by January 17, 2021, that addresses how sampling will be performed during unforeseen events and must include explanations of corrective actions taken to address the failures to sample. The Department has assessed a total civil penalty in the amount of four thousand one hundred dollars ($4,100.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand one hundred dollars **($4,100.00)** should any requirement of the Order not be met, including any implementation schedule approved by the Department.

Updates: The Individual/Entity submitted a draft Contingency Plan on January 11, 2021. Upon receiving Department comments on the draft, the Individual/Entity submitted an updated Contingency Plan, which is currently under Department review.

20) Order Type and Number: Consent Order 20-050-W
Order Date: December 31, 2020
Individual/Entity: **City of Liberty**

Facility: City of Liberty Sewer Collection System
Location: 206 West Front Street Liberty, SC 29657
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit/ID Number: SSS000852
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and § 48-1-95(D)(1), Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.610.3(a)(b) and (c), and Part III. A of NPDES Permit SC0024465

Summary: The City of Liberty (Individual/Entity) owns and is responsible for a satellite sewer collection system located in Pickens County, South Carolina. On April 16, 2020, the Department issued a Notice of Alleged Violation as a result of the unsatisfactory inspection conducted on March 22, 2019, and the subsequent unsatisfactory inspection responses. The Individual/Entity has violated the Pollution Control Act and the South Carolina Water Pollution Control Permits Regulation, as follows: failed to properly manage, operate and maintain its collection system; failed to provide adequate capacity to convey base flows and peak flows; failed to take all reasonable steps to stop and mitigate the impact of releases or wastewater; and discharged untreated wastewater into the environment not in compliance with the permit.

Action: The Individual/Entity is required to: submit preliminary engineering reports (PERs) for improvements at Pump Station 5, and written procedures for properly reporting sewer system overflows (SSOs) by January 31, 2021; submit preliminary engineering reports for improvements at Pump Stations 1, 2, and 4, and begin conducting a capacity, management, operations and maintenance (cMOM) audit by March 1, 2021; complete construction activities of Pump Station 5 within one hundred eighty (180) days from beginning the construction; and, complete construction activities of Pump Stations 1, 2 and 4 by November 30, 2021. The Department has assessed a total civil penalty in the amount of twelve thousand dollars ($12,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of twelve thousand dollars **($12,000.00)** should any requirement of the Order not be met.

Updates: None.

21) Order Type and Number: Consent Order 20-051-W
Order Date: December 31, 2020
Individual/Entity: **Mr. David Walker**
Facility: Walker Swine Slaughter Facility
Location: Located near the intersection of Highway 178 and Harris Bridge Road in Anderson, SC 29621
Mailing Address: 1011 Walker Circle Anderson, SC 29621
County: Anderson
Previous Orders: None
Permit/ID Number: ND0000396
Violations Cited: South Carolina Standards for the Permitting of Agricultural Animal Facilities, S.C. Code Ann Reg. 61-43.100.90 (2011);

Environmental Protection Fees, S.C. Code Ann. Regs. 61-30.C(2)(a), C(2)(c), C(2)(d), and 61-30.G.1(a)(v)(2)(B)(2011).

Summary: Mr. David Walker (Individual/Entity) owns and is responsible for the proper operation and maintenance of a swine slaughter facility located in Anderson County, South Carolina. On June 14, 2019, the Department issued a Notice of Alleged Violation as a result of an unsatisfactory inspection conducted on May 22, 2019 and for failure to pay past due operating fees. The Individual/Entity has violated the South Carolina Standards for the Permitting of Agricultural Animal Facilities in that it failed to properly operate and maintain the facility within Permit requirements and has not remitted past due annual operating fees.

Action: The Individual/Entity is required to: submit a corrective action plan (CAP) including a schedule of implementation to adequately address the operation and maintenance violations by January 31, 2021; and submit payment of the last three (3) years of past due operating fees by April 1, 2021. The Department has assessed a total civil penalty in the amount of five thousand, thirty-six dollars nine cents ($5,036.09). The Individual/Entity shall pay a civil penalty in the amount of five thousand, thirty-six dollars nine cents **($5,036.09)** by April 1, 2021.

Updates: None

BUREAU OF AIR QUALITY

22)

Order Type and Number:	Consent Order 20-006-A
Order Date:	December 5, 2020
Individual/Entity:	**Haile Gold Mine, Inc.**
Facility:	Haile Gold Mine, Inc.
Location:	6911 Snowy Owl Road Kershaw, SC 29067
Mailing Address:	Same
County:	Kershaw
Previous Orders:	None
Permit/ID Number:	1460-0070
Violations Cited:	EPA regulations at 40 CFR Part 63 and 5 S.C. Code Ann. Regs. 61-62.63 (Supp. 2019), Subpart EEEEEEE – National Emission Standards for Hazardous Air Pollutants: Gold Mine Ore Processing And Production Area Source Category (collectively, "Subpart 7E")

Summary: Haile Gold Mine (Individual/Entity) operates a gold mine located in Kershaw, South Carolina. The Individual/Entity has violated the U.S. EPA Regulations and the South Carolina Air Pollution Control Regulation, as follows: failed to limit mercury emissions to no more than 0.14 pounds of mercury per ton of concentrate processed during Department-approved source tests performed March 2018, December 2018, January 2019, and March 2019; submit source test results to the Department within 60 days following the date of the source test; establish operating limits for the water flow rate and pressure drop for wet scrubbers; submit operating limits to the Department for approval; submit a Subpart 7E Notice of Compliance Status to the Department; obtain a Department-issued construction permit prior to constructing, altering, or adding to a source of air

contaminants; submit a written request to the Department for a new or revised operating permit to cover any new or altered source, postmarked no later than fifteen (15) days after the actual date of initial startup; and submit accurate semi-annual reports to the Department within the prescribed timeframe.

Action: The Individual/Entity is required to: implement all reporting requirements; limit mercury emissions to no more than 0.14 pounds of mercury per ton of concentrate processed; establish required operating limits; utilize an approved method for the control of mercury emissions; obtain a Department-issued construction permit prior to constructing, altering, or adding to a source of air contaminants; implement all applicable source testing requirements, including submitting accurate and timely notification requests and source test reports, in accordance with the requirements of Subpart 7E, state regulatory requirements, and requirements of the Construction Permit; submit a complete operating permit request for the new mercury abatement and control system; and submit a 7E Notice of compliance Status by January 5, 2021**.** The Department has assessed a total civil penalty in the amount of one hundred thousand dollars ($100,000.00). The Individual/Entity shall pay a civil penalty in the amount of one hundred thousand dollars **($100,000.00)** by January 8, 2020**.**

Updates: On January 2, 2020, the Department issued Construction Permit 1460-0070-CB to the Individual/Entity for the mercury abatement system. On February 11-13, 2020, the Individual/Entity demonstrated compliance with its 0.14 lb/ton concentrate limit for mercury emissions during a Department-approved source test. The source test report was submitted to the Department in a timely manner. The NOCS was submitted to the Department on November 2, 2020 and the civil penalty was paid January 8, 2021.

23)

Order Type and Number:	Consent Order 20-007-A
Order Date:	December 30, 2020
Individual/Entity:	**Giant Cement Company**
Facility:	Giant Cement Company
Location:	654 Judge Street Harleyville, South Carolina 29448
Mailing Address:	Same
County:	Dorchester
Previous Orders:	18-041-A ($10,000.00)
Permit/ID Number:	0900-0002
Violations Cited:	40 CFR 63.1209(k)(1) and (n)(1) and S.C. Code Ann. Regs. 61-62.63.1209(k)(1) and (n)(1), 40 CFR 63.1206(b)(13)(i)(A)(3), S.C. Code Ann. Regs. 61-62.63.1206(b)(13)(i)(A)(3), and S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements

Summary: Giant Cement Company (Individual/Entity), operates a Portland cement manufacturing plant located in Dorchester County, South Carolina. The Individual/Entity has violated the U.S. EPA regulations and the South Carolina Air Pollution Control Regulation, as follows: failed to comply with the established gas inlet temperature operating limit for the main baghouse and the bypass baghouse during the reporting periods of January 1, 2018 through June 30, 2018, July 1, 2018 through December 31, 2018, January 1, 2019 through June 30, 2019, July 1 through December 31, 2019, and January 1 to June 30, 2020; and, failed to comply with the established THC concentration operating limit for the bypass gas and calciner first stage exit gas during the reporting periods of July

1, 2018 through December 31, 2018, July 1 through December 31, 2019, and January 1 to June 30, 2020.

Action: The Individual/Entity is required to: maintain compliance with all applicable requirements of Subpart EEE; submit to the Department, for approval, a corrective action plan for continuous compliance by March 2, 2021. The Department has assessed a total civil penalty in the amount of forty-one thousand six hundred dollars ($41,600.00). The Individual/Entity shall pay a civil penalty in the amount of forty-one thousand six hundred dollars **($41,600.00)** by February 12, 2021.

Updates: None.

24) Order Type and Number: Consent Order 20-008-A
Order Date: December 30, 2020
Individual/Entity: **Tidewater Boats LLC**
Facility: Tidewater Boats LLC
Location: 142 Brickyard Rd
Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 1560-0273
Violations Cited: 40 CFR 70.5(a)(1)(i), S.C. Code Ann. Regs 61-62.70.5(a)(1)(i), and S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements

Summary: Tidewater Boats LLC (Individual/Entity), operates a boat manufacturing facility located in Lexington County, South Carolina. The Individual/Entity has violated U.S. EPA Regulations and the South Carolina Air Pollution Control Regulation, as follows: failed to submit a timely Part 70 (Title V) Permit application within 12 months of startup.

Action: The Individual/Entity is required to: comply with all terms and conditions of Construction Permit 1560-0273, until such time as the Department issues the Title V Permit. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand dollars **($5,000.00)** by January 30, 2020.

Updates: The Individual/Entity has submitted a Title V permit application which is currently under review and the civil penalty has been paid. This Order has been closed.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

25) Order Type and Number: Consent Order 2020-02-021
Order Date: December 1, 2020
Individual/Entity: **Yee-Haw Brewery**

Facility:	Yee-Haw Brewery
Location:	307 East McAbee Avenue, Suite C Greenville, SC 29601
Mailing Address:	7100 B Kingston Pike Knoxville, TN 37919
County:	Greenville
Previous Orders:	None
Permit Number:	23-206-11955
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Yee-Haw Brewery (Individual/Entity) is a restaurant located in Greenville County, South Carolina. The Department conducted inspections on September 4, 2018, June 3, 2019, and March 2, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods; and failed to use effective methods to cool cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Updates: The Individual/Entity has complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

On Site Wastewater Enforcement

26)	Order Type and Number:	Administrative Order 20-118-OSWW
	Order Date:	December 3, 2020
	Individual/Entity:	**Tommy J. Hiott**
	Facility:	Tommy J. Hiott
	Location:	7219 Frost Avenue Columbia, SC 29203
	Mailing Address:	206 Tram Road Columbia, SC 29210
	County:	Richland
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Tommy J. Hiott (Individual/Entity) owns property located in Richland County, South Carolina. The Department conducted an investigation on October 20, 2020, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has complied with all requirements of the Order. This Order has been closed.

27)	Order Type and Number:	Administrative Order 20-119-OSWW
	Order Date:	December 3, 2020
	Individual/Entity:	**Jeffery Biggs and Amanda McCoy**
	Facility:	Jeffery Biggs and Amanda McCoy
	Location:	102 Dogwood Lane Townville, SC 29689
	Mailing Address:	Same as Location
	County:	Anderson
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Jeffery Biggs and Amanda McCoy (Individual/Entity) own property located in Anderson County, South Carolina. The Department conducted an investigation on September 8, 2020, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: On January 25, 2021, the case was referred to OGC to file a complaint with the Administrative Law Court.

28)	Order Type and Number:	Administrative Order 20-121-OSWW
	Order Date:	December 3, 2020
	Individual/Entity:	**Daniel Gorski**
	Facility:	Daniel Gorski
	Location:	580 Old Metal Road Gaffney, SC 29341
	Mailing Address:	562 Old Metal Road

	Gaffney, SC 29341
County:	Cherokee
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Daniel Gorski (Individual/Entity) owns property located in Cherokee County, South Carolina. The Department conducted an investigation on October 19, 2020, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has complied with all requirements of the Order. This Order has been closed.

29)	Order Type and Number:	Administrative Order 20-124-OSWW
	Order Date:	December 30, 2020
	Individual/Entity:	**Rufus Antley**
	Facility:	Rufus Antley
	Location:	Corner of West Church St. and Cathy St. Batesburg-Leesville, SC
	Mailing Address:	1104 Tarrytown Lane West Columbia, SC 29169
	County:	Lexington
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Rufus Antley (Individual/Entity) owns property located in Lexington County, South Carolina. The Department conducted an investigation on December 1, 2020 and observed domestic wastewater pooling and discharging onto the surface of the ground, as well as dwellings on the Site without an approved means of domestic wastewater disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department; and failed to ensure dwellings occupied for more than two (2) hours a day are provided with an approved means of domestic wastewater disposal.

Action: The Individual/Entity is required to immediately vacate the occupied dwellings at the Site and ensure they remain vacated until a permit is issued by the

Department and approved OSWW systems are installed at the Site in accordance with all requirements of S.C. Regulation 61-56. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

30)

Order Type and Number:	Consent Order 20-113-OSWW
Order Date:	December 15, 2020
Individual/Entity:	**David McManus and KW Environmental, LLC**
Facility:	David McManus and KW Environmental, LLC
Location:	104 Berrywood Court Lexington, SC 29072
Mailing Address:	Same
County:	Fairfield and Lexington
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: David McManus and KW Environmental, LLC (Individual/Entity) is a Department licensed septic tank pumper. The Department conducted an investigation on September 3, 2020 and observed a trail of sewage from the corner of Highway 34 and Old Douglass Road to the intersection of Harden Road and Old Douglass Road, a length of approximately three (3) miles. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to cease and desist allowing septic tank effluent, domestic wastewater, or sewage to be discharged to the surface of the ground without an appropriate permit from the Department. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**$500.00**).

Updates: The Individual/Entity has fulfilled all requirements of the Order and paid the civil penalty. This Order has been closed.

31)

Order Type and Number:	Consent Order 20-115-OSWW
Order Date:	December 30, 2020
Individual/Entity:	**Marvin Lane Fowler**
Facility:	Marvin Lane Fowler
Location:	28 North Main Street Cross Hill, SC 29332
Mailing Address:	P.O. Box 1610 Spartanburg, SC 29304
County:	Laurens

Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Marvin Lane Fowler (Individual/Entity) does not possess a valid Department license to engage in the construction of or repairing of OSWW systems. The Department conducted an investigation on August 7, 2020, after a request for a final inspection of an installed OSWW system. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department.

Action: The Individual/Entity is required to cease and desist engaging in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)** by January 29, 2021.

Updates: The Individual/Entity has complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

* Unless otherwise specified, "Previous Orders" as listed in this report include orders issued by Environmental Affairs Programs within the last five (5) years.

(x) ACTION/DECISION
( ) INFORMATION

Date: February 11, 2021

To: S.C. Board of Health and Environmental Control

From: Healthcare Quality

Re: Notice of Proposed Regulation Amending R.61-63, *Radioactive Materials (Title A)*

I. Introduction

Healthcare Quality proposes the attached Notice of Proposed Regulation amending R.61-63, *Radioactive Materials (Title A)*, for publication in the February 26, 2021, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Section 13-7-40, which designates the Department as the responsible agency for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department proposes these amendments for compliance with federal law.

II. Facts

1. The Department proposes amending R.61-63 to incorporate federal law as required to maintain South Carolina's status with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State.

2. The Department had a Notice of Drafting published in the October 23, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the November 23, 2020, close of the public comment period.

3. A stakeholder meeting was held on November 5, 2020. Two stakeholders attended the meeting. The meeting was opened for public comment. No public comments were given.

4. Department staff sent the proposed amendments to the NRC for review. The Department has incorporated the NRC's input regarding compatibility with the federal regulation.

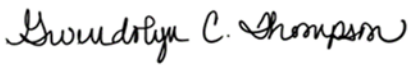
5. Department staff also provided the proposed amendments to the state Technical Advisory Radiation Control Council (TARCC) for review on December 9, 2020.

6. Department staff conducted an internal review of the proposed amendments on December 16, 2020.

III. Request for Approval

Healthcare Quality respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the February 26, 2021, *State Register*.

Submitted by



Gwen Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the October 23, 2020, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-63, *Radioactive Materials (Title A)*

February 11, 2021

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 13-7-40 et seq.

61-63. Radioactive Materials (Title A).

Preamble:

Pursuant to S.C. Code Sections 13-7-40 et seq., the Department of Health and Environmental Control ("Department") is responsible for regulatory and licensing standards, disposal, use, reports, storage, and inspections relating to various uses of radioactive materials. The Department proposes amending R.61-63 to incorporate federal law as required to maintain South Carolina's status with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State.

The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department proposes these amendments for compliance with federal law.

The Department had a Notice of Drafting published in the October 23, 2020, *South Carolina State Register*.

Section-by-Section Discussion of Proposed Amendments:

Specific Table of Contents sections amended to reflect proposed revisions in the regulation text.
RHA 1.13 amended to comply with RATS ID: 2018-2, 10 CFR 37.7(a) and RATS ID: 2019-2, 10 CFR 71.17(c)(3)
RHA 2.7 amended to comply with RATS ID: 2018-1, 10 CFR 32.72
RHA 2.10.8 amended to comply with RATS ID: 2018-1, 10 CFR 30.34(g)
RHA 2.10.10 added to comply with RATS ID: 2018-2, 10 CFR 70.32
RHA 2.22 amended to comply with RATS ID: 2018-2, 10 CFR 71.97 and RATS ID: 2018-3, 10 CFR 71.97(c)(3)
RHA 4.2 amended to comply with NRC RATS ID: 2018-1, 10 CFR 35.2
RHA 4.7 amended to comply with RATS ID: 2018-1, 10 CFR 35.12
RHA 4.8 amended to comply with RATS ID: 2018-1, 10 CFR 35.13
RHA 4.9 amended to comply with RATS ID: 2018-1, 10 CFR 35.14
RHA 4.10 amended to comply with RATS ID: 2018-1, 10 CFR 35.15
RHA 4.13 amended to comply with RATS ID: 2018-1, 10 CFR 35.15
RHA 4.17 amended to comply with RATS ID: 2018-1, 10 CFR 35.40
RHA 4.18 amended to comply with RATS ID: 2018-1, 10 CFR 35.41
RHA 4.20 amended to comply with RATS ID: 2018-1, 10 CFR 35.50
RHA 4.21 amended to comply with RATS ID: 2018-1, 10 CFR 35.51
RHA 4.22 amended to comply with RATS ID: 2018-1, 10 CFR 35.55
RHA 4.23 amended to comply with RATS ID: 2018-1, 10 CFR 35.57
RHA 4.28 amended to comply with RATS ID: 2018-1, 10 CFR 35.65

RHA 4.35 amended to comply with RATS ID: 2018-1, 10 CFR 3.65 and RATS ID: 2018-2, 10 CFR 37.77
RHA 4.36 amended to comply with RATS ID: 2018-1, 10 CFR 35.190
RHA 4.38 amended to comply with RATS ID: 2018-1, 10 CFR 35.204
RHA 4.39 amended to comply with RATS ID: 2018-1, 10 CFR 35.290
Title of Subpart E amended to comply with RATS ID 2018-1
RHA 4.40 amended to comply with RATS ID: 2018-1, 10 CFR 35.300
RHA 4.43 amended to comply with RATS ID: 2018-1, 10 CFR 35.390
RHA 4.43.3 amended to comply with RATS ID: 2018-1, 10 CFR 35.396
RHA 4.44 amended to comply with RATS ID: 2018-1, 10 CFR 35.392
RHA 4.45 amended to comply with RATS ID: 2018-1, 10 CFR 35.394
RHA 4.46 amended to comply with RATS ID: 2018-1, 10 CFR 35.400
RHA 4.52 amended to comply with RATS ID: 2018-1, 10 CFR 35.433
RHA 4.54 amended to comply with RATS ID: 2018-1, 10 CFR 35.490
RHA 4.55 amended to comply with RATS ID: 2018-1, 10 CFR 35.491
RHA 4.56 amended to comply with RATS ID: 2018-1, 10 CFR 35.500
RHA 4.57 amended to comply with RATS ID: 2018-1, 10 CFR 35.590
RHA 4.58 amended to comply with RATS ID: 2018-1, 10 CFR 35.600
RHA 4.61 amended to comply with RATS ID: 2018-1, 10 CFR 35.610
RHA 4.72 amended to comply with RATS ID: 2018-1, 10 CFR 35.655(a)
RHA 4.74 amended to comply with RATS ID: 2018-1, 10 CFR 35.690
RHA 4.89 amended to comply with RATS ID: 2018-1, 10 CFR 35.2024
RHA 4.102 amended to comply with RATS ID: 2018-1, 10 CFR 35.2310
RHA 4.116 amended to comply with RATS ID: 2018-1, 10 CFR 35.2655
RHA 4.117 amended to comply with RATS ID: 2018-1, 10 CFR 35.3045 and RATS ID: 2020-2, 10 CFR 35.3045(g)(1)(ii)
RHA 4.118 amended to comply with RATS ID: 2020-2, 10 CFR 35.3047(f)(1)(ii)
RHA 4.120 amended to comply with RATS ID: 2018-1, 10 CFR 35.3204
RHA 5.14 amended to comply with RATS ID: 2020-1, 10 CFR 34.47
RHA 5.14.7.3 amended to comply with RATS ID: 2020-1, 10 CFR 34.83
RHA 8.21 amended to comply with RATS ID: 2020-1, 10 CFR 39.65
RHA 11.20 amended to comply with RATS ID: 2020-1, 10 CFR 36.55
RHA 12.5 amended to comply with RATS ID: 2018-3, 10 CFR 37.23(b)(2)
RHA 12.5.2.2 amended to comply with RATS ID: 2019-1, 10 CFR 37.23(b)(2)
RHA 12.7 amended to comply with RATS ID: 2019-1, 10 CFR 37.27(c)(1) and (2)
RHA 12.12 amended to comply with RATS ID: 2018-3, 10 CFR 37.43(b)(2)
RHA 12.23 amended to comply with RATS ID: 2018-3, 10 CFR 37.77(a)(1)

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Healthcare Quality; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on March 29, 2021, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the amendments during its May 13, 2021, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. Because of ongoing COVID-19 concerns, interested

persons who do not wish to appear in person may participate in the public hearing by calling in through an assigned conference line. These participants may register in advance by visiting the DHEC Events webpage (www.scdhec.gov/events) and selecting the appropriate Board meeting date. A link to register will be provided on the accompanying meeting information page. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agenda.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-63, Radioactive Materials (Title A)

Purpose: The Department proposes amending R.61-63 to incorporate federal law as required to maintain South Carolina's status with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State.

Legal Authority: 1976 Code Sections 13-7-40 et seq.

Plan for Implementation: Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and any associated information. The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to these proposed amendments. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The proposed amendments are required to be implemented for South Carolina to maintain its status through the NRC as an Agreement State and to ensure compatibility with federal regulations as required by Section 274 of the Atomic Energy Act of 1954. The proposed amendments include revisions to medical event definitions, training and experience, individual monitoring devices, social security number fraud prevention, and general overall clarifications, miscellaneous corrections, and organization.

DETERMINATION OF COSTS AND BENEFITS:

Neither the state nor its political subdivisions will incur additional costs through implementation of these proposed amendments. Existing staff and resources will be utilized to implement the proposed revisions to the regulation. The proposed amendments will not create any significant additional cost to the regulated community since requirements or changes to the regulations will be substantially consistent with the current guidelines and review guidelines utilized by the Department.

UNCERTAINTIES OF ESTIMATES:

None

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

These amendments seek to ensure an effective regulatory program for radioactive material users under state jurisdiction, and protection of the public and workers from unnecessary exposure to ionizing radiation.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-63. Radioactive Materials (Title A).

(Statutory Authority: Section 13-7-40 et seq., as amended, of the 1976 Code, namely the Atomic Energy and Radiation Control Act)

Amend the following Table of Contents sections to read:

SUBPART B General Administrative Requirements

RHA
4.13 Authority and Responsibilities for the Radiation Protection Program
4.14 Radiation Protection Program Changes
4.15 Supervision
4.17 Written Directives
4.18 Procedures for Administrations Requiring a Written Directive
4.19 Suppliers for Sealed Sources or Devices for Medical Use
4.20 Training for Radiation Safety Officers and Associate Radiation Safety Officer
4.21 Training for an Authorized Medical Physicist
4.22 Training for an Authorized Nuclear Pharmacist
4.23 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist
4.24 Recentness of Training

SUBPART D Unsealed Radioactive Material—Written Directive Not Required

RHA
4.35 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required
4.36 Training for Uptake, Dilution, and Excretion Studies
4.37 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required
4.38 Permissible Molybdenum-99, ~~Concentration~~Strontium-82, and Strontium-85 Concentrations
4.39 Training for Imaging and Localization Studies

SUBPART E Unsealed Radioactive Material—Written Directive Required

RHA

SUBPART F Manual Brachytherapy

SUBPART G Sealed Sources for Diagnosis

SUBPART H Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

4.74 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

SUBPART L Records

RHA

4.89 Records of Authority and Responsibilities for Radiation Protection Programs
4.90 Records of Radiation Protection Program Changes
4.91 Records of Written Directives
4.92 Records For Procedures For Administrations Requiring a Written Directive
4.93 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material
4.94 Records of Radiation Survey Instrument Calibrations
4.95 Records of Dosages of Unsealed Radioactive Material For Medical Use
4.96 Records of Leaks Tests and Inventory of sealed Sources and Brachytherapy Sources
4.97 Records of Surveys For Ambient Radiation Exposure Rate
4.98 Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
4.99 Records of Mobile Medical Services
4.100 Records of Decay-in-Storage
4.101 Records of Molybdenum-99 Concentrations
4.102 Records of Safety Instruction
4.103 Records of Surveys After Source Implant and Removal
4.104 Records of Brachytherapy Source Accountability
4.105 Records of Calibration Measurements of Brachytherapy Sources
4.106 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments
4.107 Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic and Radiosurgery Units
4.108 Records of Safety Procedures
4.109 Records of Dosimetry Equipment Used with Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
4.110 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations
4.111 Records of Periodic Spot-Checks for Teletherapy Units
4.112 Records of Periodic Spot-Checks for Remote Afterloader Units
4.113 Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units
4.114 Records of Additional Technical Requirements for Mobile Remote Afterloader Units
4.115 Records of Surveys of Therapeutic Treatment Units
4.116 Records of ~~5-Year Inspection~~Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units

SUBPART M Reports

RHA

4.117 Report and Notification of a Medical Event
4.118 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child
4.119 Report of a Leaking Source
4.120 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

Amend 2.7.5.1.4 to read:

2.7.5.1.4 The applicant ~~satisfies~~commits to the following labeling requirements:

Amend 2.7.5.2.5.1 to read:

2.7.5.2.5.1 A copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State as specified in ~~Part 4 of this Regulation with the written attestation signed by a preceptor as required by Part 4 of this Regulation~~RHA 4.22.1; or

Amend 2.7.5.4 to read:

2.7.5.4 A licensee shall satisfy the labeling requirements in paragraph 2.7.5.1.4 of this section.

2.7.5.45 Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

Amend 2.10.8 to read:

2.10.8 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, respectively, in accordance with RHA 4.38. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 4.38.1 of this chapter at the time of generator elution, in accordance with RHA 4.120 of this chapter.

Add 2.10.10:

2.10.10 Conditions of licenses.

2.10.10.1 Each license shall contain and be subject to the following conditions:

2.10.10.1.1 [Reserved]

2.10.10.1.2 No right to the special nuclear material shall be conferred by the license except as defined by the license;

2.10.10.1.3 Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act;

2.10.10.1.4 [Reserved]

2.10.10.1.5 [Reserved]

2.10.10.1.6 [Reserved]

2.10.10.1.7 [Reserved]

2.10.10.1.8 The license shall be subject to and the licensee shall observe, all applicable rules, regulations, and orders of the Department.

2.10.10.1.9 Notification of Bankruptcy.

2.10.10.1.9.1 Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

2.10.10.1.9.1.1 The licensee;

2.10.10.1.9.1.2 An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

2.10.10.1.9.1.3 An affiliate (as that term is defined in 11 U.S.C. 101(a)) of the licensee.

2.10.10.1.9.2 The notification required in 2.10.10.1.9.1 must indicate:

2.10.10.1.9.2.1 The bankruptcy court in which the petition for bankruptcy was filed; and

2.10.10.1.9.2.2 The date of the filing of the petition.

Amend 4.2 to read:

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

4.2.2 “Agreement State” means any State with which the Nuclear Regulatory Commission (hereafter referred to as NRC) or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

4.2.3 “Area of use” means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

4.2.4 "Associate Radiation Safety Officer" means an individual who—

4.2.4.1 Meets the requirements in RHA 4.20 and RHA 4.24; and

4.2.4.2 Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on—

4.2.4.2.1 A specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; or

4.2.4.2.2 A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

4.2.45 “Authorized medical physicist” means an individual who—

4.2.45.1 Meets the requirements in RHA 4.21.1 and RHA 4.24; or

4.2.45.2 Is identified as an authorized medical physicist or teletherapy physicist on—

4.2.45.2.1 A specific medical use license issued by the NRC or an Agreement state;

4.2.~~4~~5.2.2 A medical use permit issued by an NRC master material licensee;

4.2.~~4~~5.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee; or

4.2.~~4~~5.2.4 A permit issued by an NRC master material license broad scope medical use permittee.

4.2.~~5~~6 "Authorized nuclear pharmacist" means a pharmacist who—

4.2.~~5~~6.1 Meets the requirements in RHA 4.22.1 and RHA 4.24; or

4.2.~~5~~6.2 Is identified as an authorized nuclear pharmacist on—

4.2.~~5~~6.2.1 A specific license issued by the NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.2.2 A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.2.4 A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.3 Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4.2.~~5~~6.4 Is designated as an authorized nuclear pharmacist in accordance with RHA 2.7.5.2.4.

4.2.~~6~~7 "Authorized user" means a physician, dentist, or podiatrist who—

4.2.~~6~~7.1 Meets the requirements in RHA 4.24 and RHA 4.36.1, RHA 4.39.1, RHA 4.43.1, RHA 4.44.1.1, RHA 4.45.1.1, RHA 4.54.1.1, RHA 4.57.1.1, or RHA 4.74.1.1; or

4.2.~~6~~7.2 Is identified as an authorized user on—

4.2.~~6~~7.2.1 An NRC or Agreement State license that authorizes the medical use of radioactive material;

4.2.~~6~~7.2.2 A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

4.2.~~6~~7.2.3 A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4.2.~~6~~7.2.4 A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

4.2.~~7~~8 “Brachytherapy” means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

4.2.~~8~~9 “Brachytherapy source” means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

4.2.~~9~~10 “Client’s address” means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with RHA 4.33.

4.2.1~~0~~1 “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.

4.2.1~~1~~2 “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.

4.2.1~~2~~3 “Dentist” means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

4.2.1~~3~~4 “High dose-rate remote afterloader,” as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.1~~4~~5 “Low dose-rate remote afterloader,” as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

4.2.1~~5~~6 “Management” means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee’s activities, or those persons’ delegate or delegates.

4.2.1~~6~~7 “Manual brachytherapy,” as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

4.2.1~~7~~8 “Medical event” means an event that meets the criteria in RHA 4.117.1.

4.2.1~~8~~9 “Medical institution” means an organization in which more than one medical discipline is practiced.

4.2.~~19~~20 “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.

4.2.2~~0~~1 “Medium dose-rate remote afterloader,” as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.2~~1~~2 “Mobile medical service” means the transportation of radioactive material to and its medical use at the client’s address.

4.2.23 “Ophthalmic physicist” means an individual who—

4.2.23.1 Meets the requirements in RHA 4.52.1.2 and RHA 4.24; and

4.2.23.2 Is identified as an ophthalmic physicist on a—

4.2.23.2.1 Specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State;

4.2.23.2.2 Permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

4.2.23.2.3 Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

4.2.23.2.4 Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

4.2.2~~2~~4 “Output” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for specified set of exposure conditions.

4.2.2~~3~~5 “Patient intervention” means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

4.2.2~~4~~6 “Pharmacist” means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

4.2.2~~5~~7 “Physician” means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

4.2.2~~6~~8 “Podiatrist” means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

4.2.2~~7~~9 “Positron Emission Tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

4.2.~~28~~30 “Preceptor” means an individual who provides, directs or verifies the 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.

4.2.~~29~~31 “Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented—

4.2.~~29~~31.1 In a written directive; or

4.2.~~29~~31.2 In accordance with the directions of the authorized user for procedures performed pursuant to RHA 4.35 and 4.37.

4.2.~~30~~32 "Prescribed dose" means—

4.2.~~30~~32.1 For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

4.2.~~30~~32.2 For teletherapy, the total dose and dose per fraction as documented in the written directive;

4.2.~~30~~32.3 For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4.2.~~30~~32.4 For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

4.2.3~~1~~3 "Pulsed dose-rate remote afterloader," as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but—

4.2.3~~1~~3.1 Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

4.2.3~~1~~3.2 Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

4.2.3~~2~~4 "Radiation Safety Officer" means an individual who—

4.2.3~~2~~4.1 Meets the requirements in RHA 4.20.1 or 4.20.3 and RHA 4.24; or

4.2.3~~2~~4.2 Is identified as a Radiation Safety Officer on—

4.2.3~~2~~4.2.1 A specific medical use license issued by the NRC or Agreement State; or

4.2.3~~2~~4.2.2 A medical use permit issued by an NRC master material licensee.

4.2.3~~3~~5 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

4.2.3~~4~~6 "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

4.2.3~~5~~7 "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

4.2.3~~6~~8 "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

4.2.3~~7~~9 “Teletherapy,” as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

4.2.~~38~~40 “Temporary job” means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

4.2.~~39~~41 “Therapeutic dosage” means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

4.2.4~~0~~2 “Therapeutic dose” means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

4.2.4~~1~~3 “Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

4.2.4~~2~~4 “Type of use” means use of radioactive material under RHA 4.35, 4.37, 4.40, 4.46, 4.56 4.58 or 4.88.

4.2.4~~3~~5 “Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

4.2.4~~4~~6 “Written directive” means an authorized user’s written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in RHA 4.17.

Amend 4.7.2.1 to read:

4.7.2.1 Filing an original of DHEC Form 0813, “Application for Radioactive Material License,” that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

Amend 4.7.3.1.2 to read:

4.7.3.1.2 A letter ~~requesting the amendment or renewal~~containing all information required by DHEC Form 0813; and

Amend 4.7.4 to read:

4.7.4 In addition to the requirements in RHA 4.7.2 and 4.7.3 of this section an application for a license or amendment for medical use of radioactive material as described in RHA 4.88 must also include ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.~~:

4.7.4.1 ~~The applicant shall also provide specific information on:~~ Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

4.7.4.2 Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific RHA 4.88 medical use;

4.7.4.3 Any additional specific information on --

4.7.4.~~1~~3.1 Radiation safety precautions and instructions;

4.7.4.~~1~~3.2 Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4.7.4.~~1~~3.3 Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety~~.~~; and

4.7.4.~~2~~4 ~~The applicant or licensee shall also provide a~~Any other information requested by the Department in its review of the application.

Amend 4.8 to read:

A licensee shall apply for and must receive a license amendment—

4.8.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

4.8.2 Before it permits anyone to work as an authorized user, ~~authorized nuclear pharmacist, or~~ authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—

4.8.2.1 For an authorized user, an individual who meets the requirements in RHA 4.24, ~~RHA~~ 4.36.1, 4.39.1, 4.43.1, 4.44.1.1, 4.45.1.1, 4.54.1.1, 4.57.1.1, and 4.74.1.1~~, 4.76, 4.77, 4.78, 4.79, 4.80, 4.81, 4.82, 4.83 or 4.84 and RHA 4.24~~;

4.8.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in RHA 4.22.1 ~~or 4.86~~ and RHA 4.24;

4.8.2.3 For an authorized medical physicist, an individual who meets the requirements in RHA 4.21.1 ~~or 4.85~~ and RHA 4.24

4.8.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or an ophthalmic physicist—

4.8.2.4.1 On an NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

4.8.2.4.2 On a license issued by an NRC or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

4.8.2.4.3 On a license issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

4.8.2.4.4 By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

4.8.3 Before it changes Radiation Safety Officers, except as provided in RHA 4.13.3;

4.8.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

4.8.45 Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

4.8.56 Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either RHA 4.35 or 4.37;

4.8.67 Before it changes the address(es) of use identified in the application or on the license; and

4.8.78 Before it revises procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable, where such revision reduces radiation safety.; and

4.8.9 Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

Amend 4.9 to read:

~~4.9.1 A licensee shall provide the Department a copy of the board certification, the NRC or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee 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, or an authorized medical physicist, under RHA 4.8.2.1 through 4.8.2.4.~~

~~4.9.2 A licensee shall notify the Department by letter no later than 30 days after:~~

~~4.9.2.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;~~

~~4.9.2.2 The licensee's mailing address changes;~~

~~4.9.2.3 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.15; or~~

~~4.9.2.4 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 RHA 4.35 or 4.37.~~

~~4.9.3 The licensee shall mail the documents required in this section to the appropriate address identified in RHA 1.13.~~

4.9.1 A licensee shall provide the Department, no later than 30 days after the date that the licensee permits an individual to work under the provisions of RHA 4.8.2 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist—

4.9.1.1 A copy of the board certification and, as appropriate, verification of completion of:

4.9.1.1.1 Training for the authorized medical physicist under RHA 2.21.4;

4.9.1.1.2 Any additional case experience required in RHA 4.43.2.2.7 for an authorized user under RHA 4.40; or

4.9.1.1.3 Device specific training in RHA 4.74.1.5 for the authorized user under RHA 4.58; or

4.9.2 A copy of the Nuclear Regulatory Commission or Agreement State license, the permit issued by a Nuclear Regulatory Commission master material licensee, the permit issued by a Nuclear Regulatory Commission or Agreement State licensee of broad scope, the permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, or 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 Nuclear Regulatory Commission for each individual whom the licensee permits to work under the provisions of this section.

4.9.2.1 A licensee shall notify the Department no later than 30 days after:

4.9.2.1.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

4.9.2.1.2 The licensee permits an individual qualified to be a Radiation Safety Officer under RHA 4.20 and 4.24 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with RHA 4.13.3;

4.9.2.1.3 The licensee's mailing address changes;

4.9.2.1.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.10.2.1 of this chapter;

4.9.2.1.5 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 RHA 4.35 or RHA 4.37 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; or

4.9.2.1.6 The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RHA 4.8.9. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

4.9.3 The licensee shall send the documents required in this section to the appropriate address identified in RHA 1.13.

Amend 4.10.3 and 4.10.5 to read:

4.10.3 The provisions of RHA 4.8.~~5~~6 regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

4.10.5 The provisions of RHA 4.9.2.1.1 for an authorized user, an authorized nuclear pharmacist, ~~or an~~ authorized medical physicist, or an ophthalmic physicist;

Amend 4.13.2 and 4.13.3 to read:

4.13.2 A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, 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 Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer 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.

4.13.3 For up to 60 days each year, a licensee may permit ~~an authorized user or~~ an individual qualified to be a Radiation Safety Officer, under RHA 4.20 and 4.24, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in RHA 4.13.7 of this section, if the licensee takes the actions required in RHA 4.13.2, 4.13.3, 4.13.7 and 4.13.8 of this section and notifies the Department in accordance with RHA 4.9.2.

Amend 4.17.2.5 and 4.17.2.6 to read:

4.17.2.5 For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

4.17.2.6 For permanent implant brachytherapy:

4.17.2.6.1 Before implantation: The treatment site, the radionuclide, and the total source strength; and

4.17.2.6.2 After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

4.17.2.~~6~~7 For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

4.17.2.~~6~~7.1 Before implantation: The treatment site, ~~the~~ radionuclide, and dose; and

4.17.2.~~6~~7.2 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.

Amend 4.18.2 to read:

4.18.2 At a minimum, the procedures required by RHA 4.18.1 must address the following items that are applicable to the licensee's use of radioactive material—

4.18.2.1 Verifying the identity of the patient or human research subject;

4.18.2.2 Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

4.18.2.3 Checking both manual and computer-generated dose calculations; ~~and~~

4.18.2.4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RHA 4.58~~.~~ or RHA 4.88;

4.18.2.5 Determining if a medical event, as defined in RHA 4.117, has occurred; and

4.18.2.6 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.

Amend 4.20 to read:

RHA 4.20. Training for Radiation Safety Officers and Associate Radiation Safety Officer

Except as provided in RHA 4.23, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RHA 4.13 to be an individual who—

4.20.1 Is certified by a specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 4.20.4 and 4.20.5 of this section. ~~(The names of board certifications, which have been recognized by the NRC or an Agreement State, will be posted on the NRC's Web page, www.nrc.gov.)~~The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.

4.20.1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.20.1.1.1 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;

4.20.1.1.2 Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

4.20.1.1.3 Pass an examination administered by diplomats of the specialty board, which 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

4.20.1.2.1 Hold a master's or ~~doctorate~~doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

4.20.1.2.2 Have 2 years of full-time practical training and/or supervised experience in medical physics:

4.20.1.2.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State; or

4.20.1.2.2.2 In clinical nuclear medicine facilities providing diagnostic ~~and/~~or therapeutic services under the direction of physicians who meet the requirements for authorized users in RHA 4.23, 4.39 or RHA 4.43~~.~~; and

4.20.1.2.3 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

4.20.2 Has completed a structured educational program consisting of both:

4.20.2.1 200 hours of classroom and laboratory training in the following areas—

4.20.2.1.1 Radiation physics and instrumentation;

4.20.2.1.2 Radiation protection;

4.20.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.20.2.1.4 Radiation biology; and

4.20.2.1.5 Radiation dosimetry; and

4.20.2.2 One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Office on ~~NRC~~Nuclear Regulatory Commission or Agreement State license or on a permit issued by an ~~NRC~~Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material ~~involving the following~~. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following—

4.20.2.2.1 Shipping, receiving, and performing related radiation surveys;

4.20.2.2.2 Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

4.20.2.2.3 Securing and controlling radioactive material;

4.20.2.2.4 Using administrative controls to avoid mistakes in the administration of radioactive material;

4.20.2.2.5 Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

4.20.2.2.6 Using emergency procedures to control radioactive material; and

4.20.2.2.7 Disposing of radioactive material; and

4.20.2.3 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 paragraphs RHA 4.20.2 and RHA 4.20.4 of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

~~4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.21 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 Radiation Safety Officer and who meets the requirements RHA 4.20.4 and 4.20.5; or~~

~~4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and~~

4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RHA 4.21.1, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.2 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 the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material license. The individual must also meet the requirements in paragraph 4.20.4 of this section.

~~4.20.4 Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in RHA 4.20.5, and 4.20.1.1.1 and 4.20.1.1.2, or 4.20.1.2.1 and 4.20.1.2.2 or 4.20.3 or 4.20.3.1 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

4.20.~~5~~4 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 Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical

physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Amend 4.21 to read:

Except as provided in RHA 4.23, the licensee shall require the authorized medical physicist to be an individual who—

4.21.1 Is certified by a specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s~~ ~~4.21.3 and~~ 4.21.4 of this section. ~~(The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.)~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission 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:

4.21.1.1 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.

4.21.1.2 Have 2 years of full-time practical training and/or supervised experience in medical physics—

4.21.1.2.1 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 Nuclear Regulatory Commission or an Agreement State; or

4.21.1.2.2 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 for authorized users in RHA 4.23, 4.54 or 4.74; and

4.21.1.3 Pass an examination, administered by diplomats 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

4.21.2 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; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

4.21.2.1 Performing sealed source leak tests and inventories;

4.21.2.2 Performing decay corrections;

4.21.2.3 Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.2.4 Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.~~3~~2.5 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA ~~4.21.4 and 4.21.1.1 and 4.21.1.2 or~~ 4.21.2 and 4.21.4~~3~~ of this section, and ~~has achieved a level of competency sufficient to function independently~~ 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 must be signed by a preceptor authorized medical physicist who meets the requirements in RHA 4.21 or 4.23, or equivalent ~~NRC~~Nuclear Regulatory Commission 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~~; and~~.

4.21.4~~3~~ Has training for the type(s) 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 type(s) of use for which the individual is seeking authorization.

Amend 4.22.1 and 4.22.3 to read:

4.22.1 Is certified ~~as a nuclear pharmacist~~ by a specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph 4.22.3 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.)~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.22.3 Has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in RHA 4.22.2 of this section and ~~has achieved a level of competency sufficient to function independently~~is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Amend 4.23 to read:

RHA 4.23. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

~~4.23.1 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before April 29, 2005, need not comply with the training requirements of RHA 4.20, 4.21 or 4.22, respectively.~~

~~4.23.2 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee April 29, 2005, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D-H of this part.~~

~~4.23.3 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 or Agreement State licenses for the same uses for which these individuals are authorized.~~

4.23.1 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, and Nuclear Pharmacist.

4.23.1.1 An individual identified on a Nuclear Regulatory Commission or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RHA 4.20.4 or RHA 4.21.3, as appropriate, for any material or uses for which they were not authorized prior to this date.

4.23.1.2 Any individual 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 RHA 4.20 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Nuclear Regulatory Commission or an Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.3 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 RHA 4.21, for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, 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 Nuclear Regulatory Commission, need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, 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 during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

4.23.2 Training for Experienced Authorized User

4.23.2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before 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 subparts D through H of this part.

4.23.2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

4.23.2.2.1 For uses authorized under RHA 4.35 or RHA 4.37, 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 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;

4.23.2.2.2 For uses authorized under RHA 4.40, 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;

4.23.2.2.3 For uses authorized under RHA 4.46 or RHA 4.58, 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

4.23.2.2.4 For uses authorized under RHA 4.56, 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.

4.23.2.3 Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, 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 Nuclear Regulatory Commission, need not comply with the training requirements of subparts D through H 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 paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

Amend 4.28 to read:

Any person authorized by RHA 4.6 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use.

4.28.1 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent NRC or Agreement State regulations.

4.28.2 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

4.28.3 Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

4.28.4 Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 uCi) or 1000 times the quantities in Appendix C, RHA 3.54, of Part III of these regulations.

4.28.5 Technetium-99m in amounts as needed.

4.28.6 Radioactive material in sealed sources authorized by this provision shall not be:

4.28.6.1 Used for medical use as defined in RHA 4.2 except in accordance with the requirements in RHA 4.56 or

4.28.6.2 Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

4.28.6.3 A licensee using calibration, transmission, and reference sources in accordance with the requirements in this section need not list these sources on a specific medical use license.

Amend the title of 4.35 to read:

RHA 4.35. Use of Unsealed ~~Byproduct~~Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required.

Amend 4.36 to read:

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.35 to be a physician who—

4.36.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph 4.36.4 of this section. (~~.The names of board certifications ~~which~~that have been recognized by the NRC or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov.)~~Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.36.1.1 Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 4.36.3 through 4.36.3.2.6 of this section; and 4.36.1.2 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.36.2 Is an authorized user under RHA 4.39 or 4.43 or equivalent NRC requirements; or 4.36.3—

4.36.3 Has completed 60 hours of training and experience, including a minimum of 8 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 must include—

4.36.3.1 Classroom and laboratory training in the following areas—

4.36.3.1.1 Radiation physics and instrumentation;

4.36.3.1.2 Radiation protection;

4.36.3.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.36.3.1.4 Chemistry of radioactive material for medical use; and

4.36.3.1.5 Radiation biology; and

4.36.3.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, involving—

4.36.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.36.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

4.36.3.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.36.3.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.36.3.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.36.3.2.6 Administering dosages of radioactive drugs to patients or human research subjects; and

4.36.3.3 ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.36.1.1 or 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.36.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 4.35. The attestation must be obtained from either:

4.36.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39, or 4.43, or equivalent Agreement State requirements; or

4.36.3.3.2 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 RHA 4.23, 4.36, 4.39, or 4.43, or equivalent 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 specified in paragraph 4.36.3 of this section.

~~4.36.4 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in RHA 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35.~~

Amend 4.38 to read:

RHA 4.38. Permissible Molybdenum-99, ~~Concentration~~Strontium-82, and Strontium-85 Concentrations.

4.38.1 A licensee may not administer to humans a radiopharmaceutical that contains:

4.38.1.1 More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

4.38.1.2 More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

4.38.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration ~~of the first eluate after receipt of a~~in each eluate from a generator to demonstrate compliance with RHA 4.38.1.

4.38.3 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-85 to demonstrate compliance with RHA 4.38.1.

4.38.~~3~~4 If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with RHA 4.101.

4.38.5 The licensee shall report any measurement that exceeds the limits in RHA 4.38.1 of this section at the time of generator elution, in accordance with RHA 4.120.

Amend 4.39 to read:

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.37 to be a physician who—

4.39.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State~~and who meets the requirements in paragraph 4.39.3 of this section. (~~.The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web~~

~~page.)~~Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.39.1.1 Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in paragraphs RHA 4.39.3 through 4.39.3.2.7; and

4.39.1.2 Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.39.2 Is an authorized user under RHA 4.43 and meets the requirements in RHA 4.39.3.2.7 or equivalent NRC requirements; or

4.39.3 Has 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 must include, at a minimum,-

4.39.3.1 Classroom and laboratory training in the following areas—

4.39.3.1.1 Radiation physics and instrumentation;

4.39.3.1.2 Radiation protection;

4.39.3.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.39.3.1.4 Chemistry of radioactive material for medical use;

4.39.3.1.5 Radiation biology; and

4.39.3.2 Work experience, under the supervision of an authorized user~~,~~ who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7 or equivalent NRC or Agreement State requirements~~, involving —~~. An authorized nuclear pharmacist who meets the requirements in RHA 4.22 or RHA 4.23 may provide the supervised work experience for paragraph 4.39.3.2.7 of this section. Work experience must involve—

4.39.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.39.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

4.39.3.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.39.3.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.39.3.2.5 Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

4.39.3.2.6 Administering dosages of radioactive drugs to patients or human research subjects; and

4.39.3.2.7 Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

4.39.3.3 ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7, or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.39.1 or 4.39.3 through 4.39.3.2.7 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35 and 4.37.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.39.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.35 and 4.37. The attestation must be obtained from either:

4.39.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.39.3.3.2 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 RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent Nuclear Regulatory Commission or 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 specified in paragraph 4.39.3 of this section.

Amend the title of Subpart E to read:

SUBPART E
Unsealed ~~Byproduct~~Radioactive Material–Written Directive Required

Amend the title and introductory paragraph of 4.40 to read:

RHA 4.40. Use of Unsealed ~~Byproduct~~Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed ~~byproduct~~radioactive material identified in RHA 4.43.2.2.7 prepared for medical use and for which a written directive is required that is—

Amend 4.43 to read:

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.40 to be a physician who—

4.43.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 4.43.2.2.7 ~~and 4.43.3~~ of this section. ~~(Specialty boards whose certification processes~~ The names of board certifications that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov.)~~Medical Uses Licensee Toolkit Web page. To be recognized, a specialty board shall require all candidates for certification to:

4.43.1.1 Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 4.43.2.1 through 4.43.2.2.5 of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.43.1.2 Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

4.43.2 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 must include—

4.43.2.1 Classroom and laboratory training in the following areas—

4.43.2.1.1 Radiation physics and instrumentation;

4.43.2.1.2 Radiation protection;

4.43.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.2.1.4 Chemistry of radioactive material for medical use; and

4.43.2.1.5 Radiation biology; and

4.43.2.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages in the same dosage category or categories (i.e., RHA 4.43.2.2.7) as the individual requesting authorized user status. The work experience must involve—

4.43.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.43.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.2.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.2.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

4.43.2.2.6 [Reserved]

4.43.2.2.7 ~~Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is~~

~~requesting authorized user status —~~ Administering dosages of radioactive drugs to patients or research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RHA 4.88. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

4.43.2.2.7.1 Oral administration of less than or equal to 1.22 ~~G~~gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

4.43.2.2.7.2 Oral administration of greater than 1.22 ~~G~~gigabecquerels (33 millicuries) of sodium iodide I-131;[2]

4.43.2.2.7.3 ~~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; and/or~~ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

~~4.43.2.2.7.4 Parenteral administration of any other radionuclide, for which a written directive is required; and~~

~~4.43.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.43.1 and 4.43.2.2.7 or 4.43.2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.40. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, or equivalent NRC requirements. The preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages in the same dosage category or categories (i.e., RHA 4.43.2.2.7) as the individual requesting authorized user status.~~

4.43.2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.43.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.40 for which the individual is requesting authorized user status. The attestation must be obtained from either:

4.43.2.3.1 A preceptor authorized user who meets the requirements in 4.23, 4.43, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

4.43.2.3.2 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 4.23, 4.43, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories 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 on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.43.2 of this section.

4.43.4~~3~~ Training for the parenteral administration of unsealed byproduct material requiring a written directive.

4.43.3.1 Except as provided in RHA 4.23, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

4.43.43.1.1 Is an authorized user under RHA 4.43 uses listed in RHA 4.43.2.2.7.3 ~~or 4.43.2.2.7.4~~ or equivalent NRC or Agreement State requirements; or

4.43.43.1.~~1~~.2 Is an authorized user under RHA 4.~~46~~54, 4.74, or equivalent NRC or Agreement State requirements and who meets the requirements in RHA 4.43.43.2 of this section; or

4.43.43.1.~~2~~3 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.~~46~~54 or 4.74, and who meets the requirements in RHA 4.43.43.2 of this section.

4.43.3.2 The Physician--

4.43.43.2.1 Has successfully 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, and/or parenteral administration of any other radionuclide for which a written directive is required~~listed in RHA 4.43.2.2.7.3. The training must include—

4.43.43.2.1.1 Radiation physics and instrumentation;

4.43.43.2.1.2 Radiation protection;

4.43.43.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.43.2.1.4 Chemistry of radioactive material for medical use; and

4.43.43.2.1.5 Radiation biology; and

4.43.4.3.2.2 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.43 or equivalent NRC or 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, and/or parenteral administration of any other radionuclide for which a written directive is required~~listed in RHA 4.43.2.2.7.3. A supervising authorized user who meets the requirements in RHA 4.43, 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements must have experience in administering dosages ~~as specified in RHA 4.43.2.2.7.3 and/or RHA 4.43.2.2.7.4~~in the same category or categories as the individual requesting authorized user status. The work experience must involve—

4.43.4.3.~~1~~2.2.1 Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

4.43.4.3.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.4.3.~~3~~2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.~~4.~~3.4~~2~~.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.~~4.~~3.~~5~~2.2.5 Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

4.43.~~4.~~3.~~6~~2.2.6 Administering dosages to patients or human research subjects, that include at least ~~3~~three cases ~~involving 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 and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required~~ of parenteral administrations as specified in RHA 4.43.2.2.7.3; and

~~4.43.4.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.4.1.1 and 4.43.4.1.2 of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.4, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in RHA 4.43, must have experience in administering dosages as specified in RHA 4.43.2.2.7.3 and/or RHA 4.43.2.2.7.4.~~

4.43.3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

4.43.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

4.43.3.3.2 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 RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories 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 on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section.

[2]Experience with at least ~~3~~three cases in RHA 4.43.2.2.7.2 also satisfies the requirement in RHA 4.43.2.2.7.1.

Amend 4.44 to read:

~~4.44.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

—4.44.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.44.1.3 and 4.44.1.4 of this section and whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State~~and who meets the requirements in paragraph 4.44.1.5 of this section. (~~.The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov.)~~Medical Uses Licensee Toolkit Web page; or

—4.44.1.2 Is an authorized user under RHA 4.43, for uses listed in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2, RHA 4.45, or equivalent NRC requirements; or

—4.44.1.3 Has successfully 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 must include—

—4.44.1.3.1 Radiation physics and instrumentation;

—4.44.1.3.2 Radiation protection;

—4.44.1.3.3 Mathematics pertaining to the use and measurement of radioactivity;

—4.44.1.3.4 Chemistry of radioactive material for medical use; and

—4.44.1.3.5 Radiation biology; and

4.44.1.43.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, RHA 4.44, RHA 4.45, or equivalent NRC requirements. A supervising authorized user who meets the requirements in RHA 4.43.2 must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2. The work experience must involve—

4.44.1.4.13.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.44.1.4.23.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.44.1.4.33.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.44.1.4.43.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.44.1.4.53.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.44.1.4.63.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

4.44.1.53.7 ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.44.1.3 and 4.44.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written attestation~~

must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.44, 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirement in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.44.3 of this section, and 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 RHA 4.40. The attestation must be obtained from either:

4.44.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2; or

4.44.3.7.2 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 RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Agreement State requirements, has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2, 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 paragraphs 4.44.1.3 and 4.44.1.4 of this section.

Amend 4.45 to read:

4.45.1 Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

4.45.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.45.1.3 and 4.45.1.4 of this section, and whose certification has been recognized by the NRCNuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph 4.45.1.5 of this section. (The names of board certifications whichthat have been recognized by the NRCNuclear Regulatory Commission or an Agreement State will beare posted on the NRC's Web page, www.nrc.gov.)Medical Uses Licensee Toolkit Web page.; or

4.45.1.2 Is an authorized user under RHA 4.43.1, 4.43.2 for uses listed in RHA 4.43.2.2.7.2, or equivalent NRC requirements; or

4.45.1.3 Has successfully 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 must include—

4.45.1.3.1 Radiation physics and instrumentation;

4.45.1.3.2 Radiation protection;

4.45.1.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.45.1.3.4 Chemistry of radioactive material for medical use; and

4.45.1.3.5 Radiation biology; and

—4.45.~~1.4~~3.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages as specified in RHA 4.43.2.2.7.2. The work experience must involve—

—4.45.~~1.4.1~~3.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

—4.45.~~1.4.2~~3.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

—4.45.~~1.4.3~~3.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

—4.45.~~1.4.4~~3.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

—4.45.~~1.4.5~~3.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

—4.45.~~1.4.6~~3.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

—4.45.~~1.5~~3.7 ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.45.1.3 and 4.45.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, RHA 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.2.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.45.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

—4.45.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in 4.43.2.2.7.2; or

—4.45.3.7.2 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 RHA 4.23, 4.43, 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 4.43.2.2.7.2, 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 paragraphs 4.45.3 of this section.

Amend 4.46 to read:

4.46.1 A licensee ~~shall~~must use only brachytherapy sources ~~for therapeutic medical uses~~:

4.46.1.1 ~~As approved in the Sealed Source and Device Registry~~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

4.46.1.2 ~~In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of~~ In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

Amend 4.52 to read:

RHA 4.52. ~~Decay of Strontium-90 Sources for Ophthalmic Treatments~~Strontium-90 Sources for Ophthalmic Treatments.

~~4.52.1 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 must be based on the activity determined under RHA 4.51.~~

~~4.52.2 A licensee shall retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.~~

4.52.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 4.52.2 of this section are performed by either:

4.52.1.1 An authorized medical physicist; or

4.52.1.2 An individual who:

4.52.1.2.1 Is identified as an ophthalmic physicist on a specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

4.52.1.2.2 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; and

4.52.1.2.3 Has successfully completed 1 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

4.52.1.2.4 Has documented training in:

4.52.1.2.4.1 The creation, modification, and completion of written directives;

4.52.1.2.4.2 Procedures for administrations requiring a written directive; and

4.52.1.2.4.3 Performing the calibration measurements of brachytherapy sources as detailed in RHA 4.51.

4.52.2 The individuals who are identified in 4.52.1 of this section must:

4.52.2.1 Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RHA 4.51; and

4.52.2.2 Assist the licensee in developing, implementing, and maintaining written procedures to provide 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 4.52.1 of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

4.52.3 Licensees must retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.

Amend 4.54 to read:

~~4.54.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RHA 4.46 to be a physician who—

~~4.54.1.1~~ Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State~~,~~. ~~and who meets the requirements in paragraph 4.54.1.4 of this section. (~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page.)~~Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

~~4.54.1.1.1~~ Successfully complete a minimum of 3 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

~~4.54.1.1.~~2 Pass an examination, administered by diplomats 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

~~4.54.1.~~2 Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

~~4.54.1.~~2.1 200 hours of classroom and laboratory training in the following areas:

~~4.54.1.~~2.1.1 Radiation physics and instrumentation;

~~4.54.1.~~2.1.2 Radiation protection;

~~4.54.1.~~2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

~~4.54.1.~~2.1.4 Radiation biology; and

—4.54.~~1.~~2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.54, or equivalent NRC or Agreement State requirements at a medical ~~institution~~facility authorized to use radioactive material under RHA 4.46, involving—

—4.54.~~1.~~2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

—4.54.~~1.~~2.2.2 Checking survey meters for proper operation;

—4.54.~~1.~~2.2.3 Preparing, implanting, and removing brachytherapy sources;

—4.54.~~1.~~2.2.4 Maintaining running inventories of material on hand;

—4.54.~~1.~~2.2.5 Using administrative controls to prevent a medical event involving the use of radioactive material;

—4.54.~~1.~~2.2.6 Using emergency procedures to control radioactive material; and

—4.54.~~1~~2.3 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC 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 RHA 4.54.~~1.~~2.2; and

—4.54.~~1~~2.4 ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.54.1.1 or 4.54.1.2 and RHA 4.54.1.3 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.54.2.1 and 4.54.2.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46. The attestation must be obtained from either:

4.54.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.54.2.4.2 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 RHA 4.23, RHA 4.54, or equivalent 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 specified in paragraphs 4.54.2.1 and 4.54.2.2 of this section.

Amend 4.55 to read:

~~4.55.1~~ Except as provided in RHA 4.23, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

~~4.55.1.~~1 Is an authorized user under RHA 4.54 or equivalent NRC requirements; or

~~4.55.1.~~2 Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

~~4.55.1.~~2.1 Radiation physics and instrumentation;

~~4.55.1.~~2.2 Radiation protection;

~~4.55.1.~~2.3 Mathematics pertaining to the use and measurement of radioactivity; and

~~4.55.1.~~2.4 Radiation biology; and

~~4.55.1.~~3 Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

~~4.55.1.~~3.1 Examination of each individual to be treated;

~~4.55.1.~~3.2 Calculation of the dose to be administered;

~~4.55.1.~~3.3 Administration of the dose; and

~~4.55.1.~~3.4 Follow up and review of each individual's case history; and

~~4.55.1.~~4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54, 4.55, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in ~~RHA 4.55.1.1 and 4.55.1.2~~ paragraphs 4.55.2 and 4.55.3 of this section and ~~has achieved a level of competency sufficient to function independently~~is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Amend 4.56 to read:

RHA 4.56. Use of Sealed Sources and Medical Devices for Diagnosis.

~~A licensee shall use only sealed sources for diagnostic medical uses as approved in the NRC Sealed Source and Device Registry.~~

4.56.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources 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.

4.56.2 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.

4.56.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

Amend 4.57 to read:

RHA 4.57. Training for Use of Sealed Sources and Medical Devices for Diagnosis.

~~4.57.1~~ Except as provided in RHA 4.23, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under RHA 4.56 to be a physician, dentist, or podiatrist who—

~~4.57.1.1 Is certified by a specialty board whose certification process includes all of the requirements in RHA 4.57.1.2 and 4.57.1.3 and whose certification has been recognized by the NRC or an Agreement State; or~~

4.57.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.57.3 and 4.57.4 of this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

4.57.2 Is an authorized user for uses listed in RHA 4.37 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~4.57.1.2~~3 Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

~~4.57.1.2~~3.1 Radiation physics and instrumentation;

~~4.57.1.2~~3.2 Radiation protection;

~~4.57.1.2~~3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.57.~~1.2~~3.4 Radiation biology; and

~~4.57.1.3~~4 Has completed training in the use of the device for the uses requested.

Amend 4.58 to read:

~~4.58.1 A licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:~~

~~4.58.1.1 As approved in the NRC Sealed Source and Device Registry; or~~

~~4.58.1.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.~~

4.58.1 A licensee must only use sealed sources:

4.58.1.1 Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

4.58.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

4.58.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

4.58.2.1 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

4.58.2.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.

Amend 4.61.4 to read:

~~4.61.4 A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in~~

~~4.61.4.1 The procedures identified in RHA 4.61.1.4; and~~

~~4.61.4.2 The operating procedures for the unit.~~

4.61.4 Training and Instructions.

4.61.4.1 Prior to the first use for 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.

4.61.4.2 A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—

4.61.4.2.1 The procedures identified in paragraph 4.61.1.4 of this section; and

4.61.4.2.2 The operating procedures for the unit.

Amend 4.61.7 to read:

4.61.7 A licensee shall retain a copy of the procedures required by RHA 4.61.1.4 and 4.61.4.2.2 of this section in accordance with RHA 4.108.

Amend the title of 4.72 to read:

RHA 4.72. ~~Five-Year Inspection~~Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

Amend 4.72.1 to read:

4.72.1 ~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

Amend 4.74 to read:

~~—4.74.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user of a sealed source for a use authorized under RHA 4.58 to be a physician who—

~~—~~4.74.1.~~1~~ Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s 4.74.1.4 and 4.74.1.5~~ 4.74.3 of this section. ~~(~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's Medical Uses Licensee Toolkit Web page~~, www.nrc.gov.)~~. To have its certification process recognized, a specialty board shall require all candidates for certification to:

~~—~~4.74.1.~~1.~~1 Successfully complete a minimum of 3 years of residency training in radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physician and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

~~—~~4.74.1.~~1.~~2 Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

~~—~~4.74.~~1.~~2 Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

~~—~~4.74.~~1.~~2.1 200 hours of classroom and laboratory training in the following areas—

~~—~~4.74.~~1.~~2.1.1 Radiation physics and instrumentation;

~~—~~4.74.~~1.~~2.1.2 Radiation protection;

~~—~~4.74.~~1.~~2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

~~—~~4.74.~~1.~~2.1.4 Radiation biology; and

—4.74.~~1.~~2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements at a medical ~~institution~~facility that is authorized to use radioactive materials in RHA 4.58, involving—

—4.74.~~1.~~2.2.1 Reviewing full calibration measurements and periodic spot-checks;

—4.74.~~1.~~2.2.2 Preparing treatment plans and calculating treatment doses and times;

—4.74.~~1.~~2.2.3 Using administrative controls to prevent a medical event involving the use of radioactive material;

—4.74.~~1.~~2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

—4.74.~~1.~~2.2.5 Checking and using survey meters; and

—4.74.~~1.~~2.2.6 Selecting the proper dose and how it is to be administered; and

4.74.~~1~~2.3 Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or 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 RHA 4.74.~~1.~~2.2; and

4.74.~~1~~2.4 ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.74.1.1.1, or 4.74.1.2 and 4.74.1.3 and 4.74.1.5 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.74 or equivalent NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.~~Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.74.2.1, 4.74.2.2, 4.74.2.3, and 4.74.3 of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

4.74.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

4.74.2.4.2 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 RHA 4.23, 4.74, or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) 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 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 paragraphs 4.74.2.1, 4.74.2.2, and 4.74.2.3 of this section.

—4.74.~~1.5~~3 Has received training in device operation, safety procedures, and clinical use for the type(s) 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 authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Add 4.89.3 to read:

4.89.3. For each Associate Radiation Safety Officer appointed under RHA 4.13.2, the licensee shall retain, for 5 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 the licensee's management.

Amend 4.102 to read:

A licensee shall maintain a record of safety instructions required by RHA 4.41, 4.49, and the operational and safety instructions required by RHA 4.61 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Amend the title of 4.116 to read:

RHA 4.116. Records of ~~5-Year Inspection~~Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

Amend 4.116.1 to read:

4.116.1 A licensee shall maintain a record of the ~~5-year inspections~~full-inspection and servicing for teletherapy and gamma stereotactic radiosurgery units required by RHA 4.72 for the duration of use of the unit.

Amend 4.117.1 to read:

4.117.1 A licensee 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 results in –~~

4.117.1.1 The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in –

4.117.1.1.1 A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

4.117.1.1.1.1 The total dose delivered differs from the prescribed dose by 20 percent or more; or

4.117.1.1.1.2 The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

__4.117.1.1.1.3 The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

__4.117.1.1.2 A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

__4.117.1.1.2.1 An administration of a wrong radioactive drug containing radioactive material; or

__4.117.1.1.2.2 An administration of a radioactive drug containing radioactive material by the wrong route of administration; or

__4.117.1.1.2.3 An administration of a dose or dosage to the wrong individual or human research subject; or

__4.117.1.1.2.4 An administration of a dose or dosage delivered by the wrong mode of treatment; or

__4.117.1.1.2.5 A leaking sealed source.

~~4.117.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

4.117.1.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

4.117.1.1.3.1 0.5 Sv (50 rem) 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; and

4.117.1.1.3.2 50 percent 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.

4.117.1.2 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 results in—

4.117.1.2.1 The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

4.117.1.2.2 The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

4.117.1.2.3 An administration that includes any of the following:

4.117.1.2.3.1 The wrong radionuclide;

4.117.1.2.3.2 The wrong individual or human research subject;

4.117.1.2.3.3 Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

4.117.1.2.3.4 A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

Amend 4.117.7.1.2 to read:

4.117.7.1.2 ~~Social security number or other identification number, if one has been assigned,~~Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

Amend 4.118.6.1.2 to read:

4.118.6.1.2 ~~Social security number or other identification number, if one has been assigned,~~Identification number or if no other identification number is available, the social security number of the ~~pregnant individual or the nursing child~~individual who is the subject of the event; and

Add 4.120 to read:

RHA 4.120 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

4.120.1 The licensee shall notify by telephone the Department and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 4.38.1 at the time of generator elution. The telephone report to the Department 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.

4.120.2 By an appropriate method listed in RHA 1.13 of this chapter, the licensee shall submit a written report to the Department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must 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; and the probable cause and an assessment of failure in the licensee's equipment, procedures 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 4.120.1 of this section.

Amend 5.14 to read:

5.14.1 The licensee 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 direct reading dosimeter, an operating alarm rate meter and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters

that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

5.14.2 Pocket dosimeters or electronic personal dosimeters must be read and exposures recorded at the beginning and end of each shift. The licensee shall retain each record of these exposures in accordance with RHA 5.14.7.1.

5.14.3 Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records must be maintained in accordance with RHA 5.14.7.1.

5.14.4 If an individual's pocket chamber is found to be off scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's 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 licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in records to be maintained by the licensee until the Department terminates the license.

If the personnel dosimeter that is required by RHA 5.14.1 is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records to be maintained until the Department terminates the license.

5.14.5 ~~Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months. After replacement, each personnel dosimeter must be processed as soon as possible. Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with RHA 5.14.7.3. 3~~Dosimetry results must be retained in accordance with RHA 5.14.7.

5.14.6 Each alarm rate meter must:

5.14.6.1 Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

5.14.6.2 Be set to give an alarm signal at a preset dose rate of 500 mR/hr.;

5.14.6.3 Require special means to change the preset alarm function; and

5.14.6.4 Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable rate meters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of these calibrations must be maintained in accordance with RHA 5.14.7.2.

5.14.7 Each licensee shall maintain the following exposure records specified in RHA 5.14:

5.14.7.1 Direct reading dosimeter readings and yearly operability checks required by RHA 5.14.2 and 5.14.3 for 3 years after the record is made.

5.14.7.2 Records of alarm ratemeter calibrations for 3 years after the record is made.

5.14.7.3 Personnel dosimeter results ~~received from the accredited NVLAP processor~~ must be retained until the Department terminates the license.

5.14.7.4 Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters until the Department terminates the license.

Amend 8.21.1 to read:

8.21.1 The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears~~,~~ a personnel dosimeter at all times during the handling of radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed.~~All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

Amend 11.20.1 to read:

11.20.1 Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be ~~accredited by the National Voluntary Laboratory Accreditation Program for~~capable of detecting high energy photons in the normal and accident dose ranges ~~(see RHA 3.16.3)~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

Amend 12.5.2.2 to read:

12.5.2.2 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. Licensees shall provide oath or affirmation certificates to the Department. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RHA 12.6.3.

Amend 12.7.3 to read:

12.7.3.1 For the purpose of complying with this ~~S~~subpart ~~B~~, Department 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 U.S NRC~~Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program, Mail Stop T-8B20, Rockville, MD 20852~~ ATTN: Criminal History Program, Mail Stop TWB-05 B32M~~, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), 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 the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to~~e-mailing

~~*FORMS.*~~*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.

12.7.3.2 Fees for the processing of fingerprint checks 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 "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 301-415-7513~~Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals~~Licensee Criminal History Records Check & 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?).

12.7.3.3 The U.S. Nuclear Regulatory Commission will forward to the submitting Department licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Amend 12.12.4 to read:

12.12.4 Protection of information.

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

12.12.4.2 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 that have been approved for unescorted access.

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

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

12.12.4.3.2 If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, safeguards information, or safeguards information modified handling, the licensee must 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 RHA 12.6.1.2 through 12.6.1.7.

12.12.4.4 Licensees need not subject the following individuals to the background investigation elements for protection of information:

12.12.4.4.1 The categories of individuals listed in RHA 12.8.1.1 through 12.8.1.13; or

12.12.4.4.2 Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RHA 12.6.1.2 through 12.6.1.7, has been provided by the security service provider.

12.12.4.5 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 that have been approved for unescorted access.

12.12.4.6 Licensees shall maintain a list of persons currently approved for access to the security plan ~~or,~~ implementing procedures, or the list of individuals that 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 that 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 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.7 When not in use, the licensee shall store its security plan ~~and,~~ implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

12.12.4.8 The licensee shall retain as a record for 3 years after the document is no longer needed:

12.12.4.8.1 A copy of the information protection procedures; and

12.12.4.8.2 The list of individuals approved for access to the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

Amend 12.23.1.1 to read:

12.23.1.1 The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal~~, and Rulemaking~~ Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the Department may be made by email to RAMQC_shipments@dhec.sc.gov or by fax to 803-898-0391. Notifications to the Department must be to the Director, Division of Land & Waste Management, Bureau of Waste Management, 2600 Bull Street, Columbia, SC 29201

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 13-7-40 et seq.

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-63, Radioactive Materials (Title A). Interested persons may submit comment(s) on the proposed amendments to the Bureau of Radiological Health; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on November 23, 2020, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to R.61-63, Radioactive Materials (Title A), the Department is responsible for regulatory and licensing standards, disposal, use, reports, storage, and inspections relating to various uses of radioactive materials. The Department proposes amending R.61-63 to incorporate federal regulations to maintain its status with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State and ensure compatibility with federal regulations as required by Section 274 of the Atomic Energy Act of 1954.

The NRC promulgates amendments to NRC Regulation Title 10, Code of Federal Regulations ("CFR") throughout each calendar year. Recent amendments include definitions, training and experience, and clarification regarding medical use of byproduct material as published in the Federal Register at 83 FR 33046 on July 16, 2018; organizational corrections in 10 CFR parts 37, 40, 70, and 71 as published in the Federal Register at 83 FR 57231 on November 21, 2018; miscellaneous corrections to 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140 as published in the Federal Register at 83 FR 30285 on June 28, 2018; miscellaneous corrections to 10 CFR Parts 2, 21, 37, 50, 52, 73, and 110 as published in the Federal Register at 83 FR 63565 on November 18, 2019; organizational changes and conforming amendments to 10 CFR Parts 1, 2, 37, 40, 50, 51, 52, 55, 71, 72, 73, 74, 100, 140, and 150 as published in the Federal Register at 84 FR 65639 on December 5, 2019; individual monitoring devices in 10 CFR Parts 34, 36, and 39 as published in the Federal Register at 85 FR 15347 on March 18, 2020; and social security number fraud prevention 10 CFR Parts 9 and 35 as published in the Federal Register at 85 FR 33527 and 85 FR 44685 on June 2, 2020.

The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department proposes these amendments for compliance with federal law.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

February 11, 2021

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for a fourth nine-month Board extension, the sixth extension in total, of Certificate of Need ("CON") SC-16-19, issued to Trident Medical Center, LLC doing business as Berkeley Medical Center ("BMC") for construction of a new 50 bed acute care hospital to include an MRI and a CT scanner.

II. SUBJECT: Request for a fourth nine-month Board extension, sixth extension in total, of CON SC-16-19, issued to Trident Medical Center, LLC doing business as Berkeley Medical Center.

III. FACTS:

CON SC-16-19 was issued to BMC on May 26, 2016 for the referenced project. The original CON had an expiration date of May 26, 2017. BMC requested a first staff extension of the CON on April 24, 2017, which was more than 30 days prior to expiration. BMC received CON SC-16-19-EXT-1 on May 17, 2017, valid until February 26, 2018, a period of nine months from the original expiration of the CON.

BMC requested a second staff extension of the CON on January 26, 2018, which was 30 days prior to expiration. BMC received CON SC-16-19-EXT-2 on March 5, 2018, valid until November 26, 2018, a period of nine months from the revised expiration of the CON.

BMC requested a third extension from the Board, first Board extension, on August 24, 2018, which was 90 days prior to expiration, and the Board approved this request on November 11, 2018. BMC received CON SC-16-19-EXT-3 on November 28, 2018, and it expired on August 26, 2019.

BMC requested a fourth extension from the Board, second Board extension, on May 22, 2019 which was 90 days prior to expiration, and the Board approved this request on August 8, 2019. BMC received CON SC-16-19-EXT-4 on August 28, 2019, and it expired May 26, 2020.

BMC requested a fifth extension from the Board (third Board extension) on February 25, 2020, which was 90 days prior to expiration, and the Board approved this request on May 7, 2020. BMC received CON SC-16-19-EXT-5 on May 27, 2020, and it will expire on February 26, 2021.

In accordance with R. 61-15, Section 601, BMC submitted a sixth extension request (fourth Board extension request) to the Department on November 20, 2020, which is more than 90 days prior to expiration.

IV. ANALYSIS:

Department staff have reviewed all relevant information concerning this extension request and find that BMC has not demonstrated substantial progress sufficient to warrant further extension of CON SC-16-19.

BMC's stated grounds for its request are delay in implementing the project due to:

1. An unforeseen wetland issue;

2. Opposition by Medical University Hospital Authority (MUHA), the parent of MUSC, in connection with BMC's second and third extension requests;

3. The ongoing pandemic; and

4. The approval of a 128-bed hospital to be constructed by MUSC, a project which is under appeal but is moving forward after a lifting of the automatic stay and issuance of CON SC-20-25.

Although the Department has extended expiration of this CON nearly four years past its original expiration date, BMC has not yet determined when, or if, it will be able to resume any progress with the project, and has not demonstrated that this delay is caused by extenuating circumstances beyond BMC's control. According to the documentation submitted to the Department by BMC in support of this request, while the issue with wetlands mitigation has been resolved for at least a year, BMC has ceased negotiation towards securing an architectural contract.

While BMC's second extension request was opposed by MUSC, MUSC did not oppose any subsequent extension requests, and thus MUSC's challenge has no bearing on the current request.

While the COVID-19 pandemic has almost certainly impacted operations of healthcare facilities throughout South Carolina, BMC has not demonstrated how the pandemic impacts progress on a not-yet-existing facility.

The timeline proposed by BMC for continuation of the project hinges not on contracts, land issues, resources, or even the ongoing pandemic, but focuses solely on BMC's ongoing appeal of the Administrative Law Court's order approving MUSC's project (SC-20-25). BMC has not demonstrated how it's appeal in an unrelated matter constitutes circumstances beyond its control that would prevent this project from moving forward immediately.

In the months since the wetlands issues were resolved and the Board approved a previous extension of SC-16-19, BMC has demonstrated no additional progress towards development of final architectural drawings and has failed to provide reasonable assurance that the project will be under construction or implemented within the requested extension timeframe.

V. RECOMMENDATION:

Department staff recommend that the Board finds BMC has not demonstrated substantial progress in connection with CON SC-16-19, that circumstances causing delay are within the control of BMC, and that the Board deny BMC's request for a fourth nine-month Board extension, the sixth extension in total.

Submitted by:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

Attachments:

A. CON SC-16-19
B. Letter granting first extension of CON
C. Letter granting second extension of CON
D. Letter granting third extension of CON
E. Letter granting fourth extension of CON
F. Letter granting fifth extension of CON
G. Letter requesting sixth extension of CON

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until May 26, 2017 which is a period of twelve (12) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 26th day of May, 2016.

Louis W. Eubank
Director, Certificate of Need Program

D H E C
PROMOTE PROTECT PROSPER

Article #: 9214896900999790140838699 1

May 17, 2017

VIA EMAIL AND CERTIFIED MAIL
William R. Thomas
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley Medical Center

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a nine (9) month initial extension** for Certificate No. SC-16-19. The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank
Director, Certificate of Need Program

Enclosures: Guide to Board Review.
CON SC-16-19-EXT-1

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
    - include the place, date and time of the Conference;
    - state the presentation times allowed in the Conference;
    - state evidence may be presented at the Conference;
    - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
    - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
    - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
        - Type of decision (permit, enforcement, etc.) and description of the program.
        - Parties
        - Description of facility/site
        - Applicable statutes and regulations
        - Decision and materials relied upon in the administrative record to support the staff decision.
    - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
    - Rebuttal by Department staff [15 minutes]
    - Rebuttal by Requestor(s) [10 minutes]
      Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-1

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until February 26, 2018 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 17th day of May.

Louis W. Eubank
Director, Certificate of Need Program

dhec
Healthy People. Healthy Communities.

Article #: 9214896900999790141109103 5

March 5, 2018

VIA EMAIL AND CERTIFIED MAIL
William R. Thomas, Esquire
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Based on the assurances you have provided the Department, it is understood that the wetlands permitting process currently before the U.S. Army Corps of Engineers will be complete, or nearly complete, by the time of expiration of this second CON extension. Further extensions of SC-16-19 may be granted by the Department Board, with recommendations made by staff, based on current information **to include the status of this permitting process**.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: M. Elizabeth Crum, Esquire (email)

Enclosures: Guide to Board Review.
CON SC-16-19-EXT-2

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
    - include the place, date and time of the Conference;
    - state the presentation times allowed in the Conference;
    - state evidence may be presented at the Conference;
    - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
    - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
    - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
        - Type of decision (permit, enforcement, etc.) and description of the program.
        - Parties
        - Description of facility/site
        - Applicable statutes and regulations
        - Decision and materials relied upon in the administrative record to support the staff decision.
    - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
    - Rebuttal by Department staff [15 minutes]
    - Rebuttal by Requestor(s) [10 minutes]

    Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-2

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until November 26, 2018 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 5th day of March, 2018.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

dhec
Healthy People. Healthy Communities.

Healthy People. Healthy Communities.

Article #: 9214896900999790141344465 5

November 28, 2018

VIA EMAIL AND CERTIFIED MAIL
William R. Thomas, Esquire
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Please note that all subsequent requests for extension of SC-15-26 are subject to approval by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: William R. Thomas, Esquire (email)
M. Elizabeth Crum, Esquire (email)

Enclosures: CON SC-16-19-EXT-3

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-3

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until August 26, 2019 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 28th day of November, 2018.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

dhec
Healthy People. Healthy Communities.

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
   - include the place, date and time of the Conference;
   - state the presentation times allowed in the Conference;
   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Healthy People. Healthy Communities

Article #: 9214896900999790141570677 5

August 26, 2019

VIA EMAIL AND CERTIFIED MAIL

Jim Rardin
Trident Medical Center
9330 Medical Plaza Drive
North Charleston, SC 29406

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a fourth nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Please note that all subsequent requests for extension of SC-15-26 are subject to approval

by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: William R. Thomas, Esquire (email)

Enclosures: CON SC-16-19-EXT-4

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
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3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
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7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

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   - include the place, date and time of the Conference;
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   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

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   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
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   - Rebuttal by Requestor(s) [10 minutes]

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3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
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6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-4

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until May 26, 2020 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 26th day of August, 2019.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

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Healthy People. Healthy Communities.

THE ENCLOSED LETTER CONTAINS VITAL INFORMATION. PLEASE REVIEW IT CAREFULLY AND COMPLETELY TO ENSURE COMPLIANCE WITH RELEVANT LAWS AND REGULATIONS.

May 27, 2020

VIA EMAIL AND CERTIFIED MAIL
Todd Gallati
Trident Medical Center
9330 Medical Plaza Drive
North Charleston, SC 29406

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Gallati:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a fifth nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Please note that all subsequent requests for extension of SC-16-19 are subject to approval

by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: William R. Thomas, Esquire (email)

Enclosures: CON SC-16-19-EXT-5

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-5

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until February 26, 2021 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 27th day of May, 2020.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

dhec
Healthy People. Healthy Communities.

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
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   - The grounds for amending, modifying, or rescinding the staff decision;
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    - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
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        - Description of facility/site
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    - Rebuttal by Department staff [15 minutes]
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7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Parker Poe

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November 20, 2020

Via Hand Delivery and Email

The Honorable M. Denise Crawford
Clerk of the Board
South Carolina Department of Health and
Environmental Control
2600 Bull Street
Columbia, SC 29201

Re: **Trident Medical Center, LLC, d/b/a Berkeley Medical Center**
Certificate of Need for the Construction of a New 50-Bed Hospital to Include an MRI and CT Scanner
CON Number: SC-16-19
Sixth Extension Request

Dear Ms. Crawford:

On behalf of our client, Trident Medical Center, LLC, d/b/a Berkeley Medical Center ("Trident"), and pursuant to S.C. Code Ann. § 44-7-230(D) and S.C. Reg. 61-15, §§ 601 – 603, Trident respectfully requests an extension of the above-referenced Certificate of Need (SC-16-19). The CON is due to expire on February 26, 2021. Thus, Trident is requesting that the Board extend SC-16-19 expiration date to November 26, 2021. As required, Trident is submitting this request more than three months before the expiration date of the Certificate of Need, and is providing the information required under Sections 601(4), 602 and 603.

a. A detailed description of any changes in the configuration, costs, services, or scope of the project.

RESPONSE: There are no changes to the scope of the project, its configuration, costs, or services. As the Board is aware, Trident experienced delays in implementing the project due to an unforeseen wetlands issue and opposition filed by the Medical University Hospital Authority's ("MUHA") in connection with the Department's staff approval of Trident's second CON extension request, and the Department's Board decision to grant a third extension request. MUHA's opposition was defeated after the Administrative Law Court granted Trident summary judgment motion in the action filed by MUHA.

To date, Trident has incurred in costs approximately $3,772,322, which includes the cost of the wetlands mitigation credits, the purchase of the property, consultant costs related to the wetlands issues, and wetlands construction costs.

b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.

RESPONSE: The site has been procured, conceptual site plans for the hospital have been completed, and the wetlands mitigation credits were released in August 2019. The USACOE issued the required permit to relocate the man-made ditch/stream that was classified as wetlands, and after working with the engineers and site contractors to plan for site grading and erosion control, Trident released the contractors to begin construction to relocate the ditch/stream. The relocation of the ditch/stream was completed in January 2020, and Trident was in the process of negotiating the architectural contract with the architects. However, with the onslaught of the COVID pandemic, which continues today and is worsening, and the unforeseen financial and operational issues resulting therefrom, Trident decided to postpone negotiations in connection with the architectural contract for this project and devote its resources towards combatting the pandemic and keeping its permanent staff employed, which it has been able to do. Currently, cases and hospitalizations are spiking in the Charleston area and Trident is focused on maintaining its operational feasibility during this time into the foreseeable future.

Further, given the Department's approval of the 128-bed MUHA hospital project in Berkeley County, and the subsequent decision by the South Carolina Administrative Law Court to uphold the Department's decision, Trident is assessing its options with respect to its 50 bed hospital in Moncks Corner because it is unlikely to be operationally viable given the presence of a second hospital in the County that will be nearly three times larger than Trident's proposed project. Trident has, however, filed a Notice of Appeal with the South Carolina Court of Appeals in an effort to overturn the ALC's recent order approving MUHA's CON application. It believes its effort will be successful given the errors of law and fact in the ALC's Order.

c. An estimated timetable for commencement and completion of all remaining components of the project.

Trident proposes the following timeline for completion of the project after successfully appealing the ALC's Order approving MUHA's Berkeley hospital project.

Finalize Site	2 months after appeal decision
Architectural Contract	3 months after appeal decision
Architectural Design	8 months after appeal decision
Construction Contract	10 months after appeal decision
Start of Construction	11 months after appeal decision
Completion of Construction	2 years, 7 months after appeal decision
Occupy new hospital	2 years, 9 months after appeal decision

d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstance[s] beyond the control of the applicant [exist] if the timetable was not met.

RESPONSE: As described above, the Berkeley Medical Center project has been delayed due to unforeseen wetlands issues, a lawsuit brought by another hospital challenging Trident's CON extension, the COVID-19 pandemic, and the unlikely approval of a third hospital in Berkeley County that will consist of 128 beds and serve the same service area that Trident

Medical Center currently serves, that Roper's Berkeley hospital currently serves, and that Trident's Berkeley Medical Center would have served. Trident believes the pandemic and the approval of a large hospital in the service area Trident's Moncks Corner hospital would have served constitute extenuating circumstances beyond Trident's control.

For these reasons, Trident respectfully requests that the Board find that Trident has made as much progress as possible given the circumstances; that its project has been delayed due to extenuating circumstances beyond its control; and that a sixth extension of Berkeley Medical Center project is justified and approved.

With best regards, I am

Sincerely,

William R. Thomas

cc: Margaret P. Murdock, Esquire (via hand delivery)
Todd Gallati (via email)