SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 8, 2022

( ) 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 July 1, 2022, through July 31, 2022.

III. **FACTS:** For the period of July 1, 2022, through July 31, 2022, Healthcare Quality reports 2 Administrative Orders and 6 Consent Orders totaling $31,500 in assessed monetary penalties.

Name of Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Emergency Suspension Orders	Assessed Penalties	Required Payment
Community Care	Community Residential Care Facility (CRCF)	1	1	0	$20,300	$15,000
	Residential Treatment Facilities for Children and Adolescents (RTF)	0	1	0	$3,000	$3,000
Healthcare Systems and Services	Paramedic	1	0	0	$800	$800
Radiological Health	Dental X-ray	0	1	0	$1,700	$425
	Chiropractic X-ray	0	3	0	$5,700	$1,425
TOTAL		**2**	**6**	**0**	**$31,500**	**$20,650**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

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

September 8, 2022

Bureau of Community Care

Facility Type	Total Number of Licensed Facilities	Total Number of Licensed Beds
Community Residential Care Facility (CRCF)	473	21,577

1. Hannah Residential Manor – Pamplico

Investigation and Violations: The Department conducted investigations on March 1, 2021, March 9, 2021, April 21, 2021, June 23, 2021, September 16, 2021, and October 6, 2021, a routine licensing inspection on May 11, 2021, and follow-up licensing inspections on June 23, 2021 and February 24, 2022. The Department cited the facility for a total of 87 violations during these visits.

More specifically, the Department cited the facility for violating Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, as follows:

- The facility was cited twice for employing a person under the age of 18.
- The facility failed to submit to the Department timely acceptable written plans of correction.
- The facility repeatedly failed to have documentation of initial and/or annual in-service training in the following: basic first aid for staff, management/care of persons with contagious and/or communicable disease, medication management, care of persons specific to the physical/mental condition being care for in the facility, use of physical restraint techniques, OSHA bloodborne pathogens, confidentiality of resident information and records, *Bill of Rights for Residents of Long-Term Care Facilities*, S.C. Code Sections 44-81-10 *et seq.*, fire response, and emergency procedures/disaster preparedness.
- The facility failed to report a serious incident to the Department within 24 hours of the incident.
- The facility twice failed to document resident orders and recommendations for medication, care, services, procedures, and diet from physicians or other authorized healthcare providers.
- The facility repeatedly failed to document notes of observation for residents at least monthly.
- The facility failed to have documentation of a written assessment of a resident no later than 72 hours after admission.
- The facility repeatedly failed to have documentation of a resident's individual care plan.
- The facility repeatedly failed to render care in accordance with physician's orders for administering medications.
- The facility failed to have a current activity schedule posted for residents.
- The facility repeatedly failed to have documentation of residents' physical examinations completed within 30 days prior to admission and at least annually thereafter.
- The facility twice failed to ensure residents had a two-step TST upon admission.
- The facility provided or administered medications ordered for a specific resident to another resident.

- The facility repeatedly failed to initial the medication administration records (MARs) as medications were administered.
- The facility twice failed to have documented reviews of MARs at each shift change by outgoing staff with incoming staff.
- The facility failed to update a medication label after a physician changed the dosage for the medication.
- The facility stored expired and/or discontinued medication with current medications.
- The facility failed to maintain records of receipt, administration, and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation.
- The facility repeatedly failed to have documented reviews of the control sheets at each shift change by outgoing staff with incoming staff.
- The facility left medication unsecured and accessible in resident's room.
- The facility repeatedly failed to ensure the kitchen and food prepared onsite meet the requirements of Regulation 61-25.
- The facility repeatedly failed to maintain all equipment and building components in good repair and operating condition.
- The facility repeatedly failed to promote conditions that prevent the spread of infectious, contagious, and/or communicable diseases in compliance with guidelines from the CDC.
- The facility repeatedly failed to ensure it is free of vermin and/or offensive odors.
- The facility repeatedly failed to ensure that each specific interior area was cleaned.
- The facility failed to ensure harmful chemicals were stored safely and inaccessible to residents.
- The facility failed to keep the grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.
- The facility failed to store clean linen/clothing in a sanitary manner.
- The facility failed to ensure all flooring and finishes were free from hazards.
- The facility repeatedly failed to ensure oxygen cylinders and concentrators are properly secured in place.
- The facility failed to ensure smoking is only allowed in designated area outside of facility.
- The facility failed to provide a sanitary individualized method of drying hands in a shared restroom and by failing to have hand soap in a shared restroom.
- The facility failed to have a supply of toilet tissue in each bathroom.

Enforcement Action: The Department held an enforcement conference with the facility but the parties were unsuccessful in trying to reach an agreement. As a result, the Department issued an Administrative Order revoking the license to operate Hannah Residential Care as a community residential care facility (CRCF) in part due to engaging in conduct or practices detrimental to the health or safety of residents or employees of a facility. The residents of the facility were safely relocated before the facility closed on August 2, 2022.

Remedial Action: N/A.

Prior Orders: None in the past five years.

2. Harmony House Residential Care – Calhoun Falls

Investigation and Violations: The Department conducted routine licensing inspections, kitchen and sanitation inspections, fire and life safety inspections, investigations, and follow-up inspections in February 2021, June 2021, August 2021, September 2021, November 2021, and December 2021.

As a result of these visits, the Department found the facility in violation of Regulation 61-84, *Standards for Licensing Community Residential Care Facilities,* as follows:

- The facility repeatedly failed to submit to the Department written plans of correction when there was noncompliance with the licensing standards.
- The facility failed to demonstrate a working knowledge of applicable regulations.
- The facility failed to have at least one staff member/direct care volunteer for each eight residents or fraction thereof on duty during periods of peak hours.
- The facility twice failed to have documentation of initial and/or annual staff in-service training in medication management.
- The facility twice failed to have documentation of initial and/or current annual staff in-service training in the *Bill of Rights for Residents of Long-Term Care Facilities*, S.C. Code Sections 44-81-10 *et seq.*
- The facility twice failed to post a current monthly activity schedule.
- The facility twice failed to have residents' physician-ordered medications available for administration.
- The facility twice failed to initial the medication administration records (MARs) as medications were administered.
- The facility twice failed to have documented reviews of the control sheets at each shift change by outgoing staff with incoming staff.
- The facility twice failed to ensure that the facility's kitchen and the food prepared onsite meet the requirements of Regulation 61-25.
- The facility failed to maintain and test fire protection and suppression systems in accordance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.
- The facility failed to ensure unannounced fire drill are conducted at least quarterly and records of fire drills are maintained in the facility.
- The facility failed to ensure that all drills were designed to ensure that residents attain the experience of exiting through all exits.
- The facility repeatedly failed to maintain all equipment and building components in good repair and operating condition.
- The facility repeatedly failed to promote conditions that prevent the spread of infectious, contagious, and/or communicable diseases in compliance with guidelines from the CDC.
- The facility repeatedly failed to ensure the facility was free of vermin.
- The facility repeatedly failed to provide a sanitary individualized method of drying hands in shared restroom and failed to have liquid soap available in a shared resident restroom.

Enforcement Action: The parties agreed to resolve this matter by Consent Order. The Department imposed a civil monetary penalty totaling $20,300 against the facility. The facility is required to pay $15,000 in five monthly installments of $3,000 each, and the remaining $5,300 will be stayed upon a six-month period of substantial compliance with Regulation 61-84 and this Consent Order. The facility agreed to initiate action to correct the violations that initiated the enforcement action and attend a compliance assistance meeting with the Department within 45 days of the Consent Order.

Remedial Action: The facility has made the first payment of $3,000. The facility attended a compliance assistance meeting with the Department on August 2, 2022.

Prior Orders: None in the past five years.

Facility Type	Total Number of Licensed Facilities	Total Number of Licensed Beds
Residential Treatment Facilities for Children and Adolescents	8	518

3. Riverside Behavioral Health Services at Windwood Farm – Awendaw

Investigation and Violations: On March 8, 2022, the Department conducted an investigation. As a result of the investigation, the Department found the facility in violation of Regulation 61-103, *Residential Treatment Facilities for Children and Adolescents.* More specifically, the Department found the facility failed to ensure that residents were free from harm, abuse, or neglect as outlined in the "Statement of Rights of Residents."

Enforcement Action: After meeting for an enforcement conference, the parties agreed to resolve this matter with a Consent Order. The facility agreed to pay a $3,000 monetary penalty. The facility further agreed to initiate action to correct the violations that prompted the enforcement action and ensure violations are not repeated.

Remedial Action: The facility has paid the $3,000 monetary penalty. The facility terminated the staff member involved.

Prior Orders: None in the past five years.

Bureau of Healthcare Systems and Services

Level of Certification	Total Number of Certified Paramedics
Paramedic	4,207

4. Jason Ramsey – Paramedic

Investigation and Violations: The Department conducted a compliance inspection and investigation into Mr. Rasmey and found that Mr. Ramsey had been providing patient care with an expired certification between August 2021 and October 2021. During that time, Mr. Ramsey was the primary attendant for 87 patient encounters with Dorchester County EMS. The Department determined Mr. Ramsey violated the EMS Act and Regulation 61-7, *Emergency Medical Services*, by performing patient care within the scope of a paramedic for 87 ambulance runs without obtaining proper certification from the Department. The Department sent Mr. Ramsey a Notice of Alleged Violation on May 3, 2022, requesting Mr. Ramsey submit a written corrective action plan demonstrating how he intended to prevent recurrences of the alleged violation.

Enforcement Action: The Department notified Mr. Ramsey that enforcement action was being considered and invited him to attend an enforcement conference. Mr. Ramsey was notified that failure to attend the

scheduled enforcement conference may result in an enforcement action by issuance of an Administrative Order without his consent. Mr. Ramsey did not attend the enforcement conference. The Department therefore issued an Administrative Order imposing a civil monetary penalty of $800 against Mr. Ramsey.

Remedial Action: The Department has not received Mr. Ramsey's payment.

Prior Orders: None in the past five years.

Bureau of Radiological Health

X-Ray Facility Registrant Type	Total Number of Registrants
Dental Facility	1,802

5. Aiken Augusta Oral & Facial Surgery – Aiken

Investigation and Violations: In September 2021, the Department conducted a routine inspection of the registrant. The Department determined the registrant failed to conduct equipment performance testing within 30 days of installation for its dental computed tomography and dental handheld x-ray systems. Additionally, the Department determined the registrant failed to conduct annual equipment performance testing in 2020 for the dental computed tomography x-ray system. The Department had previously cited the registrant for these violations of Regulation 61-64, *X-Rays (Title B)*, in September 2012 and June 2017.

Enforcement Action: The parties agreed to resolve this matter with a Consent Order. The Department imposed a civil monetary penalty totaling $1,700 against the registrant. The registrant is required to pay $425 within 30 days of executing the Consent Order with the remaining $1,275 stayed for 36 months.

Remedial Action: Prior to the execution of the Consent Order, the registrant provided a detailed plan of correction to prevent recurrence of the violation. The Department has received the registrant's payment.

Prior Orders: None in the past five years.

X-Ray Facility Registrant Type	Total Number of Registrants
Chiropractic Facility	497

6. Total Healthcare Chiropractic Clinic, LLC – Piedmont

Investigation and Violations: On May 19, 2021, the Department conducted a routine inspection of the registrant. During the inspection, the registrant provided the Department with records indicating the last equipment performance tests on its medical radiographic x-ray systems occurred in April 2019. After the inspection, the registrant emailed records to the Department indicating additional equipment performance tests were completed on May 24, 2021. As a result, the Department found the registrant failed to conduct

equipment performance testing for 2020. The Department had previously cited the registrant for this violation of Regulation 61-64, *X-Rays (Title B)*, in August 2012, August 2015, and March 2018.

Enforcement Action: The parties agreed to resolve this matter with a Consent Order. The Department imposed a civil monetary penalty totaling $1,900 against the registrant. The registrant is required to pay $475 within 30 days of executing the Consent Order with the remaining $1,425 stayed for 24 months.

Remedial Action: Prior to the execution of the Consent Order, the registrant provided a detailed plan of correction to avoid future violation. The Department has received the registrant's payment.

Prior Orders: None in the past five years.

7. Set Apart Health, LLC – Mauldin

Investigation and Violations: On August 12, 2021, the Department conducted a routine inspection of the registrant. During the inspection, the Department was provided with records indicating the last equipment performance test on its medical radiographic x-ray systems occurred on March 15, 2019. Following the inspection, the registrant provided documentation of equipment performance testing conducted on August 16, 2021, by a Department registered vendor and a corrective action plan to prevent recurrence of the violation. As a result, the Department found the registrant failed to conduct equipment performance testing for 2020 and timely conduct equipment performance testing for 2021. The Department had previously cited the registrant for this violation of Regulation 61-64, *X-Rays (Title B)*, in December 2015, December 2016, and September 2018.

Enforcement Action: The parties agreed to resolve this matter with a Consent Order. The Department imposed a civil monetary penalty totaling $1,900 against the registrant. The registrant is required to pay $475 within 30 days of executing the Consent Order with the remaining $1,425 stayed for 24 months.

Remedial Action: The Department has received the registrant's payment.

Prior Orders: None in the past five years.

8. Carolina Chiropractic Center – Florence

Investigation and Violations: On June 2, 2021, the Department conducted a routine inspection of the registrant. During the inspection, the registrant provided the Department with records indicating the last equipment performance tests on its medical radiographic x-ray system occurred on March 29, 2018. As a result, the Department found the registrant failed to conduct equipment performance testing for 2019, 2020, and 2021. The Department had previously cited the registrant for this violation of Regulation 61-64, *X-Rays (Title B)*, in March 2018.

In addition, the Department requested the registrant's corrective action plan for the June 2, 2021, violation on June 16, 2021, September 10, 2021, November 9, 2021, and December 7, 2021. As a result, the Department cited the registrant's failure to provide documentation of corrective action for violations alleged during the June 2, 2021, inspection within 60 days of the citation.

Enforcement Action: The parties agreed to resolve the matter with a Consent Order. The Department imposed a civil monetary penalty totaling $1,900 against the registrant. The registrant is required to pay $475 within 30 days of executing the Consent Order with the remaining $1,425 stayed for 24 months.

Remedial Action: Prior to executing the Consent Order, the registrant provided a detailed plan of correction describing steps to be taken to ensure future compliance with the cited violations. The registrant further provided documentation of equipment performance testing conducted by a Department registered vendor on June 7, 2022. The Department has received the registrant's payment.

Prior Orders: None in the past five years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
September 8, 2022

_____ 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 July 1, 2022, through July 31, 2022.

3. **FACTS:** For the reporting period of July 1, 2022, through July 31, 2022, the Office of Environmental Affairs issued forty-two (42) Consent Orders with total assessed civil penalties in the amount of one hundred two thousand, six hundred fifty dollars ($102,650.00). Also, thirteen (13) Administrative Orders with total assessed civil penalties in the amount of one hundred twenty thousand, five hundred eighteen dollars and twenty-five cents ($120,518.25) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	6	$89,758.25	9	$34,270.00
Aboveground Tanks	0	0	0	0
Solid Waste	1	$13,860.00	2	$6,300.00
Hazardous Waste	0	0	2	$25,500.00
Infectious Waste	0	0	0	0
Mining	0	0	0	0
SUBTOTAL	**7**	**$103,618.25**	**13**	**$66,070.00**
Water				
Recreational Water	0	0	8	$8,180.00
Drinking Water	0	0	1	0
Water Pollution	1	$6,000.00	2	$7,500.00
Dam Safety	0	0	0	0
SUBTOTAL	**1**	**$6,000.00**	**11**	**$15,680.00**
Air Quality				
SUBTOTAL	**0**	**0**	**0**	**0**
Environmental Health Services				
Food Safety	1	$10,400.00	18	$20,900.00
Onsite Wastewater	4	$500.00	0	0
SUBTOTAL	**5**	**$10,900.00**	**18**	**$20,900.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**13**	**$120,518.25**	**42**	**102,650.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
September 8, 2022

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 21-0422-UST
Order Date: April 12, 2022
Individual/Entity: **William J. Smith**
Facility: Smith & Brewington
Location: 1930 Main Street
Newberry, SC 29108
Mailing Address: 1216 Crenshaw Street
Newberry, SC 29202
County: Newberry
Previous Orders: None
Permit/ID Number: 19345
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 62-92, 280.65 (2012 & Supp 2020).

Summary: William J. Smith (Individual/Entity) owned property in Newberry County, South Carolina which formerly contained underground storage tanks (USTs). A release of petroleum products to the environment was confirmed during the time the Individual/Entity owned the property. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to determine the full extent of groundwater contamination at the Site.

Action: The Individual/Entity is required to submit a Tier II Assessment Report by July 8, 2022. The Department has assessed a civil penalty in the amount of ten thousand, nine hundred thirty-eight dollars and twenty-five cents ($10,938.25). The Individual/Entity shall pay a civil penalty in the amount of ten thousand, nine hundred thirty-eight dollars and twenty-five cents (**$10,938.25**) by June 23, 2022.

Update: The Individual/Entity did not file a Request for Review and has not complied with the Order. This has been referred to Office of General Counsel for further action. A summons and complaint has been filed. We have met with the Individual/Entity and are working to resolve the violation.

2) Order Type and Number: Administrative Order 21-0124-UST
Order Date: June 6, 2022
Individual/Entity: **Willie Dave Cooper Family Trust**
Facility: Cooper's Grocery
Location: 2129 I M Graham Road
Lake City, SC 29560
Mailing Address: 702 San Antonio Trail

Lake City, SC 76063
County: Williamsburg
Previous Orders: None
Permit/ID Number: 15828
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 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 2020).

Summary: Willie Dave Cooper Family Trust (Individual/Entity) owns an underground storage tank (UST) in Williamsburg County, South Carolina. On November 30, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain corrosion protection or appropriate release detection on a temporarily closed UST and failure to conduct monthly and annual walkthrough inspections.

Action: The Individual/Entity is required to submit: evidence a Walk-through Inspection log has been initiated and is being maintained and evidence the three thousand (3,000) gallon regular UST contains less than one (1) inch of liquid by August 8, 2022. The Department has assessed a total civil penalty in the amount of one thousand, eight hundred dollars ($1,800.00). The Individual/Entity shall pay a total civil penalty in the amount of one thousand, eight hundred dollars **($1,800.00)** by August 8, 2022.

Update: The Department received evidence the 3,000-gallon UST contained less than one inch of liquid. This has been referred to Office of General Counsel for further action.

3) Order Type and Number: Administrative Order 21-0011-UST
Order Date: June 8, 2022
Individual/Entity: **Rafat Abudayya**
Facility: Scotchman Mart
Location: 1109 East Liberty Street
Marion, SC 29571-4332
Mailing Address: 401 Lockemy Highway
Dillon, SC 29536
County: Marion
Previous Orders: None
Permit/ID Number: 06274
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.31(a), 280.34(c), 280.35(a)(2), 280.36(a)(1)(i), 280.36(a)(1)(ii), 280.40(a), 280.45(b)(1), and 280.242(b)(3) (2012 and Supp. 2020).

Summary: Rafat Abudayya (Individual/Entity) owns and operates underground storage tanks (USTs) in Marion County, South Carolina. On November 9, 2020, the Department conducted an inspection of the Facility and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain and operate a corrosion protection system continuously; failed to provide records to the Department

upon request; failed to test overfill prevention equipment once every three (3) years; failed to document monthly and annually required equipment walkthrough inspections; failed to provide an adequate release detection method; failed to maintain results of annual operation tests for three (3) years; and, failed to validate that monthly requirements have been met.

Action: The Individual/Entity is required to submit: proof the liquid from dispenser 1/2's under dispenser containment sump has been removed and disposed of properly; proof a Class A/B walkthrough/operator inspection log has been initiated and is being properly maintained; overfill prevention equipment operability test results for the 4,000-gallon regular and 6,000-gallon premium USTs; and a current passing automatic tank gauge record for all USTs at the facility as proof a valid release detection method is in place by August 27, 2022. The Department has assessed a total civil penalty in the amount of twelve thousand, seven hundred thirty dollars ($12,730.00). The Individual/Entity shall pay a civil penalty in the amount of twelve thousand, seven hundred thirty dollars **($12,730.00)** by August 27, 2022.

Update: The Individual/Entity did not file a Request for Review, therefore the Order is effective July 13, 2022. No documentation has been submitted.

4) Order Type and Number: Administrative Order 22-0075-UST
Order Date: June 14, 2022
Individual/Entity: **Gordhanbhai Patel**
Facility: Quick Food Mart 1
Location: 2555 North Dawson Drive
Chester, SC 29706
Mailing Address: 1139 Johnston Parkway
Kenly, NC 27542
County: Chester
Previous Orders: None
Permit/ID Number: 12357
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. and § 44-2-10(A) (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.21(b)&(c), 280.22(b), 280.31(a), 280.70(c), 280.93(a), and 280.110(c) (2012 & Supp 2020).

Summary: Gordhanbhai Patel (Individual/Entity) owns and operates underground storage tanks (USTs) in Chester County, South Carolina. Based on a file review, the Department issued a Notice of Alleged Violation on December 16, 2021. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to protect an operating UST system from corrosion; failed to submit written notification with supporting documentation within thirty (30) days of acquisition of a regulated UST system; failed to operate and maintain cathodic protection equipment continuously; failed to properly abandon a temporarily closed UST system after twelve (12) months; failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to submit: a completed Certificate of Financial Responsibility form and evidence of financial assurance; a completed Transfer of Ownership form; and a completed UST Tank and Sludge Disposal Form for the permanent closure of all USTs at the Facility by August 15, 2022; within thirty (30) days of the Department's approval of the UST Tank and Sludge Disposal Form, permanently

close the USTs; and within sixty (60) days of the permanent closure of the USTs, submit an UST Closure and Assessment Report. The Department has assessed a total civil penalty in the amount of fifty thousand, five hundred seventy-five dollars ($50,575.00). The Individual/Entity shall pay a civil penalty in the amount of fifty thousand, five hundred seventy-five dollars **($50,575.00)** by August 15, 2022.

Update: The Individual/Entity did not file a Request for Review.

5) Order Type and Number: Administrative Order 22-0500-UST
Order Date: June 21, 2022
Individual/Entity: **Raja Ram, LLC**
Facility: Quick C Food Mart
Location: 583 Lancaster Highway
Chester, SC 29706
Mailing Address: 3434 Millstone Creek Road
County: Chester
Previous Orders: None
Permit/ID Number: 16060
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. and § 44-2-10(A) (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.40(a)(2) (2012 & Supp 2020).

Summary: Raja Ram, LLC (Individual/Entity) owns and operates a compartmented underground storage tank (USTs) in Chester County, South Carolina. Based on a file review, the Department issued a Notice of Alleged Violation on August 10, 2021. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to properly maintain release detection equipment.

Action: The Individual/Entity is required to submit passing line leak detector function check results for the 2,000-gallon kerosene compartment of tank 2 by August 31, 2022. The Department has assessed a total civil penalty in the amount of five thousand, two hundred fifteen dollars ($5,215.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand, two hundred fifteen dollars **($5,215.00)** by August 31, 2022.

Update: Kerosene tank was emptied to less than one inch of liquid and will remain tagged until new line leak detector can be installed (backordered). Paid $1,500.00 civil penalty with remainder suspended. The Order is closed.

6) Order Type and Number: Administrative Order 21-0606-UST
Order Date: June 28, 2022
Individual/Entity: **Johnnie Capers**
Facility: Pringletown Quick Stop
Location: 1088 Old Gillard Road
Ridgeville, SC 29472
Mailing Address: P. O. Box 264
Ridgeville, SC 29472
County: Berkeley
Previous Orders: None
Permit/ID Number: 18369

Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 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 2020).

Summary: Johnnie Capers (Individual/Entity) own an underground storage tank (UST) in Berkeley County, South Carolina. On November 2, 2021, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: 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 thousand, five hundred dollars ($8,500.00). The Individual/Entity shall pay a total civil penalty in the amount of eight thousand, five hundred dollars **($8,500.00)** by August 12, 2022.

Update: The Individual/Entity did not file a Request for Review. The civil penalty was paid ($6,000.00) was paid July28, 2022; the remaining balance ($2,500.00) was suspended. The Order is closed.

7) Order Type and Number: Consent Order 22-0058-UST
Order Date: July 5, 2022
Individual/Entity: **South Carolina Aeronautics Commission**
Facility: SC Aeronautics Commission
Location: 2553 Airport Boulevard
West Columbia, SC 29169
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 05797
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.30(a) and 280.40(a)(3) (2012 and Supp. 2020).

Summary: South Carolina Aeronautics Commission (Individual/Entity) owns and operates underground storage tanks (USTs) in Lexington County, South Carolina. On November 10, 2021, the Department conducted an inspection of the Facility and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to ensure that releases due to spilling or overfilling do not occur; and failed to test tank release detection equipment annually.

Action: The Individual/Entity has corrected all violations. 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 August 19, 2022.

Update: The civil penalty has been paid. The Order is closed.

8) Order Type and Number: Consent Order 22-0153-UST
Order Date: July 5, 2022
Individual/Entity: **Lexington County**
Facility: Public Safety East Region Service Center
Location: 407 Foster Brothers Drive
West Columbia, SC 29171
Mailing Address: 401 Ballpark Road
Lexington, SC 29072-2241
County: Lexington
Previous Orders: None
Permit/ID Number: 19915
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 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 2020).

Summary: Lexington County (Individual/Entity) owns and operates underground storage tanks (USTs) in Lexington County, South Carolina. On May 31, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity corrected all violations prior to issuance of the Order. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a total civil penalty in the amount of six thousand dollars **($6,000.00)** by August 19, 2022.

Update: The civil penalty has been paid in full. The Order is closed.

9) Order Type and Number: Consent Order 22-0084-UST
Order Date: July 11, 2022
Individual/Entity: **Jones Petroleum Transport Co.**
Facility: Bradley's Marathon
Location: 1601 Harbor View Road
Charleston, SC 29412
County: Charleston
Previous Orders: None
Permit/ID Number: 01530
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-2-10 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 and Supp. 2020).

Summary: Jones Petroleum Transport Company (Individual/Entity) owns and operates underground storage tanks (USTs) in Charleston County, South Carolina. On January 25, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment of an UST system.

Action: The Individual/Entity corrected the violation prior to issuance of the

order. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars **($6,000.00)** by August 25, 2022.

Update: The Department received the civil penalty on July 12, 2022. The Order is closed.

10) Order Type and Number: Consent Order 22-0134-UST
Order Date: July 13, 2022
Individual/Entity: **RL Jordan Oil Company of NC, Inc.**
Facility: Hot Spot 1607
Location: 12340 Old 6 Highway
Eutawville, SC 29048
Mailing Address: P.O. Box 2527
Spartanburg, SC 29304-2527
County: Orangeburg
Previous Orders: None
Permit/ID Number: 13186
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-2-10 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 and Supp. 2020).

Summary: R. L. Jordan Oil Company of North Carolina, Inc. (Individual/Entity) owns and operates underground storage tanks (USTs) in Orangeburg County, South Carolina. On May 4, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment of an UST system.

Action: The Individual/Entity corrected the violation prior to issuance of the order. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2,000.00)** by August 29, 2022.

Update: The civil penalty has been paid in full. The Order is closed.

11) Order Type and Number: Consent Order 21-0628-UST
Order Date: July 19, 2022
Individual/Entity: **Digvijay Singh**
Facility: Godwin Brothers Grocery
Location: 105 E. Myrtle Beach Highway
Lake City, SC 29560
Mailing Address: 287 Traditions Court
Columbia, SC 29229
County: Florence
Previous Orders: None
Permit/ID Number: 11700
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-

2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.21(a)(3) and 280.70(c) (2012 and Supp. 2020).

Summary: Digvijay Singh (Individual/Entity) owns and operates underground storage tanks (USTs) in Florence County, South Carolina. On October 11, 2021, the Department conducted an inspection of the Facility and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to properly close a substandard UST system; and failed to properly abandon a temporarily closed system after twelve (12) months that does not meet either performance standards in Section 280.20 for new UST systems or the upgrading requirements in Section 280.21.

Action: The Individual/Entity is required to: submit a completed Tank and Sludge Disposal form by September 2, 2022; within sixty (60) days of the Department's approval, permanently close UST tank 3 and submit a UST Closure and Assessment Report. The Department has assessed a total civil penalty in the amount of ten thousand, nine hundred fifty dollars ($10,950.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand, nine hundred fifty dollars **($10,950.00)** by September 2, 2022.

Update: None.

12)

Order Type and Number:	Consent Order 22-0157-UST
Order Date:	July 19, 2022
Individual/Entity:	**Sam Cox**
Facility:	Bi Fast Mart 2
Location:	2800 Greenville Highway Easley, SC 29641
Mailing Address:	P.O. Box 1422 Easley, SC 29641-1422
County:	Pickens
Previous Orders:	None.
Permit/ID Number:	07182
Violations Cited:	The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 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 2020).

Summary: Sam Cox (Individual/Entity) operates underground storage tanks (USTs) in Spartanburg County, South Carolina. On June 2, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity corrected all violations prior to issuance of the Order. The Department has assessed a total civil penalty in the amount of three thousand, three hundred dollars ($3,300.00). The Individual/Entity shall pay a total civil penalty in the amount of three thousand, three hundred dollars **($3,300.00)** by September 2, 2022.

Update: The civil penalty has been paid. The order is closed.

13) Order Type and Number: Consent Order 22-0169-UST
Order Date: July 19, 2022
Individual/Entity: **TA Operating, LLC**
Facility: Travel Centers of America 262
Location: 7400 Wilson Boulevard
Columbia, SC 29203
Mailing Address: 24601 Center Ridge Road
Westlake, OH 44145
County: Richland
Previous Orders: None
Permit/ID Number: 09732
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 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 2020).

Summary: TA Operating, LLC (Individual/Entity) owns underground storage tanks (USTs) in Richland County, South Carolina. On June 2, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity corrected all violations prior to issuance of the Order. The Department has assessed a total civil penalty in the amount of three thousand, six hundred dollars ($3,600.00). The Individual/Entity shall pay a total civil penalty in the amount of three thousand, six hundred dollars **($3,600.00)** by September 2, 2022.

Update: The civil penalty payment was received on July 18, 2022. The Order is closed.

14) Order Type and Number: Consent Order 22-0149-UST
Order Date: July 29, 2022
Individual/Entity: **XPO Logistics Freight, Inc.**
Facility: XPO Logistics Freight, Inc. NAG
Location: 11026 Atomic Road
North Augusta, SC 29841
Mailing Address: 2211 Old Earhart Road, Suite 100
Ann Arbor, MI 48105
County: Aiken
Previous Orders: None
Permit/ID Number: 00241
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.93(a), and 280.110(c) (2012 and Supp. 2020).

Summary: XPO Logistics Freight, Inc. (Individual/Entity) owns an underground storage tank (UST) in Aiken County, South Carolina. On April 4, 2022, the Department conducted a file review of the Facility and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to demonstrate financial responsibility for an

UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to submit a completed Certificate of Financial Responsibility form and evidence of financial assurance by September 12, 2022. The Department has assessed a total civil penalty in the amount of twenty-six thousand, two hundred dollars ($26,200.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred dollars (**$1,200.00**) by September 12, 2022, and pay a suspended penalty in the amount of twenty-five thousand dollars ($25,000.00) should any of the requirements not be met.

Update: The Individual/Entity has submitted a completed Certificate of Financial Responsibility form and evidence of financial assurance.

15) Order Type and Number: Consent Order 22-0190-UST
Order Date: July 29, 2022
Individual/Entity: **RPR, LLC**
Facility: RPR
Location: 4512 Augusta Road
Greenville, SC 29605-1442
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 04159
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. §§ 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.93(a), and 280.110(c) (2012 and Supp. 2020).

Summary: RPR, LLC (Individual/Entity) owns underground storage tanks (USTs) in Greenville County, South Carolina. On May 2, 2022, the Department conducted a file review of the Facility and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to submit a civil penalty only. The Department has assessed a total civil penalty in the amount of one thousand, two hundred dollars ($1,200.00). The Individual/Entity shall pay a civil penalty in the amount of seven hundred twenty dollars **($720.00)** by September 12, 2022, and pay a suspended penalty in the amount of four hundred eighty dollars ($480.00) should any of the requirements not be met.

Update: A completed Certificate of Financial Responsibility and evidence of financial assurance was received on July 6, 2022. The civil penalty has been paid. The Order is closed.

Solid Waste Enforcement

16) Order Type and Number: Administrative Order 22-04-SW
Order Date: June 8, 2022
Individual/Entity: **378 Recycle Center, LLC**
Facility: 378 Recycle Center Composting Facility
Location: 4989 Sunset Boulevard
Lexington County, SC
Mailing Address: 5009 Sunset Boulevard
Lexington, SC 29072
County: Lexington
Previous Orders: 19-27-SW ($500.00)
Permit/ID Number: 322456-3002
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 (2018 & Supp. 2019) (Act) and the Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residuals Regulation (2015) (Regulation), R.61-107.4, Part III.E.1.d. and .E.1.e and Permit # 322456-3002 (Permit).

Summary: 378 Recycle Center, LLC (Individual/Entity), owns a composting facility in Lexington, South Carolina. Based on inspections, conducted September 24, 2021, December 31, 2021, and January 31, 2022, and the enforcement conference, the Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residuals Regulation, and Permit 322456-3002 as follows: exceeded the permitted capacity of unprocessed feedstocks and other material at the facility.

Action: The Individual/Entity is required to: cease receipt and/or transport of solid waste debris at the facility; and submit proof the storage of unprocessed feedstocks or other materials at the facility is less than 1,425 cubic yards by August 27, 2022. The Department assessed a total civil penalty in the amount of thirteen thousand, eight hundred sixty dollars ($13,860.00). The Individual/Entity shall pay a civil penalty in the amount of thirteen thousand, eight hundred sixty dollars **($13,860.00)** by August 27, 2022.

Update: The Individual/Entity did not file a Request for Review. The Order is effective July 13, 2022.

17) Order Type and Number: Consent Order 22-14-SW
Order Date: July 5, 2022
Individual/Entity: **H. V. Gore, Jr.**
Facility: Gore Tire Service
Location: 1400 East Liberty Street
Marion, SC 29571
Mailing Address: Same
County: Marion
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: Solid Waste Policy and Management Act of 1991, S.C. Code Ann. 44-96-10 et seq. (Rev. 2018 & Supp. 2019); Solid Waste Management: Waste Tires, R.61-107.3, Part III A.1, Part III.B.1, Part III B.3. (2015)

Summary: H. V. Gore, Jr. (Individual/Entity), owns a retail tire business in Columbia, South Carolina. After multiple inspections, the Department issued a Notice of Alleged Violation/Notice of Enforcement Conference on May 9, 2022. The Individual/Entity has violated the Act and the Regulations as follows: failed to obtain a permit to operate a waste tire collection facility from the Department before storing greater than one thousand (1,000) waste tires at the Facility and failed to separate used tires from waste tires, store by size, and stack or rack not more than two (2) rows wide in a manner that allowed for inspection of each tire.

Action: The Individual/Entity is required to: dispose of the waste tires over one thousand (1,000) at a Facility permitted by the Department to accept waste tires and provide disposal receipts to the Department; separate used tires from waste tires, store them by size in stacks or racks not more than two (2) rows wide in a manner that allows for the inspection of each tire; and submit a plan to maintain compliance with the Act and Regulations by August 5, 2022. The Department assessed a total civil penalty in the amount of one thousand, eight hundred dollars **(**$1,800.00**)**. The Individual/Entity shall pay a civil penalty in the amount of one thousand, eight hundred dollars **($1,800.00)** by August 5, 2022.

Update: The civil penalty has been paid. The plan was submitted and approved. The Order is closed.

18) Order Type and Number: Consent Order 22-12-SW
Order Date: July 20, 2022
Individual/Entity: **VLS Piedmont, LLC**
Facility: TMS # 095-00-00-047
Location: 1650 North Old Laurens Road
Gray Court, SC 29645
Mailing Address: 305 South Main Street
Mauldin, SC 29662
County: Laurens
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-40(34) (2002 & Supp. 2018).

Summary: The VLS Piedmont, LLC (Individual/Entity), operates a Recovered Materials Recycling Facility located in Laurens County, South Carolina. Based a records review, the Department issued a Notice of Alleged Violation. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, in that the Individual/Entity: failed to use, reuse, recycle, or transfer to a different site for use, reuse, or recycling the required 75% by weight of materials received the previous calendar year.

Action: The Individual/Entity is required to: ensure compliance with the 75% by weight recycling rate as required by S.C. Code Ann., Section 44-96-40(34) by the end of 2022; submit a permit application for a Solid Waste Processing Facility by April 1st of the following year should the 75% by weight recycling rate for 2022, 2023, or 2024 not be met; and submit annual reports for 2022, 2023, and 2024 on or before January 31st of the following year. The Department has assessed a civil penalty of four thousand, five hundred dollars ($4,500.00). The Individual/Entity shall pay a civil penalty of four thousand, five hundred dollars **($4,500.00)** by September 6, 2022.

Update: None.

Hazardous Waste Enforcement

19) Order Type and Number: Consent Order 22-12-HW
Order Date: July 5, 2022
Individual/Entity: **MUSC Health Florence Medical Center**
Facility: MUSC Health Florence Medical Center
Location: 805 Pamplico Highway, Florence, SC 29505
Mailing Address: Same
County: Florence
Previous Orders: N/A
Permit/ID Number: SCR 000 776 740
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. 2021).

Summary: MUSC Health Florence Medical Center (Individual/Entity) is an acute care facility providing an extensive range of services that include, but not limited to: emergency care, heart and vascular care, cancer treatment, orthopedic and general surgery at its facility located in Florence County, South Carolina. The Department conducted an inspection at the facility on February 17, 2022. 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 containers with an indication of the hazards of the contents; failed to equip areas where hazardous waste is either generated or accumulated with the equipment necessary to prepare for and respond to emergencies; failed to post the name and telephone number of the emergency coordinator, the location of fire extinguishers and spill control materials, and the telephone number of the fire department next to the telephones or in areas where hazardous waste is generated and accumulated; failed to keep a copy of signed manifest onsite for three (3) years; failed to declare generator status annually, failed to notify the Department that it was operating under Subpart P – Hazardous Waste Pharmaceuticals; failed to label containers of universal waste lamps and contain any lamps in a manner to prevent a release and to keep such containers closed; and failed to demonstrate the length of time universal waste had been accumulated from the date it became a waste.

Action: The Individual/Entity has corrected the violations. The Department assessed a total civil penalty in the amount of ten thousand, five hundred dollars ($10,500.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand five hundred dollars **($10,500.00)** by August 5, 2022.

Update: The civil penalty has been paid. The Order is closed.

20) Order Type and Number: Consent Order 22-11-HW
Order Date: July 19, 2022
Individual/Entity: **GKN Aerospace South Carolina, Inc.**
Facility: GKN Aerospace South Carolina, Inc.
Location: 174 Millennium Drive
Orangeburg, SC 29115

Mailing Address: Same
County: Orangeburg
Previous Orders: 20-01-HW ($6,000.00)
Permit/ID Number: SCR 000 784 041
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. 2018).

Summary: GKN Aerospace South Carolina, Inc. (Individual/Entity), specializes in the manufacturing of aerospace structures, engine systems, and special technologies at its facility located in Orangeburg County South Carolina. The Department conducted an inspection on January 25, 2021. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations: failed to mark or label its container with the following: (i) the words "Hazardous Waste" and (ii) an indication of the hazards of the contents; failed to ensure that a container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste; failed to ensure the container holding hazardous waste must not be opened, handled, or stored in a manner that may rupture the container or cause it to leak; failed to, at least weekly, inspect central accumulation areas; failed to label hazardous waste containers with an indication of the hazards of the contents and to ensure the date upon which the period of accumulation begins is clearly visible for inspection on each container; failed to ensure that facility personnel successfully complete a program of classroom instruction, online training, or on-the-job training that teaches them to perform their duties; failed to ensure that facility personnel successfully complete a hazardous waste training program within six (6) months after the date of their employment or assignment to the facility, or to a new position at the facility, whichever is later and to ensure that facility personnel must take part in an annual review of the initial training; failed to maintain at the facility the job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job and a written job description for each position listed under paragraph (a)(7)(iv)(A) of this section; failed to ensure that each battery or a container or package in which such batteries are contained, are labeled or marked clearly with any one of the following phrases: "Universal Waste -Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies)"; failed to ensure that each or a container in which the aerosol cans are contained is labeled or marked with one of the following phrases: "Universal Waste – Aerosol Can(s)," "Waste Aerosol Can(s)," or "Used Aerosol Can(s)"; failed to manage universal waste aerosol cans in a way that prevents releases of any universal waste or component of a universal waste to the environment; accumulated universal waste for longer than one (1) year from the date the universal waste was generated, or received from another handler; and failed to demonstrate the length of time that the universal waste had been accumulated from the date it became a waste or was received.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of fifteen thousand dollars ($15,000.00). The Individual/Entity shall pay a civil penalty in the amount of fifteen thousand dollars **($15,000.00)** by August 19, 2022.

Update: None.

BUREAU OF WATER

Recreational Waters Enforcement

21)	Order Type and Number:	Consent Order 22-019-RW
	Order Date:	July 11, 2022
	Individual/Entity:	**Airport Properties, Inc.**
	Facility:	Sandcastle North
	Location:	1802 North Ocean Boulevard Myrtle Beach, SC 29577
	Mailing Address:	P.O. Box 1362 Myrtle Beach, SC 29578
	County:	Horry
	Previous Orders:	None
	Permit/ID Number:	26-J85-1 & 26-J87-1
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Airport Properties, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a lazy river and a kiddie pool located in Horry County, South Carolina. The Department conducted inspections on May 31, 2022, and June 22, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: waterline tiles were missing; the chlorine and pH levels were not within the acceptable range of water quality standards; the letters on the "Shallow Water – No Diving Allowed" signs were not the appropriate size; 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 one thousand, three hundred sixty dollars ($1,360.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, three hundred sixty dollars **($1,360.00)** by July 21, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

22)	Order Type and Number:	Consent Order 22-020-RW
	Order Date:	July 11, 2022
	Individual/Entity:	**5516 Lakeshore Drive Association, Inc.**
	Facility:	Lakeshore Condos
	Location:	5516 Lakeshore Drive Columbia, SC 29206
	Mailing Address:	5516 Lakeshore Drive, Apt. 411 Columbia, SC 29206
	County:	Richland
	Previous Orders:	None
	Permit/ID Number:	40-023-1
	Violations Cited:	S.C. Code Ann. Regs. 61-51(K)(1)(c)

Summary: 5516 Lakeshore Drive Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. On June 20, 2022, the pool was inspected, and a violation was issued for re-opening prior to receiving Department approval. The Individual/Entity has violated the

Public Swimming Pools Regulation as follows: the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of three hundred dollars ($300.00). The Individual/Entity shall pay a civil penalty in the amount of three hundred dollars **($300.00)** by July 21, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

23)

Order Type and Number:	Consent Order 22-021-RW
Order Date:	July 13, 2022
Individual/Entity:	**Grand Oaks Preserve Property Owners Association, Inc.**
Facility:	Grand Oaks Preserve
Location:	9612 Avenue of Oaks Ladson, SC 29456
Mailing Address:	4401 Leeds Avenue, Suite 120 North Charleston, SC 29405
County:	Dorchester
Previous Orders:	None
Permit/ID Number:	18-1031B
Violations Cited:	S.C. Code Ann. Regs. 61-51(K)(1)(c)

Summary: Grand Oaks Preserve Property Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. On June 16, 2022, the pool was inspected, and a violation was issued for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of three hundred dollars ($300.00). The Individual/Entity shall pay a civil penalty in the amount of three hundred dollars **($300.00)** by July 23, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

24)

Order Type and Number:	Consent Order 22-022-RW
Order Date:	July 15, 2022
Individual/Entity:	**North Beach Towers Homeowners' Association, Inc.**
Facility:	North Beach Resort and Villas
Location:	48th Ave S North Myrtle Beach, SC 29582
Mailing Address:	P.O. Box 7706 Myrtle Beach, SC 29572
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1719D & 26-1720D
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: North Beach Towers Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of two spas located in Horry County, South Carolina. The Department conducted inspections on February 15, 2022, and June 20, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the water level was too high; the chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was not monitored by the facility; the spa rules sign was not completely filled out; the bound and numbered log book was not maintained on a daily basis; and the coping was not grouted.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, three hundred sixty dollars ($1,360.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, three hundred sixty dollars **($1,360.00)** by July 12, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

25)

Order Type and Number:	Consent Order 22-023-RW
Order Date:	July 18, 2022
Individual/Entity:	**1600 Marina Road, LLC**
Facility:	The Residence at Marina Bay Apartments
Location:	1600 Marina Bay Road Irmo, SC 29063
Mailing Address:	700 Gervais Street, Suite 275 Columbia, SC 29201
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1133B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: 1600 Marina Road, 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 9, 2022, and June 14, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the waterline tiles were dirty; the plaster on the pool floor was deteriorating; the frost proof tiles on the pool wall were broken; skimmers were missing weirs; the water level was too low; the drinking water fountain was not operating properly; non-pool related items were stored in the pump room; the fans and light in the pump room and chemical storage room were not operating; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign did not have all of the required rules; the wording on the "No Lifeguard On Duty – Swim At Your Own Risk" signs was not correct and the letters were not the appropriate size; there were chlorine sticks in the skimmer baskets; the bound and numbered log book was not the correct year and was not dated properly; and the bound and numbered log book was not maintained a minimum of three times per week by the operator of record.

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)** by July 28, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

26) Order Type and Number: Consent Order 22-024-RW
Order Date: July 18, 2022
Individual/Entity: **The Village at Hilton Homeowners Association, Inc.**
Facility: Village at Hilton
Location: 205 Lake Hilton Drive, Chapin, SC 29036
Mailing Address: 1722 Min Street, Suite 150, Columbia, SC 29201
County: Richland
Previous Orders: None
Permit/ID Number: 40-1016B
Violations Cited: S.C. Code Ann. Regs. 61-51(K)(1)(c)

Summary: The Village at Hilton Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. On June 16, 2022, the pool was inspected, and a violation was issued for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of three hundred dollars ($300.00). The Individual/Entity shall pay a civil penalty in the amount of three hundred dollars **($300.00)** by August 8, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

27) Order Type and Number: Consent Order 22-025-RW
Order Date: July 25, 2022
Individual/Entity: **CHP Columbia SC Owner, LLC**
Facility: Wellmore Health Care Community
Location: 200 Wellmore Drive, Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1104B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: CHP Columbia SC Owner, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Lexington County, South Carolina. The Department conducted inspections on March 29, 2022, and June 2, 2022, 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 was dirty; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the disinfection equipment was not operating properly; and the automatic controller was not operating properly.

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)** by August 8, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

28)

Order Type and Number:	Consent Order 22-026-RW
Order Date:	July 28, 2022
Individual/Entity:	**South Aiken Fitness, Inc.**
Facility:	Max Fitness Aiken
Location:	101 Corporate Parkway Aiken, SC 29803
Mailing Address:	Same
County:	Aiken
Previous Orders:	21-022-RW ($680.00) 22-012-RW ($2,000.00)
Permit/ID Number:	02-1014B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: South Aiken Fitness, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Aiken County, South Carolina. The Department conducted inspections on January 28, 2022, and May 23, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the waterline tiles were dirty; skimmers were missing weirs; electrical wiring was exposed in a hole that surrounds the pool area; the chlorine level was not within the acceptable range of water quality standards; only one "Shallow Water – No Diving Allowed" sign was posted; only one "No Lifeguard On Duty - Swim At Your Own Risk" 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 three thousand, two hundred dollars ($3,200.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, two hundred dollars **($3,200.00)** by August 16, 2022.

Update: The civil penalty has been paid and the Consent Order is closed.

Drinking Water Enforcement

29)

Order Type and Number:	Consent Order 22-022-DW
Order Date:	July 20, 2022
Individual/Entity:	**Camp Long Ridge Corporation**
Facility:	Camp Longridge
Location:	10 Longridge Road Ridgeway, SC 29130
Mailing Address:	P.O. Box 220 Ridgeway, SC 29130
County:	Fairfield
Previous Orders:	None

Permit/ID Number: 2070675
Violations Cited: S.C. Code Ann. Regs. 61-58.7 & 61-58.1.B & 61-58.1.K(1)

Summary: Camp Long Ridge Corporation (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Fairfield County, South Carolina. The Department conducted an inspection on December 30, 2021, and the PWS was rated needs improvement for failure to properly operate and maintain, and failure to obtain a permit and approval to operate prior to modifying the PWS. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the sample tap located at Well 1 was threaded; the sanitary seal for Well 1 was dirty and there was an open pipe on the well pad; the casing vent at Well 3 did not have a screen; the electrical wiring at Well 3 was not in conduit; there was a gap in the sanitary seal at Well 3; there were items stored in the well house for Well 3 that were unrelated to the operation of the PWS; and the hydro-pneumatic storage tank was replaced with bladder storage tanks.

Action: The Individual/Entity is required to: correct the deficiencies by August 20, 2022; submit to the Department for review and approval a corrective action plan with a schedule to obtain a permit for the modifications of the PWS by January 20, 2023; and complete the construction and obtain approval to operate by March 20, 2023. The Department has assessed a total civil penalty in the amount of ten thousand dollars ($10,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of ten thousand dollars **($10,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has corrected the deficiencies.

Water Pollution Enforcement

30) Order Type and Number: Administrative Order 22-045-W
Order Date: July 27, 2022
Individual/Entity: **Hutto's Salvage**
Facility: Hutto's Salvage
Location: 396 Broxton Bridge Road
Bamberg, SC 29003
Mailing Address: Same
County: Bamberg
Previous Orders: None
Permit/ID Number: SCR004010
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.26(a)(1) and (6), and Industrial Stormwater Permit SCR004010.

Summary: Hutto's Salvage (Individual/Entity) owns and is responsible for the proper operation and maintenance of a salvage facility in Bamberg County, South Carolina. On January 5, 2022, a Notice of Alleged Violation (NOAV) was issued for failure to properly operate and maintain its salvage facility in accordance with Industrial Stormwater Permit SCR004010. The Individual/Entity has violated Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to properly operate and maintain its salvage facility in accordance with Industrial Stormwater Permit SCR004010.

Action: The Individual/Entity is required to: submit a Stormwater Pollution Prevention Plan (SWPPP) by August 26, 2022; submit an implementation plan detailing necessary actions to return to compliance and a schedule for conducting quarterly facility inspections, quarterly benchmark monitoring of constituents specified in Industrial Stormwater Permit SCR004010, and annual comprehensive site inspections by September 10, 2022; submit a notarized document certifying that all appropriate employees of the Individual/Entity have been trained on the proper handling of oil, used mineral spirits, anti-freeze, mercury switches and solvents by September 10, 2022; and submit a notarized document certifying that all necessary Best Management Practices (BMPs) have been installed in order to minimize pollutant discharges from the site by September 25, 2022. The Department has assessed a civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay the civil penalty in the amount of six thousand dollars **($6,000.00)** by August 26, 2022.

Update: None

31) Order Type and Number: Consent Order 22-043-W
Order Date: July 15, 2022
Individual/Entity: **City of Columbia**
Facility: Columbia Metro WWTF
Location: 1200 Simmon Tree Lane
Columbia, SC 29201
Mailing Address: P.O. Box 147
Columbia, SC 29202
County: Richland
Previous Orders: None
Permit/ID Number: SC0020940
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a)

Summary: The City of Columbia (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Richland County, South Carolina. On December 9, 2021, a Notice of Violation was issued as a result of violations of the permitted discharge limits for Escherichia coli (E.coli) as reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for E.coli.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by August 15, 2022; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of three thousand five hundred dollars ($3,500.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand five hundred dollars **($3,500.00)** by August 15, 2022.

Update: None

32) Order Type and Number: Consent Order 22-044-W

Order Date: July 27, 2022
Individual/Entity: **Sonoco Products Company**
Facility: Sonoco Products Company
Location: 1 North Second Street
Hartsville, SC 29550
Mailing Address: P.O. Box 160-112
Hartsville, SC 29550
County: Darlington
Previous Orders: 21-065-W
Permit/ID Number: SC0003042
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2016), Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41(a), and Part III.A. of NPDES Permit SC0003042

Summary: Sonoco Products Company (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Darlington County, South Carolina. The Individual/Entity: reported violations of pH on discharge monitoring reports (DMRs) submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the permitted effluent limitations for pH.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by August 26, 2022; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay the civil penalty in the amount of four thousand dollars **($4,000.00)** by August 26, 2022.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

33) Order Type and Number: Administrative Order 22-24-FOOD
Order Date: July 13, 2022
Individual/Entity: **Young Yu**
Facility: Nick's Gyro and Seafood
Location: 780 St. Andrews Road
Columbia, SC 29210
Mailing Address: 4214 Bethel Church Road, Apt. C-22
Columbia, SC 29206
County: Lexington
Previous Orders: N/A
Permit Number: 32-206-07234
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Nick's Gyro and Seafood (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on June 29, 2021, February 17, 2022, February 25, 2022, March 7, 2022, March 16, 2022, April 14, 2022, April 21, 2022, April 28, 2022, May 5, 2022, May 12, 2022, June 13, 2022, and June 23, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; failed to ensure that at all times during operation, the person in charge shall be a certified food handler or a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; failed to ensure that the retail food establishment had written procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the retail food establishment; failed to provide a written plan for the restriction, exclusion, and re-instatement of food employees when they have symptoms and/or diseases that are transmissible through food; failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to maintain the premises free of insects, rodents, and other pests; failed to keep food contact surfaces of cooking equipment and pans free of encrusted grease deposits and other soil accumulations and non-food contact surfaces clean and free of accumulation of dust, dirt, food residue, and other debris; failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; failed to clearly and individually identify with the common name of the material, on all working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies; failed to convey sewage to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law; failed to clean the physical facilities as often as necessary to keep them clean.

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 Department has assessed a total civil penalty in the amount of ten thousand, four hundred dollars ($10,400.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand, four hundred dollars **($10,400.00)**.

Update: The Individual/Entity has entered into a payment agreement with the Department. The first payment is due on August 29, 2022.

34)	Order Type and Number:	Consent Order 22-64-FOOD
	Order Date:	July 1, 2022
	Individual/Entity:	**Applebee's #85047**
	Facility:	Applebee's #85047
	Location:	4505 Devine Street Columbia, SC 29205
	Mailing Address:	193 Palm Street Chapin, SC 29036
	County:	Richland

Previous Orders: None
Permit Number: 40-206-08375
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Applebee's #85047 (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on November 16, 2021, May 11, 2022, and May 19, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; and failed to maintain the premises free of insects, rodents, and other pests.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

35) Order Type and Number: Consent Order 22-73-FOOD
Order Date: July 5, 2022
Individual/Entity: **Maria's Mexican Grill**
Facility: Maria's Mexican Grill
Location: 2817 Maybank Highway
John's Island, SC 29455
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit Number: 10-206-06131
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Maria's Mexican Grill (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on May 9, 2022, May 17, 2022, May 27, 2022, and May 31, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 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**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

36) Order Type and Number: Consent Order 22-50-FOOD
Order Date: July 6, 2022

Individual/Entity: **Pee Dee Grocery**
Facility: Pee Dee Grocery
Location: 9150 Highway 701 South
Conway, SC 29527
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-10614
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Pee Dee Grocery (Individual/Entity) operates a retail food establishment located in Horry County, South Carolina. The Department conducted inspections on October 1, 2021, March 7, 2022, March 17, 2022, March 25, 2022, and April 4, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; and failed to ensure that at all times during operation, the person in charge shall be a certified food handler or a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

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 Department has assessed a total civil penalty in the amount of six hundred dollars ($600.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred dollars **($600.00)**.

Update: The Department intends to move forward with issuance of further enforcement action based on the continued noncompliance with the regulation and the Order.

37) Order Type and Number: Consent Order 22-82-FOOD
Order Date: July 11, 2022
Individual/Entity: **The Whole Food Mediterranean Grill**
Facility: The Whole Food Mediterranean Grill
Location: 3711 Highway 17 South
North Myrtle Beach, SC 29582
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-12908
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: The Whole Food Mediterranean Grill (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted an inspection on June 6, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

38) Order Type and Number: Consent Order 22-78-FOOD
Order Date: July 13, 2022
Individual/Entity: **Tienda Mexicana El Mariachi #3**
Facility: Tienda Mexicana El Mariachi #3
Location: 1735 Decker Boulevard
Columbia, SC 29206
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: 40-211-07656
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Tienda Mexicana El Mariachi #3 (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on April 5, 2022, April 14, 2022, and June 2, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the handwashing sinks were accessible at all times; failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; and failed to ensure that surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized or discarded if they are not capable of being resurfaced.

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 Department has assessed a total civil penalty in the amount of one thousand, two hundred dollars ($1,200.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred dollars **($1,200.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

39) Order Type and Number: Consent Order 22-51-FOOD
Order Date: July 13, 2022
Individual/Entity: **Duffy Street Seafood Shack Main Street**
Facility: Duffy Street Seafood Shack Main Street
Location: 202 Main Street
North Myrtle Beach, SC 29582
Mailing Address: Same

County: Horry
Previous Orders: 2016-206-06-083 ($800.00)
Permit Number: 26-206-08364
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Duffy Street Seafood Shack Main Street (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on August 26, 2021, March 24, 2022, and April 1, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

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 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)**.

Update: If payment is not received by August 29, 2022, a payment demand letter will be issued.

40) Order Type and Number: Consent Order 22-90-FOOD
Order Date: July 13, 2022
Individual/Entity: **Ichiro's Express**
Facility: Ichiro's Express
Location: 2450 U.S. 501
Conway, SC 29526
Mailing Address: 3456 Forestbrook Road
Myrtle Beach, SC 29588
County: Horry
Previous Orders: None
Permit Number: 26-206-11625
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ichiro's Express (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on April 13, 2022, April 22, 2022, May 2, 2022, and May 12, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

41) Order Type and Number: Consent Order 22-93-FOOD
Order Date: July 13, 2022
Individual/Entity: **Rancho Grande**

Facility:	Rancho Grande
Location:	136 Sea Isle Parkway, Suite 4 Beaufort, SC 29907
Mailing Address:	Same
County:	Beaufort
Previous Orders:	2018-206-08-007 ($200.00); 21-07-FOOD ($3,000.00)
Permit Number:	07-206-02367
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Rancho Grande (Individual/Entity) operates a restaurant located in Beaufort County, South Carolina. The Department conducted an inspection on June 13, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

42)

Order Type and Number:	Consent Order 22-88-FOOD
Order Date:	July 22, 2022
Individual/Entity:	**Happy Donkey Mexican Grill**
Facility:	Happy Donkey Mexican Grill
Location:	3230 South Main Street Extension Anderson, SC 29624
Mailing Address:	Same
County:	Anderson
Previous Orders:	22-37-FOOD ($3,600.00)
Permit Number:	04-206-04149
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Happy Donkey Mexican Grill (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on June 14, 2022, and June 23, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to store foods in a manner to prevent cross contamination; failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; and failed to maintain the premises free of insects, rodents, and other pests

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 is required to, within ten (10) days of the execution date of this Consent Order, correct all outstanding violations identified.. The Department has assessed a total civil penalty in the amount of two thousand two hundred fifty dollars ($2,250.00).

The Individual/Entity shall pay a civil penalty in the amount of two thousand two hundred fifty dollars **($2,250.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

43)

Order Type and Number:	Consent Order 22-67-FOOD
Order Date:	July 26, 2022
Individual/Entity:	**Pirates Cove**
Facility:	Pirates Cove
Location:	205 Main Street North Myrtle Beach, SC 29582
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit Number:	26-206-13648
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Pirates Cove (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 17, 2021, April 26, 2022, May 5, 2022, and May 12, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks; failed to ensure that each handwashing sink or group of two (2) adjacent handwashing sinks was provided with a supply of hand cleaning, liquid, powder, or bar soap; and failed to maintain the premises free of insects, rodents, and other pests.

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 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)**.

Update: If payment is not received by September 1, 2022, a payment demand letter will be issued.

44)

Order Type and Number:	Consent Order 22-79-FOOD
Order Date:	July 26, 2022
Individual/Entity:	**Menkoi Ramen**
Facility:	Menkoi Ramen
Location:	1004 Gervais Street Columbia, SC 29201
Mailing Address:	Same
County:	Richland
Previous Orders:	2019-206-03-101 ($1,000.00)
Permit Number:	40-206-06890
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Menkoi Ramen (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on May 18, 2022, May 26, 2022, and June 3, 2022. The Individual/Entity has violated the South

Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; 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 Department has assessed a total civil penalty in the amount of one thousand, two hundred fifty dollars ($1,250.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred fifty dollars **($1,250.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

45) Order Type and Number: Consent Order 22-84-FOOD
Order Date: July 26, 2022
Individual/Entity: **Charley's Grilled Subs**
Facility: Charley's Grilled Subs
Location: 10835 Kings Road
Myrtle Beach, SC 29572
Mailing Address: 2220 Whiskey Drive
Waxhaw, NC 28173
County: Horry
Previous Orders: None
Permit Number: 26-206-12158
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Charley's Grilled Subs (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on May 19, 2022, May 26, 2022, and June 3, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

46) Order Type and Number: Consent Order 22-86-FOOD
Order Date: July 26, 2022
Individual/Entity: **Asian Buffet**
Facility: Asian Buffet
Location: 364 Market Street
Seneca, SC 29678
Mailing Address: Same

County: Oconee
Previous Orders: 22-13-FOOD ($400.00)
Permit Number: 37-206-01280
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Asian Buffet (Individual/Entity) operates a restaurant located in Oconee County, South Carolina. The Department conducted inspections on January 13, 2022, January 20, 2022, May 16, 2022, May 26, 2022, and June 2, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests; and failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks.

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 Department has assessed a total civil penalty in the amount of one thousand, five hundred dollars ($1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, five hundred dollars (**$1,500.00**).

Update: On July 7, 2022, the Individual/Entity entered into a payment plan with the Department. The Individual/Entity is up to date on payments.

47) Order Type and Number: Consent Order 22-97-FOOD
Order Date: July 26, 2022
Individual/Entity: **Huddle House, Inc.**
Facility: Huddle House, Inc.
Location: 5901-B Peachtree Dunwoody NE, Ste 450
Atlanta, GA 30328
Mailing Address: 509-A Bypass 123
Seneca, SC 29678
County: Oconee
Previous Orders: None
Permit Number: 37-206-01341
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Huddle House, Inc. (Individual/Entity) operates a restaurant located in Oconee County, South Carolina. The Department conducted inspections on May 16, 2022, May 26, 2022, June 3, 2022, and June 13, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

48) Order Type and Number: Consent Order 22-71-FOOD
Order Date: July 28, 2022
Individual/Entity: **Country House Cafe**
Facility: Country House Cafe
Location: 2221 Highway 25 North
Travelers Rest, SC 29690
Mailing Address: Same
County: Greenville
Previous Orders: N/A
Permit Number: 23-206-12256
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Country House Cafe (Individual/Entity) operates a restaurant located in Greenville County, South Carolina. The Department conducted inspections on March 17, 2022, March 25, 2022, April 1, 2022, and April 20, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department and failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 Department has assessed a total civil penalty in the amount of one thousand, three hundred dollars ($1,300.00). The Individual/Entity shall pay a civil penalty in the amount one thousand, three hundred dollars **($1,300.00)**.

Update: If payment is not received by September 1, 2022, a payment demand letter will be issued.

49) Order Type and Number: Consent Order 22-92-FOOD
Order Date: July 28, 2022
Individual/Entity: **Ruby Tuesday #4467**
Facility: Ruby Tuesday #4467
Location: 1480 Sniders Highway
Walterboro, SC 29488
Mailing Address: P. O. Box 781199
Wichita, KS 67278
County: Colleton
Previous Orders: None
Permit Number: 15-206-00449
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ruby Tuesday #4467 (Individual/Entity) operates a restaurant located in Colleton County, South Carolina. The Department conducted inspections on July 15, 2021, July 21, 2021, December 30, 2021, and June 15, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 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**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

50)

Order Type and Number:	Consent Order 22-102-FOOD
Order Date:	July 28, 2022
Individual/Entity:	**El Poblano**
Facility:	El Poblano
Location:	2824 Main Street Newberry, SC 29108
Mailing Address:	2371 Dutch Fork Road Chapin, SC 29036
County:	Newberry
Previous Orders:	None
Permit Number:	36-206-01279
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: El Poblano (Individual/Entity) operates a restaurant located in Newberry County, South Carolina. The Department conducted inspections on June 6, 2022, June 16, 2022, and June 23, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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 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)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

51)

Order Type and Number:	Consent Order 22-110-FOOD
Order Date:	July 28, 2022
Individual/Entity:	**Yousef's Kitchen**
Facility:	Yousef's Kitchen
Location:	1109 E. Main Street Westminster, SC 29693
Mailing Address:	Same
County:	Oconee
Previous Orders:	22-68-FOOD ($800.00)
Permit Number:	37-206-00212
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Yousef's Kitchen (Individual/Entity) operates a restaurant located in Oconee County, South Carolina. The Department conducted inspections on January 24, 2022, April 27, 2022, June 21, 2022, and June 30, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to properly cool cooked time/temperature control for safety foods; failed to use effective methods to cool cooked time/temperature control for safety foods; and failed to maintain the premises free of insects, rodents, and other pests.

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 Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2.000.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

Onsite Wastewater Enforcement

52)	Order Type and Number:	Administrative Order 22-006-OSWW
	Order Date:	June 16, 2022
	Individual/Entity:	**Chris Valentine, Individually and DBA Valentine's House Doctor, LLC**
	Facility:	Chris Valentine, Individually and DBA Valentine's House Doctor, LLC
	Location:	855 Samworth Loop Georgetown, SC 29440
	Mailing Address:	1757 Colonial Street Georgetown, SC 29440
	County:	Georgetown
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Chris Valentine, Individually and DBA Valentine's House Doctor, LLC (Individual/Entity) installed an OSWW system at a property located in Georgetown County, South Carolina. The Department conducted an investigation in November of 2021 and determined that the Individual/Entity was not licensed to construct OSWW systems. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of constructing or repairing OSWW systems without first applying, receiving, and subsequently maintaining a Department issued license.

Action: The Individual/Entity is required to cease and desist installing or repairing OSWW systems until applying for and receiving a Department issued license to install OSWW systems. 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)**.

Update: The Individual/Entity has entered into a payment plan with the last payment due August 6, 2022. If payment is not received by September 5, 2022, a payment demand letter will be issued.

53) Order Type and Number: Administrative Order 22-029-OSWW
Order Date: June 16, 2022
Individual/Entity: **Elizabeth Evatt**
Facility: Elizabeth Evatt
Location: 280 Oak Street
Boiling Springs, SC 29316
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Elizabeth Evatt (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on April 13, 2022, and observed a camper occupied for more than two hours per day without a means of domestic wastewater treatment and disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that any building, unit, or dwelling occupied for more than two hours per day is connected to an approved means of domestic wastewater treatment and disposal.

Action: The Individual/Entity is required to apply for a permit to construct an OSWW system for the camper within five (5) days; or immediately vacate the camper to eliminate the unpermitted/unapproved discharge of domestic wastewater. 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.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

54) Order Type and Number: Administrative Order 22-038-OSWW
Order Date: July 13, 2022
Individual/Entity: **Nancy Lawson**
Facility: Nancy Lawson
Location: 815 Webber Lake Road
Union, SC 29379
Mailing Address: Same
County: Union
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Nancy Lawson (Individual/Entity) owns property located in Union County, South Carolina. The Department conducted an investigation on February 22, 2022 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.

Update: Regional staff have been asked to revisit the site. If the Department observes the continued discharge of domestic wastewater during the next visit to the Site, a legal demand letter will be issued.

55)

Order Type and Number:	Administrative Order 22-039-OSWW
Order Date:	July 13, 2022
Individual/Entity:	**Marilyn Hamrick Rogers**
Facility:	Marilyn Hamrick Rogers
Location:	5221 Highway 11 Inman, SC 29349
Mailing Address:	P.O. Box 57 Inman, SC 29349
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Marilyn Hamrick Rogers (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on May 19, 2022, and observed a building occupied for more than two hours per day without a means of domestic wastewater treatment and disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that any building, unit, or dwelling occupied for more than two hours per day is connected to an approved means of domestic wastewater treatment and disposal.

Action: The Individual/Entity is required to apply for a permit to construct an OSWW system for the building within five (5) days; or immediately vacate the building to eliminate the unpermitted/unapproved discharge of domestic wastewater. 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.

Update: A demand letter is being issued August 29, 2022 and hand delivered by Spartanburg County Sheriff's Office.

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

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
SUMMARY SHEET

September 8, 2022

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for a nine-month Board extension of Certificate of Need (CON) SC-19-82, issued to Lowcountry Rehabilitation Hospital, for the construction for the establishment of a 33 bed freestanding rehabilitation hospital in Berkeley County.

II. SUBJECT: Lowcountry Rehabilitation Hospital requests Board approval for extension of CON SC-19-82.

III. FACTS:

Certificate of Need (CON) SC-19-82 was issued to Lowcountry Rehabilitation Hospital (LRH) on July 19, 2019 for construction for the establishment of a thirty-three (33) bed freestanding rehabilitation hospital in Berkeley County. The original CON had an expiration date of July 19, 2020.

LRH requested a first staff extension of the CON on April 20, 2020, which was more than 30 days prior to expiration. In the same letter, LRH requested an amendment to the project including prepared schematics by the architect. LRH received CON SC-19-82-EXT-1 on July 19, 2020, and it was valid until April 19, 2021, a period of nine (9) months from original expiration of the CON. On August 19, 2020, the Department received a letter from LRH withdrawing the amendment request described in its letter dated April 20, 2020. On October 23, 2020, the Department received a fifth (5^{th}) quarterly report concurrent from LRH with a request to amend the CON. The amendment request included new prepared schematics and furnished a project description with an updated cost estimate and project timeline.

LRH requested a second staff extension of the CON on March 5, 2021, which was 30 days prior to expiration. The Department issued a second staff extension CON SC-19-82-EXT-2 to LRH on July 13, 2021 and it was valid until January 19, 2022. Additionally, the Department communicated to LRH via email on July 13, 2021, that the Department has determined the amendment proposed in the letter dated October 23, 2020 is not a substantial amendment to the project and does not constitute a new project. On October 18, 2021, LRH submitted a third extension request to the Department, which was 90 days prior to expiration. On January 5, 2022, the Board approved a third extension request.

In accordance with Regulation 61-15, *Certification of Need for Health Facilities and Services*, Section 601, LRH submitted a fourth extension request to the Department on July 18, 2022, which was 90 days prior to expiration.

IV. ANALYSIS:

Department staff have reviewed all relevant information concerning this fourth extension request and find that circumstances beyond the control of LRH have contributed to the need for further extension of CON SC-19-82. Specifically, LRH references delays as a result schematic re-design as the primary driver of the request for extension. LRH provided in its extension request an updated timeline for the project, which Department staff believe is achievable given the significant expertise and resources available to LRH. In addition, with the new schematic re-design, LRH will have an estimated square footage of approximately half of the proposed square footage. Department staff expect that subsequent extensions by the Board may

be unnecessary given LRH's timeline showing execution of a construction contract for the Project on or about April 2023. This contract will satisfy the requirement for implementation of the Project under R. 61-15, and will render moot the need for further extension of CON SC-19-82.

V. RECOMMENDATION:

Department staff recommend the Board finds that Lowcountry Rehabilitation Hospital has demonstrated extenuating circumstances beyond its control which have prevented the Project from advancing, the Project is likely to be implemented during the period of extension, and a 9-month extension of CON SC-19-82 be granted.

Approved by:

Gwen C. Thompson
Deputy Director
Healthcare Quality

Attachments:

A) CON SC-19-82
B) Letter requesting first extension and amendment of CON
C) Letter granting first extension of CON
D) Letter requesting to withdrawal amendment request of CON
E) Letter of 5th quarterly report and revised amendment request of CON
F) Letter requesting second extension of CON
G) Letter granting second extension of CON
H) Email copy of Department determination of amendment request of CON
I) Letter requesting third extension of CON
J) Letter granting third extension of CON
K) Letter requesting fourth extension of CON

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-19-82

FACILITY NAME: Lowcountry Rehabilitation Hospital

LOCATION: Berkeley County

LICENSEE: Lowcountry Rehabilitation Hospital

FOR: Construction for the establishment of a 33 bed freestanding rehabilitation hospital in Berkeley County.

TOTAL PROJECT COST: $39,997,285

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. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until July 19, 2020, 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 19th day of July, 2019.

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

dhec
Healthy People. Healthy Communities.

ROPER ST. FRANCIS HEALTHCARE

125 Doughty St. Suite 720
Charleston, SC 29403

April 20, 2020

Ms. Maggie Murdock, Director
DHEC CON Program
2600 Bull Street
Columbia, SC 29201

SENT VIA ELECTRONIC MAIL: murdocmp@dhec.sc.gov

Re: SC-19-82 issued to Lowcountry Rehabilitation Hospital

Dear Ms. Murdock:

This letter serves as both a request to extend the above referenced Certificate of Need ("CON") issued for the construction of a 33-bed rehabilitation facility with ten additional shelled rooms in Berkeley County (the "Project") for a period of nine months and also to request permission to amend the Project in accordance with S.C. Code Regulation 61-15, Section 605 as described below.

As stated in the CON application, Lowcountry Rehabilitation Hospital ("Lowcountry") is the applicant and a wholly owned subsidiary of Roper St. Francis Healthcare ("Roper"). The Project is located on the campus of Roper St. Francis Hospital – Berkeley, also wholly owned by Roper. The application further describes Roper's intent to develop the Project and at some future date convey a partial membership interest in Lowcountry to an affiliate of the Medical University of South Carolina ("MUSC"). However, after the CON was issued and Roper began to develop the Project, the decision was made that MUSC would no longer pursue a membership interest in Lowcountry. As a result, Roper leadership further evaluated the Project and has decided that incorporating the thirty-three rehabilitation beds into the existing Roper St. Francis Hospital - Berkeley would result in significant design efficiencies and operational cost savings compared to the approved construction of a freestanding rehabilitation hospital located on the same campus. The progress made to date consists of a feasibility analysis and proposed architectural re-design. These factors account for the delay in project implementation, and need for the requested extension.

The concurrent request to amend the Certificate of Need is twofold. First, we are seeking permission to place thirty-three rehabilitation beds and one shelled room on a second-floor extension of Roper St. Francis Hospital – Berkeley. Richard Alsop, the architect, has prepared schematics and furnished the enclosed project description with an updated cost estimate and project timeline. The approved $39,997,285 total Project cost will be slightly reduced (reference "revised total project cost" enclosure). As the documentation demonstrates, this amendment will not result in an increase in Project size, scope or cost. Secondly, we are seeking permission to change the licensee to Roper St. Francis Hospital – Berkeley, Inc. Given both corporations are wholly owned subsidiaries of Roper, we don't believe this transaction would be transfer of the CON contemplated under S.C. Code

Regulation 61-15, Section 604. This would allow Roper St. Francis Hospital – Berkeley to create a hospital-based rehabilitation unit.

With this amendment there will be efficiencies in utilities and other support services; however, the most significant anticipated savings are expected within shared services which include: dietary, respiratory therapy, pharmacy, human resources, materials management and plant operations. The initial pro-forma for a freestanding hospital identified a need for 81.9 FTEs in Year 1. By converting to a hospital-based unit, revised projections identify a need for 46.5 FTEs. This reduction translates into over $2.1MM in salaries/wages/benefits expense savings in the first year and more than $13MM over five years, demonstrating achievement of the goal to provide healthcare services in a cost-effective manner.

Accordingly, Lowcountry/Roper respectfully request that the Department:

1. Grant a nine-month extension of the CON.
2. Grant permission to amend the Project as described above with the finding that (a) the proposed amendments do not result in a substantial change under S.C. Code Regulations, Section 605, and (b) the change of licensee from one Roper wholly owned subsidiary, Lowcountry Rehabilitation Hospital, to another wholly owned subsidiary, Roper St. Francis Hospital – Berkeley, Inc. is not a transfer as described in S.C. Code Regulations, Section 604.

Should you have any questions or need additional information, please feel free to contact me at (843) 789-1754 or shannon.cantwell@rsfh.com.

Sincerely,

Shannon Cantwell
Regulatory Affairs Specialist

Enclosures

April 15, 2020

Mr. Greg Edwards, Vice President and General Counsel
Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, SC 29403
Greg.Edwards@rsfh.com

RE: 33 Bed Rehabilitation Expansion – Roper St. Francis, Berkeley Campus

Dear Mr. Edwards,

Per your request, please accept this letter for Roper St. Francis Healthcare's submission to SCDHEC as required for a Certificate of Need for a new 33 bed rehabilitation hospital unit which will be an expansion to the current Roper Hospital Berkeley campus. Please find provided below the following items: certified conceptual project construction budget (construction budget prepared by Robins + Morton); location/legal description of the property; project description; project timeline. Please find attached the following items: program for the rehabilitation expansion; conceptual plans of the expansion.

PROJECT BUDGET:

Based on conceptual plans prepared by HDR and in dialogue with Robins + Morton to discuss assumptions and clarifications, Robins + Morton has estimated the present value cost of construction at approximately $24,500,000 for 55,000 square feet of gross building square footage, equating to $445.45 per square foot. To that budget, please find estimated costs for equipment, IS, FF+E, permits, inspections, professional fees, and contingencies.

Task	Present Value	With Escalation (2021)
A. Estimated Construction Budget:	$24,500,000	$25,968,538*
B. Equipment, IS and FF+E:		$5,900,000
C. Permits and Inspections:		$160,000
D. Professional Design Fees (6% of A):		$1,558,112
E. Construction Contingency (10% of A):		$2,596,854
F. Design Contingency (10% of D):		$155,811
G. Total Project Budget:		**$36,339,315**

* 4.5% escalation from March 2020-March 2021 + 1.5% escalation from March 2021-June 2021 (anticipated bid acceptance date)

LOCATION/LEGAL DESCRIPTION:

The rehabilitation building expansion is to be located at 100 Callen Boulevard, Summerville, SC 29486 at the site of the current Roper St. Francis Hospital, Berkeley Campus, TMS # 209-00-01-080. The total site area for the expansion is approximately 0.4 acres.

Power and utility infrastructure is on site and will need to be extended to the project location. Site planning will include preparations for the building location, sidewalks, and extension of the service driveways. Stormwater detention for this expansion was calculated and installed during the hospital construction. No additional stormwater detention capacity is anticipated.

Additional parking will not need to be provided onsite to meet the zoning requirements of Goose Creek for hospitals (1 per 5 beds and 2 per main shift of staff) or the FGI Guidelines providing 1 per Patient bed, treatment area and 1 per employee per weekday shift. There are currently 711 parking spaces on site to satisfy a current hospital and MOB need of 392 leaving an excess of 319. The parking requirements for the rehabilitation expansion are 38 spaces. The remaining excess parking spaces available once this expansion is complete will be 281.

A separate service area is already designated and functioning for deliveries and Ambulance drop-off.

PROJECT DESCRIPTION:

The project includes the preparation of the documents associated with the CON application for roughly 55,000 SF of space. The rehab expansion will include 33 private inpatient beds, Rehabilitation Gym, nursing support, and associated clerical and family spaces for a rehabilitation hospital.

The building will be of the same construction type as the hospital and two stories in height. The rehabilitation hospital will occupy the upper floor of the expansion (approx. 36,000 square feet) with the lower floor (approx. 19,000 square feet) being shelled for future use. The rehabilitation hospital will be fully sprinklered. Occupancy is anticipated to be I-2 Condition 2 hospital serving more than 16 occupants incapable of self-preservation with 24 hour care per the IBC 2015 Use and Occupancy. It will meet the requirements of SCDHEC Regulation 61-16 – MINIMUM STANDARDS FOR LICENSING HOSPITALS AND INSTITUTIONAL GENERAL INFIRMARIES and other related sections 61-25 Retail Food Establishments. A program and scaled conceptual plan drawings are attached. Mechanical and electrical services will be provided to meet the redundancy requirements listed in NFPA documents for such a healthcare setting.

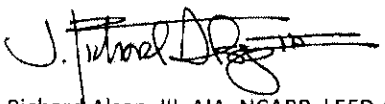
PROJECT TIMELINE:

The Design Services will be completed within 10 months of receipt of CON amendment approval. Bidding to general contractors and permitting will take approximately two months with an additional month to get the selected contractor under contract with the owner. Site and Building Construction are expected to take approximately 12 months following successful execution of the construction contract. With design services beginning in June 2020, anticipated opening date of the rehabilitation hospital after equipment installation and licensure is September 2022.

Activity	Estimated Duration	Planned Month
Receive CON Amendment Approval	2 Months	June 2020
Complete Design Documents	5 Months	November 2020
Complete Construction Documents	5 Months	April 2021
Bidding/Permitting	2 Months	June 2021
Execute Construction Contract	1 Month	July 2021

Construction	12 Months	July 2022
Equipment Installation	1 Month	August 2022
Licensure/Open	1 Month	September 2022

Sincerely,
HDR Architecture, Inc.



J. Richard Alsop, III, AIA, NCARB, LEED AP BD+C
Managing Principal
SC Registration Number: 7579

Roper St. Francis

Rehabilitation Expansion Program
Berkeley Campus

ROPER ST. FRANCIS

Expansion Summary

4/6/2020

Level 1	**18,715 BGSF**	Includes shell and upfit space
Level 2	**36,000 BGSF**	Includes 33 Rehab beds, gym, support and shell space
	54,715 BGSF	**Grand Total, Levels 1 & 2 Proposed Expansion**
Note:	**1,845 NSF**	Represents total NSF on Level 2 allocated to Rehab Patient Living Areas
	55.91 SF	SF allocated per patient for 33 Patient Beds, 55 SF per patient minimum

Level One

Departmental Net Sq. Feet:	**17,135**	
Departmental Grossing Factor:	**1.04**	Includes circulation to extend egress to exterior
Departmental Gross Sq. Feet:	**17,889**	
Building Grossing Factor:	**1.05**	(Includes Vertical Circulation, Exterior Skin)
Level 1 Building Gross Sq. Feet:	18,715 BGSF	

		Quantity	NSF/Room	Total NSF	Comments
	Building Support			**385**	**NSF Sub-Total**
2.01	Elevator Lobby	1	170	170	Two new patient/ material elevators
2.02	IDF Room	1	215	215	Intermediate Distribution Frame (Low Voltage)
2.03	Staff Vestibule	1	105	105	
	Shell Space			**16,750**	**NSF Sub-Total**
2.04	Shell Area	1	3,000	3,000	Assumed cold, dark shell
2.05	Shell Area	1	4,200	4,200	Assumed cold, dark shell
2.06	Shell Area	1	9,550	9,550	Assumed cold, dark shell

Roper St. Francis

Rehabilitation Expansion Program
Berkeley Campus

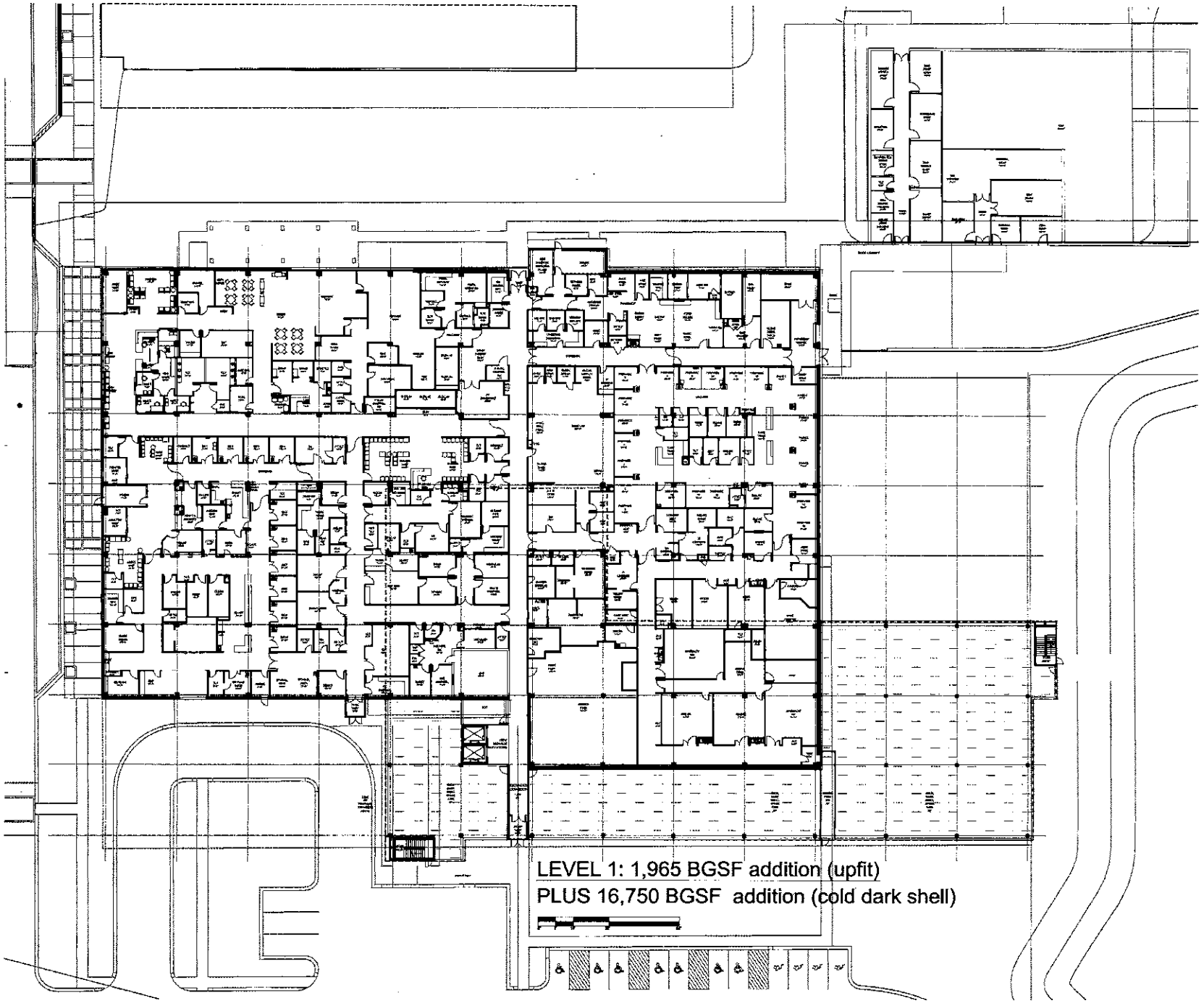
ROPER ST. FRANCIS HDR

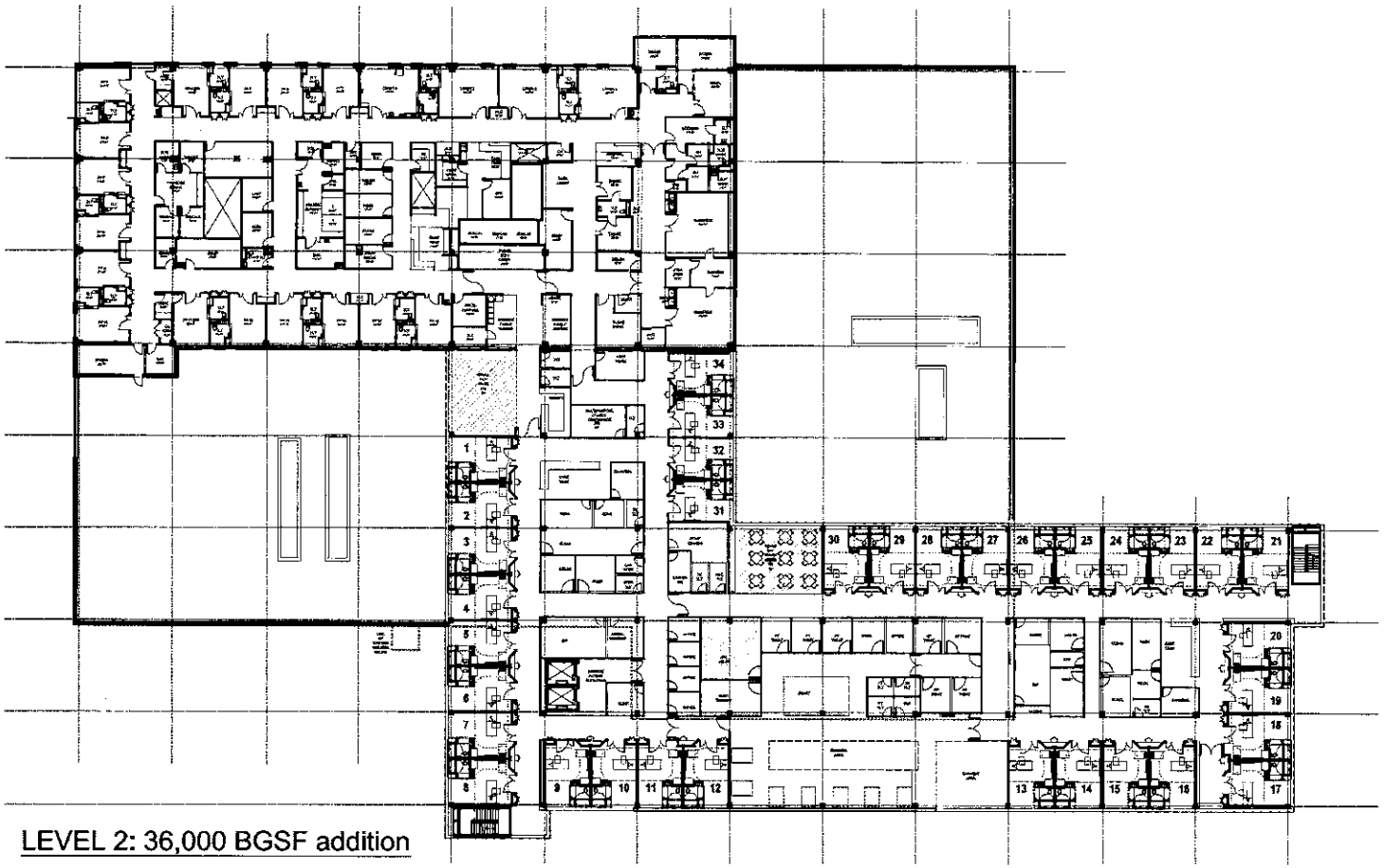
Level Two

4/6/2020

Departmental Net Sq. Feet:	**23,064**	
Departmental Grossing Factor:	**1.46**	Includes intradepartmental Circulation
Departmental Gross Sq. Feet:	**33,604**	
Building Grossing Factor:	**1.07**	Includes Vertical Circulation, Electrical Rooms, and Exterior Skin
Level 2 Building Gross Sq. Feet:	36,000 BGSF	

		Quantity	NSF/Room	Total NSF	Comments
	Entry / Public Support			**220**	**NSF Sub-Total**
2.01	Reception / Entry/ Control	1	110	110	
2.02	Public Toilet	2	55	110	
	Inpatient Unit			**15,644**	**NSF Sub-Total**
2.03	Rehab Patient Room	33	275	9,075	4' clear around bed and 5' turning radius
2.04	Rehab Patient Room Toilet	33	50	1,650	100% ADA
2.05	Rehab Nurse Server	33	5	165	Decentralized supplies
2.06	Rehab Patient Living- Day Space	1	679	679	Access to daylight, part of 55 SF/ patient minimum
2.07	Rehab Patient Living- Multipurpose Rm	1	276	276	Access to daylight, part of 55 SF/ patient minimum
2.08	Rehab Patient Living- Dining	1	760	760	Access to daylight, part of 55 SF/ patient minimum
2.09	Rehab Patient Living- Day Space Alcoves	2	65	130	Access to daylight, part of 55 SF/ patient minimum
2.10	Rehab Patient Toilets	2	55	110	
2.11	Care Team/ Nurse Station	2	320	640	
2.12	Charting/ Dictation	2	140	280	
2.13	Meds	2	165	330	
2.14	Nourishment	2	95	190	
2.15	Clean Supplies	2	263	525	
2.16	Soiled Holding	2	130	260	
2.17	Equipment Storage	2	177	354	
2.18	Housekeeping Closet	1	60	60	
2.19	Anes. Workroom	1	160	160	Replaces support for C-Section
	Diagnostic and Treatment Support			**5,365**	**NSF Sub-Total**
2.20	Activities of Daily Living Suite	1	450	450	Includes bedroom, bathroom, kitchen, training
2.21	Rehab Gym- Open Exercise Area	1	2,900	2,900	
2.22	Rehab Gym- Quiet Therapy	1	240	240	
2.23	Rehab Gym- Private Treatment	3	120	360	
2.24	Rehab Gym- Speech Treatment	3	120	360	
2.25	Rehab Gym - Speech Proc. Rm	1	150	150	
2.26	Rehab Gym- Therapist Work/ Chart	1	300	300	
2.27	Rehab Gym- Patient Locker Alc.	1	30	30	
2.28	Rehab Gym- Patient Toilet	2	55	110	
2.29	Rehab Gym- Staff Toilet	1	55	55	
2.30	Rehab Gym - Storage	1	140	140	
2.31	Rehab Gym- Office	1	100	100	
2.32	Rehab Gym- EVS	1	55	55	
2.33	Lab Work	1	60	60	
2.34	Lab Specimen Toilet	1	55	55	
	Staff Support			**1,125**	**NSF Sub-Total**
2.35	Staff Lounge	1	240	240	
2.36	Staff Locker Room	1	105	105	
2.37	Staff Toilet	3	55	165	
2.38	Office	5	90	450	
2.39	Social Services Workroom	1	165	165	
	Building Support			**385**	**NSF Sub-Total**
2.40	Elevator Lobby	1	220	220	Two new patient/ material elevators
2.41	IDF Rooms	1	165	165	Intermediate Distribution Frame (Low Voltage)
	Shell Space			**325**	**NSF Sub-Total**
2.42	Shell, Level 2	1	325	325	


LEVEL 1: 1,965 BGSF addition (upfit)
PLUS 16,750 BGSF addition (cold dark shell)



LEVEL 2: 36,000 BGSF addition

Updated Total Project Cost Estimate
4/16/20

PART A – QUESTIONNAIRE	
10. Construction and Site	
A. Type of Construction New	B. Number of Buildings Pertaining to Project 1
C. Number of Stories Pertaining to Project 2	D. Size of the Site in Acres 109.2 total acreage
E. Size of the Project Site in Acres 0.4 acre expansion	F. Square Footage of the Project 54,715 gross square feet consisting of: 36,000 2nd floor rehab unit 18,715 1st floor shell
G. Anticipated Date of Beginning Construction July 2021	H. Anticipated Date of Licensing or Project Completion September 2022
I. Anticipated Date for Submission of Final Completion Report March 2023	
11. Zoning of Construction Site General Commercial and Institutional (GC)	
12. Costs (Provide Estimated Cost Statement from Either the Architect or Engineer)	
A. Land Cost $65,770 (@ $164,424/acre)	B. Construction Cost $25,968,538 inc. sitework
C. Professional Fees $1,873,923 consisting of: $1,558,112 design fees $ 155,811 contingency $ 160,000 permits/inspections	D. Equipment Costs $6,005,767 consisting of: $1,500,000 FFE/signage inc. sales tax $4,400,000 IT/cabling/infrastructure $ 105,767 procurement consultant
E. Financing Cost During Construction $1,645,308	F. Other Costs (Specify) $2,596,854 construction contingency
G. Total Project Cost $38,156,160	H. Construction and Equipment Cost 1. Per Square Foot $584 2. Per Bed $968,918

Healthy People. Healthy Communities.

Article #: 9214896900999790141991702 3

July 19, 2020

VIA EMAIL AND CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, SC 29403

Re: Request for an Extension of Certificate of Need No. SC-19-82
Applicant: Lowcountry Rehabilitation Hospital
Project: Construction for the establishment of a 33 bed freestanding rehabilitation hospital in Berkeley County at a total project cost $39,997,285.
Berkeley County, South Carolina

Dear Ms. Cantwell:

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 have provided in support of your request, it is the decision of the Department to **grant you a nine (9) month extension** for Certificate No. SC-19-82. The Department's decision is based on the following findings:

- You have demonstrated substantial progress towards completion of the Project, and
- You have demonstrated that certain circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable.

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) 545-4492.

Sincerely,

Maggie Parham Murdock, Director
Certificate of Need Program

Enclosures: Guide to Board Review
CON SC-19-82-EXT-1

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-19-82-EXT-1

FACILITY NAME: Lowcountry Rehabilitation Hospital

LOCATION: Berkeley County

LICENSEE: Lowcountry Rehabilitation Hospital

FOR: Construction for the establishment of a 33 bed freestanding rehabilitation hospital in Berkeley County.

TOTAL PROJECT COST: $39,997,285

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. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until April 19, 2021, which is a period of nine (9) 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 19th day of July, 2020.

Maggie Parham Murdock, Director
Certificate of Need

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.
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.

125 Doughty St. Suite 720
Charleston, SC 29403

August 19, 2020

Ms. Maggie Murdock, Director
DHEC CON Program
2600 Bull Street
Columbia, SC 29201

SENT VIA ELECTRONIC MAIL: murdocmp@dhec.sc.gov

Re: SC-19-82 issued to Lowcountry Rehabilitation Hospital

Dear Ms. Murdock:

By letter dated April 20, 2020, Lowcountry Rehabilitation Hospital sought to extend the Certificate of Need ("CON") issued for the construction of a 33-bed rehabilitation facility with ten additional shelled rooms in Berkeley County (the "Project") for a period of nine months and to request permission to amend the Project in accordance with S.C. Code Regulation 61-15, Section 605. Given verbal approval of the extension request has been granted, this letter serves to document that the CON expiration date is April 19, 2021. In addition, Lowcountry Rehabilitation Hospital is hereby withdrawing the amendment request described in its letter dated April 20, 2020.

Should you have any questions or need additional information, please feel free to contact me at (843) 789-1754 or shannon.cantwell@rsfh.com.

Sincerely,

Shannon Cantwell

Shannon Cantwell
Regulatory Affairs Specialist

ROPER ST. FRANCIS HEALTHCARE

125 Doughty St. Suite 720
Charleston, SC 29403

October 23, 2020

Ms. Maggie Murdock, Director
DHEC CON Program
2600 Bull Street
Columbia, SC 29201

SENT VIA ELECTRONIC MAIL: murdocmp@dhec.sc.gov

Re: SC-19-82 issued to Lowcountry Rehabilitation Hospital

Dear Ms. Murdock:

This letter serves as both a progress report for the above referenced Certificate of Need ("CON") issued for the construction of a 33-bed rehabilitation facility with ten additional shelled rooms in Berkeley County (the "Project") and to also request permission to amend the Project in accordance with S.C. Code Regulation 61-15, Section 605 as described below.

Roper St. Francis Healthcare leadership has further evaluated the Project and decided that incorporating the thirty-three rehabilitation beds into the existing Roper St. Francis Berkeley Hospital would result in efficiencies in terms of various support and contracted services. The progress made during the most recent three-month period consists of having the architect, Richard Alsop, re-design Lowcountry Rehabilitation Hospital as a "hospital within a hospital".

The concurrent request to amend the Certificate of Need seeks permission to construct a "hospital within a hospital". Roper St. Francis Hospital – Berkeley, Inc. would build a 2-story addition whereby the first floor would be shelled and the 36,000 +/- square foot second floor leased to Lowcountry Rehabilitation Hospital for its thirty-three rehabilitation beds and one shelled room. Mr. Alsop has prepared schematics and furnished the enclosed project description with an updated cost estimate and project timeline. The approved $39,997,285 total Project cost will be slightly reduced (reference "revised total project cost" enclosure). As the documentation demonstrates, this amendment will not result in an increase in Project size, scope or cost.

Accordingly, Lowcountry Rehabilitation Hospital respectfully requests that the Department grant permission to amend the Project as described above with the finding that the proposed amendment does not result in a substantial change under S.C. Code Regulations, Section 605. Should you have any questions or need additional information, please feel free to contact me at (843) 789-1754 or shannon.cantwell@rsfh.com. Thank you in advance for your consideration.

Sincerely,

Shannon Cantwell
Regulatory Affairs Specialist

Enclosures

October 21, 2020

Mr. Greg Edwards, Vice President and General Counsel
Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, SC 29403
Greg.Edwards@rsfh.com

RE: 33 Bed Rehabilitation Hospital – Roper St. Francis, Berkeley Campus

Dear Mr. Edwards,

Per your request, please accept this letter for Roper St. Francis Healthcare's submission to SCDHEC as required for a Certificate of Need for a rehabilitation hospital as a "hospital-within-a-hospital". This new rehabilitation hospital will be a separately licensed 33 bed rehabilitation facility located within the existing Roper St. Francis Hospital, Berkeley Campus. Please find provided below the following items: certified conceptual project construction budget (construction budget prepared by Robins + Morton); location/legal description of the property; project description; project timeline. Please find attached the following items: program for the rehabilitation hospital; conceptual plans of the hospital.

PROJECT BUDGET:

Based on conceptual plans prepared by HDR and in dialogue with Robins + Morton to discuss assumptions and clarifications, Robins + Morton has estimated the present value cost of construction at approximately $24,500,000 for 55,000 square feet of gross building area, equating to $445.45 per square foot. To that budget, please find estimated costs for equipment, IS, FF+E, permits, inspections, professional fees, and contingencies.

Task		Present Value	With Escalation (2022)
A.	Estimated Construction Budget:	$24,500,000	$25,968,538*
B.	Equipment, IS and FF+E:		$5,900,000
C.	Permits and Inspections:		$160,000
D.	Professional Design Fees (6% of Task A.):		$1,558,112
E.	Construction Contingency (10% of Task A.):		$2,596,854
F.	Design Contingency (10% of Task D.):		$155,811
G.	Total Project Budget:		**$36,339,315**

* 4.5% escalation from October 2020-October 2021 + 1.5% escalation from October 2021-January 2022 (anticipated bid acceptance date)

LOCATION/LEGAL DESCRIPTION:

The rehabilitation hospital will be a separately licensed "hospital within a hospital" and will be attached to the existing Roper St. Francis Hospital, Berkeley Campus located at 100 Callen Boulevard, Summerville, SC 29486, TMS # 209-00-01-080. The total site area for the rehabilitation hospital is approximately 0.4 acres.

Power and utility infrastructure is on site and will need to be extended to the project location. Site planning will include preparations for the building location, sidewalks, and extension of the service driveways. Stormwater detention for this rehabilitation hospital was calculated and installed during the Roper St. Francis Hospital construction. No additional stormwater detention capacity is anticipated.

Additional parking will not need to be provided onsite to meet the zoning requirements of Goose Creek for hospitals (1 per 5 beds and 2 per main shift of staff) or the FGI Guidelines providing 1 per Patient bed, treatment area and 1 per employee per weekday shift. There are currently 711 parking spaces on site to satisfy a current Roper St. Francis Hospital and MOB need of 392 leaving an excess of 319. The parking requirements for the rehabilitation hospital are 38 spaces. The remaining excess parking spaces available once this rehabilitation hospital is complete will be 281.

A separate service area is already designated and functioning for deliveries and Ambulance drop-off.

PROJECT DESCRIPTION:

The project includes the preparation of the documents associated with the CON application for approximately 55,000 SF of space. The rehabilitation hospital will include 33 private inpatient beds, rehabilitation gym, nursing support, and associated clerical and family spaces.

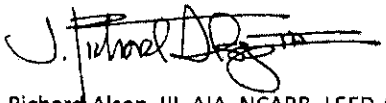
The rehabilitation hospital will be of the same construction type as the Roper St. Francis Hospital presently on site. The rehabilitation hospital will be attached to the existing Roper St. Francis Hospital and will be accessible from the upper floor of the Roper St. Francis Hospital. The rehabilitation hospital will be fully sprinklered. Occupancy is anticipated to be I-2 Condition 2 hospital serving more than 16 occupants incapable of self-preservation with 24 hour care per the IBC 2015 Use and Occupancy. The rehabilitation hospital will meet the requirements of SCDHEC Regulation 61-16 – MINIMUM STANDARDS FOR LICENSING HOSPITALS AND INSTITUTIONAL GENERAL INFIRMARIES and other related sections 61-25 Retail Food Establishments. A program and scaled conceptual plan drawings are attached. Mechanical and electrical services will be provided to meet the redundancy requirements listed in NFPA documents for such a healthcare setting.

PROJECT TIMELINE:

The Design Services will be completed within 10 months of receipt of the CON amendment approval. Bidding to general contractors and permitting will take approximately two months with an additional one month to get the selected contractor under contract with the owner. Site and Building Construction are expected to take approximately 12 months following successful execution of the construction contract. With design services beginning in January 2021, anticipated opening date of the rehabilitation hospital after equipment installation and licensure is March 2023.

Activity	Estimated Duration	Planned Month
Receive CON Amendment Approval	2 Months	December 2020
Complete Design Documents	5 Months	May 2021
Complete Construction Documents	5 Months	October 2021
Bidding/Permitting	2 Months	December 2021
Execute Construction Contract	1 Month	January 2022
Construction	12 Months	January 2023
Equipment Installation	1 Month	February 2023
Licensure/Open	1 Month	March 2023

Sincerely,
HDR Architecture, Inc.



J. Richard Alsop, III, AIA, NCARB, LEED AP BD+C
Managing Principal
SC Registration Number: 7579

Roper St. Francis

Rehabilitation Hospital Program
Berkeley Campus

ROPER ST. FRANCIS HDR

Hospital Summary

10/21/2020

Level 1	**18,715 BGSF**	Includes shell and upfit space
Level 2	**36,000 BGSF**	Includes 33 Rehab beds, gym, support and shell space
	54,715 BGSF	**Grand Total, Levels 1 & 2 Proposed Hospital**

Note:	**1,845 NSF**	Represents total NSF on Level 2 allocated to Rehab Patient Living Areas
	55.91 SF	SF allocated per patient for 33 Patient Beds, 55 SF per patient minimum

Level One

Departmental Net Sq. Feet:	**17,135**	
Departmental Grossing Factor:	**1.04**	Includes circulation to extend egress to exterior
Departmental Gross Sq. Feet:	**17,889**	
Building Grossing Factor:	**1.05**	(Includes Vertical Circulation, Exterior Skin)
Level 1 Building Gross Sq. Feet:	**18,715 BGSF**	

		Quantity	NSF/Room	Total NSF	Comments
	Building Support			**385**	**NSF Sub-Total**
2.01	Elevator Lobby	1	170	170	Two new patient/ material elevators
2.02	IDF Room	1	215	215	Intermediate Distribution Frame (Low Voltage)
2.03	Staff Vestibule	1	105	105	
	Shell Space			**16,750**	**NSF Sub-Total**
2.04	Shell Area	1	3,000	3,000	Assumed cold, dark shell
2.05	Shell Area	1	4,200	4,200	Assumed cold, dark shell
2.06	Shell Area	1	9,550	9,550	Assumed cold, dark shell

Roper St. Francis

Rehabilitation Hospital Program
Berkeley Campus

ROPER ST. FRANCIS HDR

Level Two

10/21/2020

Departmental Net Sq. Feet:	**23,064**	
Departmental Grossing Factor:	**1.46**	Includes intradepartmental Circulation
Departmental Gross Sq. Feet:	**33,604**	
Building Grossing Factor:	**1.07**	Includes Vertical Circulation, Electrical Rooms, and Exterior Skin
Level 2 Building Gross Sq. Feet:	**36,000 BGSF**	

		Quantity	NSF/Room	Total NSF	Comments
	Entry / Public Support			**220**	**NSF Sub-Total**
2.01	Reception / Entry/ Control	1	110	110	
2.02	Public Toilet	2	55	110	
	Inpatient Unit			**15,644**	**NSF Sub-Total**
2.03	Rehab Patient Room	33	275	9,075	4' clear around bed and 5' turning radius
2.04	Rehab Patient Room Toilet	33	50	1,650	100% ADA
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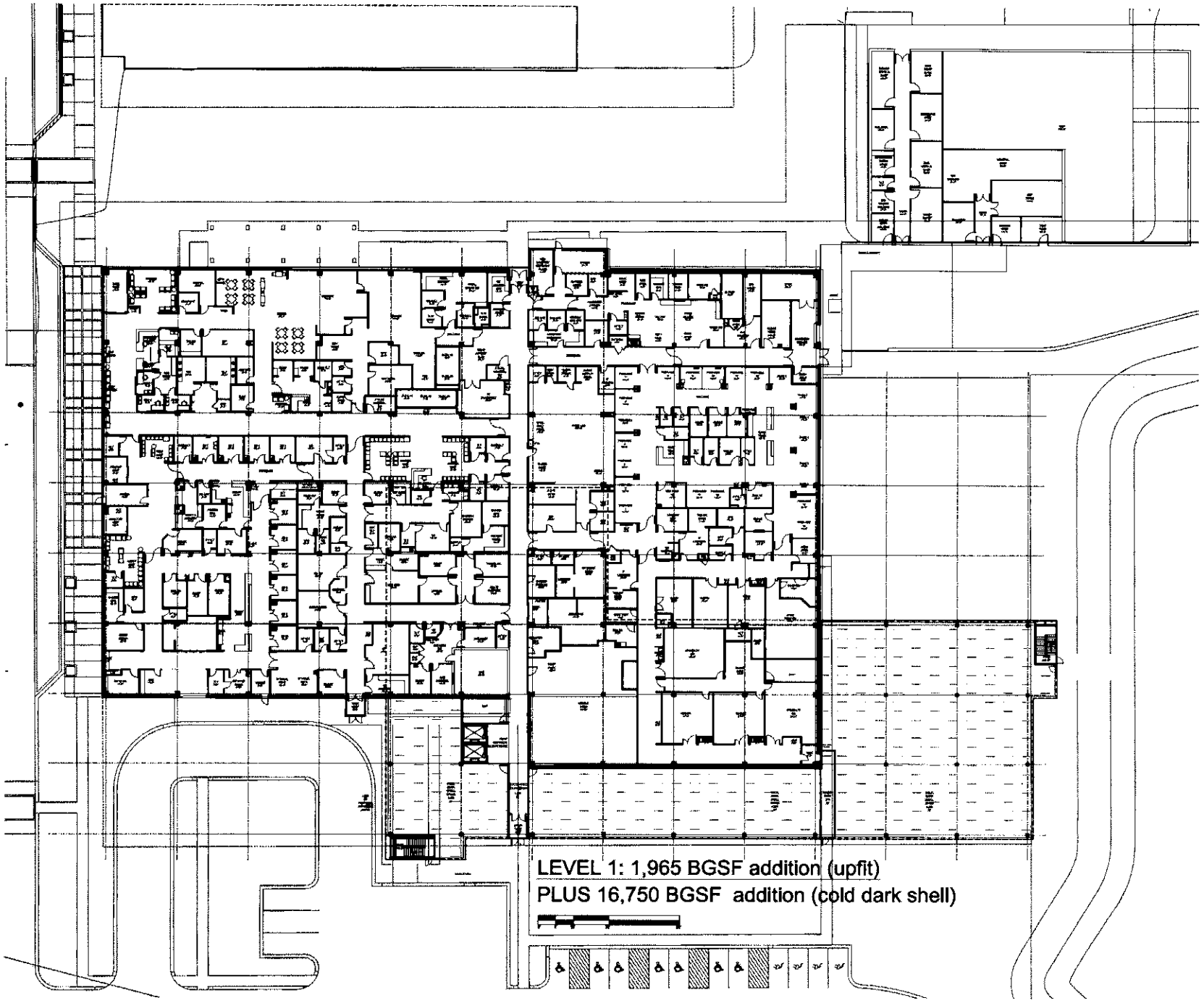
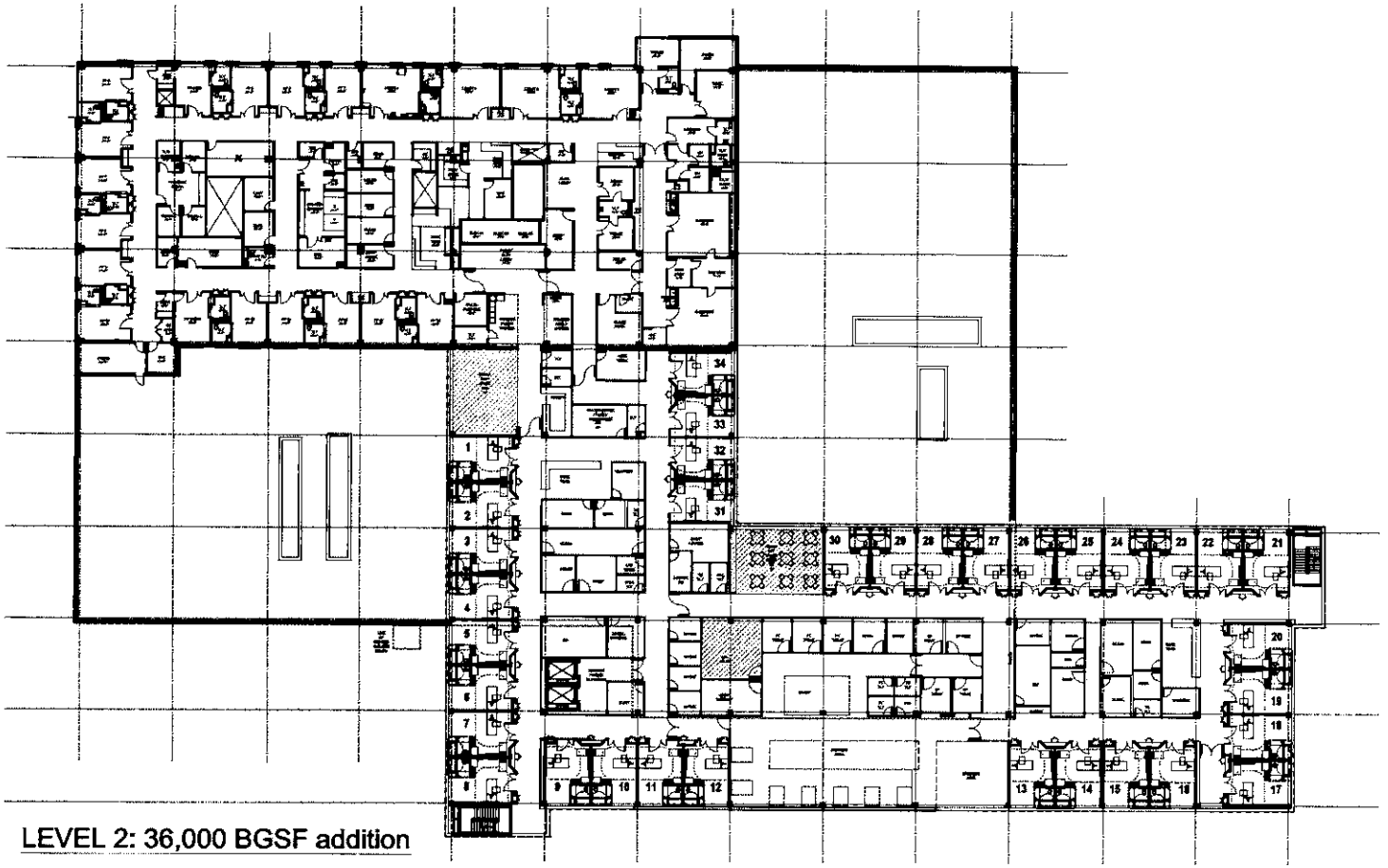
2.19	Anes. Workroom	1	160	160	Replaces support for C-Section
	Diagnostic and Treatment Support			**5,365**	**NSF Sub-Total**
2.20	Activities of Daily Living Suite	1	450	450	Includes bedroom, bathroom, kitchen, training
2.21	Rehab Gym- Open Exercise Area	1	2,900	2,900	
2.22	Rehab Gym- Quiet Therapy	1	240	240	
2.23	Rehab Gym- Private Treatment	3	120	360	
2.24	Rehab Gym- Speech Treatment	3	120	360	
2.25	Rehab Gym - Speech Proc. Rm	1	150	150	
2.26	Rehab Gym- Therapist Work/ Chart	1	300	300	
2.27	Rehab Gym- Patient Locker Alc.	1	30	30	
2.28	Rehab Gym- Patient Toilet	2	55	110	
2.29	Rehab Gym- Staff Toilet	1	55	55	
2.30	Rehab Gym - Storage	1	140	140	
2.31	Rehab Gym- Office	1	100	100	
2.32	Rehab Gym- EVS	1	55	55	
2.33	Lab Work	1	60	60	
2.34	Lab Specimen Toilet	1	55	55	
	Staff Support			**1,125**	**NSF Sub-Total**
2.35	Staff Lounge	1	240	240	
2.36	Staff Locker Room	1	105	105	
2.37	Staff Toilet	3	55	165	
2.38	Office	5	90	450	
2.39	Social Services Workroom	1	165	165	
	Building Support			**385**	**NSF Sub-Total**
2.40	Elevator Lobby	1	220	220	Two new patient/ material elevators
2.41	IDF Rooms	1	165	165	Intermediate Distribution Frame (Low Voltage)
	Shell Space			**325**	**NSF Sub-Total**
2.42	Shell, Level 2	1	325	325	


LEVEL 1: 1,965 BGSF addition (upfit)
PLUS 16,750 BGSF addition (cold dark shell)



LEVEL 2: 36,000 BGSF addition

Updated Total Project Cost Estimate
10/23/20

PART A – QUESTIONNAIRE	
10. Construction and Site	
A. Type of Construction New	B. Number of Buildings Pertaining to Project 1
C. Number of Stories Pertaining to Project 2	D. Size of the Site in Acres 109.2 total acreage
E. Size of the Project Site in Acres 0.4 acre expansion	F. Square Footage of the Project 36,000 square feet
G. Anticipated Date of Beginning Construction January 2022	H. Anticipated Date of Licensing or Project Completion March 2023
I. Anticipated Date for Submission of Final Completion Report September 2023	
11. Zoning of Construction Site General Commercial and Institutional (GC)	
12. Costs (Provide Estimated Cost Statement from Either the Architect or Engineer)	
A. Land Cost $65,770 (@ $164,424/acre)	B. Construction Cost $25,968,538 inc. sitework
C. Professional Fees $1,873,923 consisting of: $1,558,112 design fees $ 155,811 contingency $ 160,000 permits/inspections	D. Equipment Costs $6,005,767 consisting of: $1,500,000 FFE/signage inc. sales tax $4,400,000 IT/cabling/infrastructure $ 105,767 procurement consultant
E. Financing Cost During Construction $1,645,308	F. Other Costs (Specify) $2,596,854 construction contingency
G. Total Project Cost $38,156,160	H. Construction and Equipment Cost 1. Per Square Foot $888 2. Per Bed $968,918

125 Doughty St. Suite 720
Charleston, SC 29403

March 5, 2021

Ms. Maggie Murdock, Director
DHEC CON Program
2600 Bull Street
Columbia, SC 29201

SENT VIA ELECTRONIC MAIL: murdocmp@dhec.sc.gov

Re: SC-19-82 issued to Lowcountry Rehabilitation Hospital

Dear Ms. Murdock:

This letter serves to request a nine-month extension of the April 19, 2021, expiration date for the above referenced Certificate of Need issued for the construction of a 33-bed rehabilitation facility with ten additional shelled rooms in Berkeley County. Regulation 61-15 requires the following four issues be addressed: the progress made to date; an explanation of the circumstances that caused the submitted timetable not to be met; a detailed description of any changes in scope, configuration, and/or costs of the project; and a timetable for completion of all remaining project components. Each issue is addressed below in that order.

Progress Made to Date: The progress made to date consists of a feasibility analysis and proposed architectural re-design as a "hospital within a hospital".

Explanation of the Delay: The architectural re-design, subsequent amendment request, and outstanding response have all contributed to the delay in implementation.

Scope and/or Cost Changes: Please refer and respond to the amendment request dated October 23, 2020.

Timeline for completion: Once the necessary approval of the amendment is granted, design development will proceed. Assuming written approval is received in April, below is the timeline for project milestones:

Construction Drawings Completion	10/21
Project Bidding/Permitting	12/21
Execute Construction Contract	1/22
Construction Duration	2/22 – 8/23
Furnish Rooms; DHEC Licensure	10/23

Should you have any questions or need additional information, please feel free to contact me at (843) 789-1754 or shannon.cantwell@rsfh.com.

Sincerely,

Shannon Cantwell

Shannon Cantwell
Regulatory Affairs Specialist

Healthy People. Healthy Communities.

Article #: 9214896900999790141991702 3

July 13, 2021

VIA EMAIL AND CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, SC 29403

Re: Request for a Second Extension of Certificate of Need No. SC-19-82
Applicant: Lowcountry Rehabilitation Hospital
Project: Construction for the establishment of a 33 bed freestanding rehabilitation hospital in Berkeley County at a total project cost $39,997,285. Berkeley County, South Carolina

Dear Ms. Cantwell:

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 have 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-19-82. The Department's decision is based on the following findings:

- You have demonstrated substantial progress towards completion of the Project, and
- You have demonstrated that certain circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable.

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) 545-4492.

Sincerely,

Maggie Parham Murdock, Director
Certificate of Need Program

Enclosures: Guide to Board Review
CON SC-19-82-EXT-2

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-19-82-EXT-2

FACILITY NAME: Lowcountry Rehabilitation Hospital

LOCATION: Berkeley County

LICENSEE: Lowcountry Rehabilitation Hospital

FOR: Construction for the establishment of a 33 bed freestanding rehabilitation hospital in Berkeley County.

TOTAL PROJECT COST: $39,997,285

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. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until January 19, 2022, which is a period of nine (9) 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 19th day of April, 2021.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Maggie Parham Murdock, Director
Certificate of Need

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.

Amendment Request for SC-19-82

Murdock, Margaret P. <murdocmp@dhec.sc.gov>

Tue 7/13/2021 7:56 PM

To: Cantwell Shannon <Shannon.Cantwell@rsfh.com>
Cc: rbarbier@nexsenpruet.com <rbarbier@nexsenpruet.com>

Shannon,

Regarding your request, referenced below, to amend the above-referenced Project, the Department has determined that the amendment proposed in your letter is not a substantial amendment to the Project and does not constitute a new project.

Please let me know if you have any questions.
Thanks,
Maggie

Maggie Parham Murdock
Director
Certificate of Need Program
Healthcare Quality, Bureau of Planning and Construction
S.C. Dept. of Health & Environmental Control
Office: (803) 545-4492
Mobile: (803) 360-5770
Connect: www.scdhec.gov Facebook Twitter

From: Cantwell Shannon <Shannon.Cantwell@rsfh.com>
Sent: Monday, October 26, 2020 8:44 AM
To: Murdock, Margaret P. <murdocmp@dhec.sc.gov>
Subject:

Good morning Maggie,
Please see the attached progress report and amendment request on behalf of Lowcountry Rehabilitation Hospital (SC-19-82).

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare

843.789.1754

Our Mission: Healing all people with compassion, faith and excellence.

125 Doughty St. Suite 720
Charleston, SC 29403

October 18, 2021

Ms. Maggie Murdock, Director
DHEC CON Program
2600 Bull Street
Columbia, SC 29201

SENT VIA ELECTRONIC MAIL: murdocmp@dhec.sc.gov

Re: SC-19-82 issued to Lowcountry Rehabilitation Hospital

Dear Ms. Murdock:

This letter serves to request a third nine-month extension of the January 19, 2022, expiration date for the above referenced Certificate of Need issued for the construction of a 33-bed rehabilitation facility with ten additional shelled rooms in Berkeley County. Regulation 61-15 requires the following four issues be addressed: the progress made to date; an explanation of the circumstances that caused the submitted timetable not to be met; a detailed description of any changes in scope, configuration, and/or costs of the project; and a timetable for completion of all remaining project components. Each issue is addressed below in that order.

Progress Made to Date: The progress made to date consists of a feasibility analysis and proposed schematic re-design. Hord Coplan Macht (HCM), a firm in Baltimore, was recently engaged to complete the architectural design process.

Explanation of the Delay: The schematic re-design as a "hospital within a hospital" (versus the approved freestanding rehabilitation hospital on the Roper St. Francis Berkeley Hospital's campus) and subsequent amendment request that was under review by the DHEC staff for approximately nine months prior to approval on July 13, 2021, have all contributed to the delay.

Additional Changes in Scope or Cost: None

Timeline for completion:

Construction Drawings Completion (12 months)	October 2022
Construction of RSF Berkeley Hospital Addition (24 months)	October 2024
Concurrent Project Bidding/Permitting for LRH	
Execute Construction Contract for LRH	
Construction Up-fit Duration (8 months)	June 2025
Furnish Rooms; DHEC Licensure (2 months)	August 2025

Should you have any questions or need additional information, please feel free to contact me at (843) 789-1754 or shannon.cantwell@rsfh.com.

Sincerely,

Shannon Cantwell

Shannon Cantwell
Regulatory Affairs Specialist

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

Healthy People. Healthy Communities.

Article #: 9214896900999790142088814

January 12, 2022

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, SC 29403

Re: **Request for Board Approval and 3rd Extension of Certificate of Need No. SC-19-82**
Applicant: Lowcountry Rehabilitation Hospital
Project: Construction for the establishment of a 33 bed rehabilitation hospital in Berkeley County at a total project cost of $38,156,160.00.
Application No.: 2640

Dear Ms. Cantwell:

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 nine months a piece 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 Board extension** for Certificate No. **SC-19-82**. The Department's decision is based on the following findings:

- You have submitted sufficient documentation that extenuating circumstances beyond the Applicant's control have prevented compliance with the timetable; and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented with the requested extension period.

As required by Reg. No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (July 19, 2019). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

9th Quarterly Report: **1/19/2022**
10th Quarterly Report: **4/19/2022**
11th Quarterly Report: **7/19/2022**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Reg. No. 61-15, Section 701.

Please note that all subsequent requests for extension of **SC-19-82** are subject to approval by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension pursuant to Regulation No. 61-15, Sections 601 through 603. The due date for the next Department Board extension request, if one is needed, is **July 19, 2022.** Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Mr. Nigel E. Abner, (803) 545-4240.

A copy of the Department's Guide to Board Review is enclosed for your convenience. If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-4077.

Sincerely,

David Fiorini, Senior Consultant
Certificate of Need Program

Enclosures: Certificate of Need SC-19-82-EXT-3
Department's Guide to Board Review

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-19-82-EXT-3

FACILITY NAME: Lowcountry Rehabilitation Hospital

LOCATION: Berkeley County

LICENSEE: Lowcountry Rehabilitation Hospital

FOR: Construction for the establishment of a 33 bed rehabilitation hospital in Berkeley County.

TOTAL PROJECT COST: $38,156,160.00

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. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until October 19, 2022, which is a period of nine (9) 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 12th day of January 2022.

Nigel Abner, Interim Bureau Director
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.
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.

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ROPER ST. FRANCIS HEALTHCARE

316 Calhoun St. I Charleston, SC 29401
(843) 724-2000 P (843) 720-8449 F
www.rsfh.com

July 18, 2022

M. Denise Crawford (via email - crawfomd@dhec.sc.gov)
Clerk of the Board, South Carolina Board of Health and Environmental Control
Clerk of the Council, South Carolina Mining Council
S.C. Dept. of Health & Environmental Control
Office of General Counsel

Ms. Jennifer Hyman (via email - Hymanjj@dhec.sc.gov)
Senior Consultant, Certificate of Need Program
S.C. Dept. of Health & Environmental Control

Re: SC-19-82 issued to Lowcountry Rehabilitation Hospital – Extension Request

Dear Ms. Crawford and Ms. Hyman:

This letter serves as a request to the DHEC Board for a nine-month extension of the above referenced Certificate of Need issued for the construction of a 33-bed rehabilitation facility with ten additional shelled rooms in Berkeley County.

Progress Made to Date: The plan is for Lowcountry Rehabilitation Hospital to be located inside Roper St. Francis Hospital – Berkeley, rather than as a freestanding hospital on that same campus as was originally contemplated. The plan modification is continuing with progress on the architectural design with our architectural partner, Hord Coplan Macht (HCM). The design and clinical teams are meeting biweekly to optimize the design for patient flow and staff efficiency. Careful thought is being invested in the location of key spaces such as therapy treatment areas, nurses stations and equipment storage as well as placement of key rehabilitation equipment including an overhead track system to assist with safe patient ambulation. Later this month we will be reviewing our FFE needs for the rehabilitation hospital.

Explanation of the Delay: The need for schematic re-design to incorporate the proposed freestanding hospital inside the existing Roper Berkeley Hospital to establish a "hospital within a hospital" while navigating the major disruptions of our normal operations caused by COVID-19 are the primary reasons for the delay.

Changes in Scope or Cost: The relocation of the proposed rehabilitation hospital as a freestanding facility on the Berkeley Hospital to inside Berkeley Hospital will allow for greater efficiency and cost savings. The project square footage will now be approximately 27,742 which is nearly half of the 54,224 proposed square footage in the CON application that was approved

by the DHEC staff. This space efficiency is accomplished through shared support and administrative services. Please note that Lowcountry Rehabilitation Hospital, the CON applicant, will continue to implement this CON and will be the licensee when the CON is fully implemented as described in the CON application.

Timeline for completion:

- Construction Drawings and Contracting Completion (9 months)
- Construction of RSF Berkeley Hospital Addition (24 months)
    - Concurrent Project Bidding/Permitting for LRH
    - Execute Construction Contract for LRH
- Construction Up-fit Duration (8 months)
- Furnish Rooms; DHEC Licensure (2 months)

Please let me know if there are any questions or if additional information is needed on the extension request. Thank you for your consideration.

Sincerely,

Troy Powell, OTR/L, MHA

Vice President, Continuing Care

(x) ACTION/DECISION
( ) INFORMATION

Date: September 8, 2022

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

From: Bureau of Planning and Construction

Re: Notice of Proposed Regulation Amending R.61-15, *Certification of Need for Health Facilities and Services.*

I. Introduction

The Bureau of Planning and Construction proposes the attached Notice of Proposed Regulation amending R.61-15, *Certification of Need for Health Facilities and Services*, for publication in the September 23, 2022, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-7-110 et seq., which requires the Department to adopt substantive and procedural regulations considered necessary by the Department and approved by the Board to carry out the Department's Certificate of Need duties. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. R.61-15, *Certification of Need for Health Facilities and Services*, provides substantive and procedural regulations necessary to carry out the Department's Certificate of Need duties. The Department proposes amending R.61-15 for consistency with statutory requirements, to establish an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing, and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. The amendments may also revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

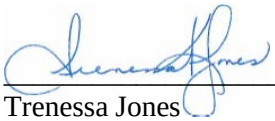
2. The Department had a Notice of Drafting published in the June 24, 2022, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from 18 parties by the July 25, 2022, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

3. Department staff conducted a virtual stakeholder meeting on July 20, 2022, to receive comments on the current regulation. More than 70 internal and external participants attended the meeting.

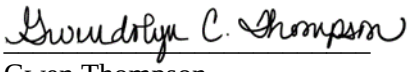
4. Appropriate Department staff conducted an internal review of the proposed amendments on August 18, 2022.

III. Request for Approval

The Bureau of Planning and Construction respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 23, 2022, *State Register*.



Trenessa Jones
Bureau Director
Bureau of Planning and Construction



Gwen Thompson
Director
Healthcare Quality

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the June 24, 2022, *State Register*
C. Summary of Public Comments Received and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-15, *Certification of Need for Health Facilities and Services*

September 8, 2022

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-340

61-15. Certification of Need for Health Facilities and Services.

Preamble:

Pursuant to S.C. Code Sections 44-7-110 et seq., the Department of Health and Environmental Control ("Department") is required to adopt substantive and procedural regulations considered necessary by the Department and approved by the S.C. Board of Health and Environmental Control ("Board") to carry out the Department's Certificate of Need duties. The Department proposes amending R.61-15 for consistency with statutory requirements, to establish an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing, and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. Additionally, the proposed amendments may revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the June 24, 2022, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
Entire Regulation	Technical Correction	Amended each instance of "these regulations" to "this regulation" for clarity and consistency.
Table of Contents	Technical Correction Reorganization	Amended language and sections to reflect technical corrections and reorganization proposed in regulation text.
Chapter 1 Title	Revision	Amended language to reflect reorganization made in regulation text.
101. Purpose.	Revision	Amended to add the word "care" to make the terminology

Section	Type of Change	Purpose
		consistent throughout the regulation.
Former 102. Applicability.	Revision	Recodified this section for clarity. Amended to increase the threshold amounts consistent with LAC and recommendation and language from prior legislation.
New 102. Definitions. (Former 103)		
Affected Persons	Technical Correction Reorganization	Amended to reformat the definition and move part of the definition to Section 402.
Competing Applicants	Technical Correction Reorganization	Amended to reformat the definition.
Fees	Technical Correction Deletion	Amended to reformat the definition and delete the language that is clarified in other sections of the regulation.
Health Care Facility	Revision Technical Correction	Amended to reformat the definition and to revise language to reflect the statutory definition.
Health Service	Revision Technical Correction	Amended to reformat the definition and to revise language to reflect the State Health Plan definition.
Total Project Cost	Technical Correction	Amended to reformat the definition and to correct grammatical error.
Board Department Like Equipment with Similar Capabilities Person Soley for Research To Develop When Used in Connection With Health Services To Offer When Used in Connection With Health Services	Technical Correction	Amended to reformat these definitions for readability.
Ambulatory Surgical Facility	Deletion	Deleted these definitions because they are otherwise

Section	Type of Change	Purpose
Arrangement for Financing Children and Adolescents in Need of Mental Health Treatment in a Residential Facility Facility for Chemically Dependent or Addicted Persons Freestanding or Mobile Technology Hospital Institutional Health Services Nursing Home Psychiatric Hospital Residential Treatment Facility for Children and Adolescents		defined in the Certification of Need and Health Facility Licensure Act.
Good Cause	Deletion	Deleted because it is no longer defined in statute.
Controlling Interest Indigent Care Majority Ownership Non-Capital Cost	Addition	Added definitions to clarify their meaning in the context of this regulation for the regulated community.
New 103. Applicability. (Former 102)	Reorganization	Recodified this section from 102 to 103 for clarity.
103.1.c.	Revision	Amended to increase the threshold amounts consistent with the LAC recommendation and language from prior legislation.
103.1.d.	Technical Correction	Amended to add the word “a” to make it consistent with statutory language.
103.1.e.	Revision	Amended to remove language that is no longer needed in regulation.
103.1.f.	Revision Technical Correction	Amended to increase the threshold amounts consistent with the LAC recommendation

Section	Type of Change	Purpose
		and language of prior legislation.
103.3.	Revision Technical Correction	Amended to add a word for consistency with statute and amended to remove language that is no longer needed in regulation. Further amened for clarification.
104. Exemption Determinations.		
104.1.a.	Technical Correction	Amended for consistency.
104.1.b.	Technical Correction	Amended for consistency.
104.1.c.	Revision	Amended to add language clarifying the requirements for an exemption.
104.2	Technical Correction	Amended for consistency.
104.3.	Revision	Amended to change timeframe from 12 months to 18 months to allow applicants more time for project implementation and further amended for clarity and consistency.
104.4.	Revision Technical Correction	Amended to increase threshold amounts, to add a word for clarification, and to update the regulation section numbers referenced therein.
105. Determinations of Non-Applicability.		
105.1.a.	Revision	Amended to update section number references.
105.1.b.	Revision	Amended to increase threshold amounts and to clarify and simplify language in line with LAC recommendation.
105.2	Technical Change	Amended for consistency.
105.3.	Revision	Amended to change timeframe from 12 months to 18 months to allow applicants more time for project implementation. Amended to change the word “proposal” to “project” for consistency.
105.4	Technical Change	Amended for consistency.
105.5.	Revision	Amended to change a particular division of the Department (“DHEC Division of Health Facilities Construction”) to the

Section	Type of Change	Purpose
		"Department" for clarity and consistency.
105.5.b.	Technical Correction	Amended to change semicolon to period.
106. South Carolina Health Plan.	Technical Correction	Amended to correct punctuation and number formatting.
201. Public Notification.	Reorganization Technical Correction	Recodified the section for consistency.
202. Application.	Deletion	Amended to remove language that is no longer needed in regulation.
301. Submission of Application.	Revision	Amended to further streamline the application process, to clarify when the filing fee must be submitted, and to update the name of the Department's Bureau responsible for administering the CON program.
302. Additional Information.		
Former 302.1.	Deletion	Amended to remove language that is no longer needed in regulation.
New 302.1.	Revision Reorganization	Amended to add clarifying language and to recodify the section.
New 302.2.	Revision Reorganization	Amended to add clarifying language and to recodify the section.
New 302.3	Reorganization	Recodified the section.
303. Payment of Filing and Application Fees.		
303.1.	Technical Correction	Amended to correct capitalization and grammar.
New 303.2.	Reorganization	Amended to move language from the Definitions section regarding fee clarification.
New 303.3. (Former 303.2)	Technical Correction Reorganization	Recodified the section and corrected grammar for consistency.
304. Relative Importance Criteria.		
304.2.	Revision	Amended to clarify review period.
305. Review Time Frames.		
305.1.	Revision	Amended to remove language that is no longer needed in regulation.

Section	Type of Change	Purpose
305.2.	Revision Reorganization	Amended to add language from former Section 305.2.a., to add language allowing for electronic notifications, and to correct grammar due to added language.
305.2.a. and b.	Reorganization Deletion	Moved language from 305.2.a to 305.2 for clarity and deleted 305.2.b because the language is no longer needed in regulation.
306. Public Hearing.	Technical Correction	Amended for corrected grammar and consistency.
307. Department Review.	Revision	Amended to clarify Department review
New 308. Certificate of Need Issuance Fee. **(Former 309)**	Reorganization Revision	Recodified Section 309 to former Section 308, added clarifying language, and amended to remove language that is no longer needed in regulation.
New 309. Project Changes During Review Period. **(Former 308)**	Revision Reorganization	Amended to add clarifying language and recodified the section.
New 310. Validity of Certificate of Need Issued. **(Former 311)**	Reorganization Technical Correction	Recodified the section, and corrected punctuation and capitalization.
New 311. Prohibited Contact. **(Former 312)**	Reorganization	Recodified the section.
401. Appeals.		
401.1.	Revision Technical Correction	Amended to clarify who may appeal a decision and to correct capitalization for consistency.
401.2	Revision	Amended to clarify who may file a request for final review in opposition to the staff decision on a Certificate of Need.
402. [Reserved]	Deletion	Section no longer needed in the regulation.
501. Findings of the Department.	Deletion	Amended to remove language that is no longer needed in regulation.
New 501. Periodic Reports. **(Former 502)**	Reorganization	Recodified Section 502 to Section 501.
503. Distribution of Procedures Criteria.	Deletion	Amended to remove language that is no longer needed in regulation.
New 502. Review Under Applicable Plan. **(Former 504)**	Reorganization	Recodified Section 504 to Section 502.

Section	Type of Change	Purpose
601. Voidance and Extension of Certificates of Need.	Revision Technical Correction	Amended to add language to clarify the voidance (matter of law) and to delete the inconsistent language. Amended to correct grammar and number formatting.
602. Extension Request.	Revision	Amended extension request submission requirements for clarity.
603. Criteria for Extension.	Technical Correction	Amended to correct capitalization.
604. Non-Transferability of Certificate of Need.	Revision Technical Correction	Amended to clarify controlling interest and majority ownership, to remove language not consistent with statute, and to correct grammar.
605. Project Changes After Receipt of Certificate of Need.	Technical Correction	Amended to correct grammar.
607. Periodic Reporting of Certificate of Need Implementation.		
607.1	Technical Correction	Amended to correct grammar.
607.3	Technical Correction Addition	Amended to correct punctuation, and to add "a listing of non-capital costs" to the requirements for the final completion report as recommended by the LAC.
701. Penalties.	Revision Technical Correction	Amended to clarify language, remove duplicative language, and to correct grammar.
702. Reserved.	Deletion	Deleted this section because it is not needed in the regulation.
801. Applicability and Weighting.	Revision Technical Correction	Amended to correct references to amended sections. Amended to correct number formatting.
802. Criteria for Project Review.		
802.2.b.	Revision	Amended to correct state agency reference.
802.3.	Revision Reorganization Technical Correction	Amended to remove language that is no longer needed in regulation, corrected punctuation, and recodified items.
802.4.d through 802.12	Reorganization	Recodified these sections to new Section 802.7. based on public comments.

Section	Type of Change	Purpose
New 802.5. (Former 802.13)	Reorganization Technical Correction	Recodified former Section 802.13 to 802.5, and corrected grammar and punctuation.
New 802.6. (Former 802.14)	Reorganization	Recodified former Section 802.15 to 802.6.
New 802.7.a. through e. (Former 802.15-16)	Reorganization	Amended to combine former Sections 802.15 and 802.16 and recodify to 802.7.a through e based on public comments.
New 802.8 (Former 802.17)	Reorganization Technical Correction	Recodified former Section 802.17 to 802.8 and corrected punctuation.
802.18.	Deletion	Deleted language because it is in the application requirements.
New 802.10 (Former 802.20)	Reorganization Revision	Recodified former Section 802.20 to 802.10 and amended language for clarity, consistency, and accuracy.
New 802.11 (Former 802.21)	Reorganization Technical Correction	Recodified former Section 802.21 to 802.10 and corrected punctuation.
New 802.12-13 (Former 802.22-23)	Reorganization	Recodified former Sections 802.22-23 to 802.12-13.
New 802.13 (Former 802.24-25)	Reorganization	Combined former Sections 802.24-25 and recodified as new Section 802.13.
New 802.14 (Former 802.26 and 29)	Reorganization Addition	Combined former Section 802.26 and 802.29 and recodified as new Section 802.14. Changed subsection title to “Zoning and Site Suitability.”
802.27	Deletion	Amended to remove language that is no longer needed in regulation.
New 802.15 (Former 802.28)	Reorganization	Recodified former Section 802.28 to new Section 802.15.
802.30	Deletion	Deleted language because it is provided on the CON application.
New 802.16 (Former 802.31)	Reorganization Technical Correction	Recodified former Section 802.31 to new Section 802.16 and corrected for punctuation.
802.32	Deletion	Deleted language because it is provided on the CON application.
New 802.17 (Former 802.33)	Reorganization	Recodified former Section 802.33 to new Section 802.17.

Section	Type of Change	Purpose
New 802.18	Addition	Added quantitative quality of care metrics to the project review criteria to align with LAC recommendation.
Appendix	Deletion	Deleted Appendix to streamline the application and to align the regulation for implementation of electronic application process.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to the Office of Policy and Communications; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Public Comment Form at https://forms.office.com/g/9VMEXLWtq0. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 24, 2022, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 8, 2022, 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. 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. Public hearing procedures are subject to change in response to COVID-19 protocols. If applicable, the Department will provide notice of these changes twenty-four (24) hours in advance of the public hearing.

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/.

Preliminary Fiscal Impact Statement

The Department does not anticipate the implementation of this regulation will require any additional resources. There is no anticipated additional cost to the Department or state due to any inherent requirements of this regulation. There are no external costs anticipated.

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: 61-15, Certification of Need for Health Facilities and Services

Purpose: The Department proposes to amend R.61-15, Certification of Need for Health Facilities and Services, for consistency with statutory requirements, to establish an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing,

and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. Additionally, the proposed amendments may also revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

Legal Authority: 1976 Code Sections 44-7-110 through 44-7-340

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendments. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, 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:

R.61-15 has not been substantively revised since 2003 and needs to be updated to reflect current technology and industry standards. In February 2022, the Legislative Audit Council (LAC) issued *A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program,* wherein the LAC provided a list of recommendations for the Certificate of Need program. The Department's Agency Response to the LAC report indicated initiating the promulgation process in 2022 to address the recommendations through regulatory revisions.

The LAC recommendations that the Department is addressing in this proposed revision include standardizing the information required for Certificate of Need applicants to ensure consistency in its evaluation process, requiring Certificate of Need applicants to provide information on net patient charges when project impact on patient charges is a factor in the evaluation process; requiring Certificate of Need applicants to report on non-capital expenses related to a project; and increasing the thresholds for equipment and capital expenditures for the Certificate of Need program and provide the adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index.

The Department's proposed amendments are in line with the abovementioned LAC recommendations, and additionally include moving to a more streamlined and modernized application format and process, increasing the timeframes for the exemption and non-applicability determinations from 12 months to 18 months, and streamlining and consolidating the project review criteria from 33 criteria to 17 criteria. Overall, the Department's proposed amendments aim to increase flexibility and minimize the undue burden to the regulated community.

DETERMINATION OF COSTS AND BENEFITS:

The Department anticipates the proposed amendments will decrease costs and increase benefits to the regulated community by improving the application process and increasing the monetary thresholds that trigger Certificate of Need review. The Department anticipates the proposed amendments will decrease the costs necessary to maintain the current Certificate of Need application and review processes. The Department anticipates the benefits will include increased time and resources to process and review Certificate of Need applications. The proposed amendments remove the requirement that Certificate of Need applications be submitted as paper applications and allow the Department to move towards implementation of an electronic application process.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties associated with the estimations beyond those normally inherent in estimating future costs and benefits.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments to R.61-15 seek to improve the Certificate of Need application and review processes involved in determining whether there is need for, among other items, construction or other establishlishment of a new health care facility. This supports the Department's mission to improve the quality of life for all South Carolinians by protecting and promoting the health of the public and the environment.

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

It may be detrimental to the regulated community and public health if the proposed amendments to R.61-15 are not implemented because the Certificate of Need application process will continue to require the submission of paper copies and limit the Department's ability to modernize and improve efficiencies in the process required prior to undertaking, among other items, the construction or other establishment of a new health care facility. This is detrimental to the accessibility of the Certificate of Need application process as well as to the new health care facility. There is no anticipated detrimental effect on the environment if the proposed amendments are not implemented.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

R.61-15, Certification of Need for Health Facilities and Services, provides substantive and procedural regulations necessary to carry out the Department's Certificate of Need duties. The Department proposes amendments to address the recommendations from the Legislative Audit Council's February 2022, report, *A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program*, that are within the Department's authority to implement through regulatory change, to bring the regulation into alignment with statutory requirements, and to improve Department processes..

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-15. Certification of Need for Health Facilities and Services.

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-340

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CHAPTER 1
PURPOSE, ~~APPLICABILITY AND~~ DEFINITIONS, AND APPLICABILITY

SECTION 101. Purpose.

The purpose of ~~these~~this ~~R~~regulation~~s~~ is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health care facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State.

~~**SECTION 102. Applicability.**~~

~~1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:~~

~~a. The construction or other establishment of a new health care facility;~~

~~b. A change bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds;~~

~~c. An expenditure by or on behalf of a health care facility in excess of two million dollars ($2,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure except those expenditures exempted in Section 104. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;~~

~~d. capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;~~

~~e. If no capital expenditure is made, the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan. For purposes of this section, operating costs include expenditures incurred by the health care facility and any person or other entity on behalf of the health care facility to establish a new service. A person or other entity shall not be allowed to incur costs thereby attempting to enable a health care facility to avoid Certificate of Need review and establish a new service as described above;~~

~~f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of six hundred thousand dollars ($600,000).~~

~~2. An applicant may not split or combine one expenditure into two or more expenditures for the purpose of avoiding Certificate of Need review, nor may the Department be allowed to lump projects together arbitrarily to bring them under Certificate of Need review.~~

~~3. When any question exists, a potential applicant shall forward a letter requesting a formal determination by the Department as to the applicability of the Certificate of Need requirements to a particular project. Such a letter shall contain a detailed description of the project including the extent of modifications, changes in services and total costs. Additional information may be requested as may be reasonably necessary to make such applicability determination. The Department shall respond within sixty (60) calendar days of receipt of the necessary information.~~

~~4. These provisions do not apply to acquisitions or changes of ownership of health care facilities, services, and equipment that are already in existence, operational, and providing services in a particular service area, and which have undergone the review and obtained the approval that was appropriate under the law at the time they first entered the relevant service area, so long as the facility or service is not being relocated. For facilities, services, and equipment which have previously undergone Certificate of Need review, the Certificate of Need must be fulfilled prior to a change of ownership.~~

SECTION ~~103~~102. Definitions.

1. ~~Affected person means the~~**Affected Person.** The applicant, a person residing within the geographic area served or to be served by the applicant, persons located in the health service area in which the project is to be located and who provide similar services to the proposed project, persons who before receipt by the Department of the proposal being reviewed have formally indicated an intention to provide similar services in the future, persons who pay for health services in the health service area in which the project is to be located and who have notified the Department in writing of their interest in Certificate of Need applications, the State Consumer Advocate and the State Ombudsman. Persons from another state who would otherwise be considered "affected persons" are not included unless that state provides for similar involvement of persons from South Carolina in its Certificate of Need process. ~~A person may not file a request for final review in opposition to the staff decision on a Certificate of Need unless the person provided written notice to the Department during the staff review that he is an affected person and specifically states his opposition to the application under review. Affected persons may request in writing to be notified of a Department decision by regular mail or electronic mail in lieu of certified mail.~~

~~2. Ambulatory surgical facility means a distinct, free-standing, self-contained entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures and/or services for which patients are scheduled to arrive, receive surgery or related care, treatment, procedures and/or services and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff.~~

~~3. Arrangement for financing means a financial commitment, i.e. enforceable contract.~~

~~4. Board means the~~2. **Board.** The State Board of Health and Environmental Control.

~~5. Children and adolescents in need of mental health treatment in a residential treatment facility means a child or adolescent under age eighteen who manifests a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree that child's capacity either to develop or to exercise age-appropriate or age-adequate behavior. The behavior includes, but is not limited to, marked disorders of~~

~~mood or thought processes, severe difficulties with self-control and judgment including behavior dangerous to self or other, and serious disturbance in the ability to care for and relate to others.~~

~~6. Competing applicants means two~~3. **Competing Applicants.** Two (2) or more persons and/or health care facilities as defined in this regulation who apply for Certificates of Need to provide similar services and/or facilities in the same service area and whose applications, if approved, would exceed the need for this facility type or service. An application shall be considered competing if it is received by the Department no later than fifteen (15) calendar days after a Notice of Affected Persons is published in the State Register for one or more applications for similar services and/or facilities in the same service area. All applications received by the Department within fifteen (15) days of publication of the Notice of Affected Persons in the State Register for the first application(s) will be considered to be competing. Any applications received by the Department later than the fifteenth day following publication of the Notice of Affected Persons in the State Register for the first application(s) will not be considered to be competing with the(se) application(s).

4. **Controlling Interest.** Ownership interest in a company (corporation, limited liability company, partnership, or other entity) with enough voting shares or other interests to prevail in any motion. A majority of voting shares or interests is always a controlling interest.

~~7. Department means the~~5. **Department.** The S.C. Department of Health and Environmental Control.

~~8. Facility for chemically dependent or addicted persons means a facility organized to provide outpatient or residential services to chemically dependent or addicted persons and their families based on an individual treatment plan including diagnostic treatment, individual and group counseling, family therapy, vocational and educational development counseling, and referral services.~~

~~9. Fees mean the~~6. **Fees.** The Department may charge and collect fees to cover the cost of operating the program. The fees for review of ~~c~~Certificate of ~~n~~Need projects include: (a) initial filing fee; (b) application fee; and (c) issuance fee.

~~a. Initial filing fee is five hundred dollars ($500), which must be submitted as a non-refundable initial payment at the time the application is submitted.~~

~~b. Application fee is one half of one percent (.5%, .005) of the total project cost (as defined in Section 103.25) which is payable when the application is deemed complete under Section 303. The application fee shall not exceed seven thousand dollars ($7,000).~~

~~c. Issuance fee is seven thousand five hundred dollars ($7,500) payable upon the granting of a Certificate of Need to any project whose total project cost (as defined in Section 103.25) is greater than one million four hundred thousand dollars ($1,400,000). Should the project not be approved, the issuance fee will not be assessed.~~

~~10. Freestanding or Mobile technology means medical equipment owned or operated by a person other than a health care facility for which the total cost is in excess of that prescribed in these regulations and for which specific standards or criteria are prescribed in the South Carolina Health Plan.~~

~~11. Good cause is defined as~~:

~~a. presentation of significant and relevant information not previously considered by the Department;~~

~~b. demonstration that there have been significant changes in factors or circumstances relied upon by the Department in reaching its decision;~~

~~c. demonstration that the Department has materially failed to follow its adopted procedures in reaching its decision; or~~

~~d. such other basis for a public hearing as the Department determines constitutes good cause.~~

~~12. Health care facility for the purposes of Certificate of Need means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care for the persons with intellectual disability, inpatient hospice facilities, radiation therapy facilities and any other facility for which Certificate of Need review is required by state law.~~7. **Health Care Facility.** Acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care facilities for persons with intellectual disability, narcotic (opioid) treatment programs, and any other facility for which Certificate of Need review is required by law.

~~13. Health service means clinically~~8. **Health Service.** Clinically related, diagnostic, treatment, or rehabilitative services, and includes alcohol, drug abuse, and mental health services for which specific standards or criteria are prescribed in the South Carolina Health Plan.

9. **Indigent Care.** Care provided to persons who do not have health insurance and who are not eligible for other health care such as Medicare, Medicaid, or private health insurance. Indigent care does not include bad debt, contractual adjustments, or care which is reimbursed by a governmental program (Medicare, Medicaid, county indigent program), church, or philanthropic organization.

~~14. Hospital means a facility organized and administered to provide services to accommodate two or more non-related persons for the diagnosis, treatment and care of such persons over a period exceeding 24 hours and provides medical or surgical care or nursing care of illness, injury, or infirmity and may provide obstetrical care, and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.~~

~~15. Institutional health services means health services provided in or through health care facilities and includes the entities in or through which such services are provided.~~

~~16. Like equipment with similar capabilities means~~10. **Like Equipment with Similar Capabilities.** A medical equipment in which functional and technological capabilities are identical to the equipment to be replaced; ~~and~~ the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and does not constitute a material change in service or a new service.

11. **Majority Ownership.** Ownership of more than 50% of the capital stock, limited liability company interests, partnership units, or other equity or ownership interests of a company.

12. **Non-Capital Cost.** Operating costs incurred that relate directly to the current project's implementation excluding exploration costs and capital costs. These costs shall include, but are not limited to, staff time, consultant fees, and legal/litigation costs, to the extent incurred.

~~17. Nursing home means a facility with an organized nursing staff to maintain and operate organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing nursing care for persons who are not in need of hospital care.~~

~~18. Person means an~~13. **Person.** An individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, a health care facility, a state, a political subdivision, or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.

~~19. Psychiatric Hospital means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.~~

~~20. Residential treatment facility for children and adolescents means a facility operated for the assessment, diagnosis, treatment, and care of two or more "children and adolescents in need of mental health treatment" which provides:~~

~~a. a special education program with a minimum program defined by the South Carolina Department of Education.~~

~~b. recreational facilities with an organized youth development program; and~~

~~c. residential treatment for a child or adolescent in need of mental health treatment.~~

~~21. Solely for research means a~~14. **Solely for Research.** A service, procedure, or equipment which has not been approved by the U.S. Food and Drug Administration (FDA) but which is currently undergoing review by the FDA as an investigational device. FDA research protocol and any applicable Investigational Device Exemption (IDE) policies and regulations must be followed by a facility proposing a project ~~'~~solely for research.~~'~~

~~22. To develop when used in connection with health services, means to~~15. **To Develop When Used in Connection With Health Services.** To undertake those activities which on their completion will result in the offering of a new institutional health services or the incurring of a financial obligation in relation to the offering of such a service.

~~23. To offer when used in connection with health services means that the~~16. **To Offer When Used in Connection With Health Services.** The health care facility holds itself out as capable of providing or as having the means for the provision of, specified health services.

~~24. Total project cost is the~~17. **Total Project Cost.** The estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect~~'~~s fees, consultant fees, financing cost, and other capital costs properly charged under generally accepted accounting ~~principals~~principles as a capital cost. The determination of project costs involving leased equipment of buildings will be calculated based on the total value (purchase price) of the equipment or building being leased.

SECTION 103. Applicability.

1. A person or health care facility as defined in this regulation is required to obtain a Certificate of Need from the Department before undertaking any of the following:

a. The construction or other establishment of a new health care facility;

b. A change in the existing bed complement of a health care facility through the addition of one (1) or more beds, or change in the classification of licensure of one (1) or more beds;

c. An expenditure by or on behalf of a health care facility in excess of five million dollars ($5,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure except those expenditures exempted in Section 104. Starting July 1, 2025, and every fifth year thereafter, the Department must determine the increase or decrease in the ratio of the Consumer Price Index for all urban consumers (CPI-U), Medical Care Commodities in the US City Average, for the prior five (5)-year period published by the United States Department of Labor; the dollar threshold for expenditures by or on behalf of a health care facility pursuant to this item shall be adjusted accordingly, except that the dollar amount shall never be adjusted below five million dollars ($5,000,000). The first adjustment shall be made on July 1, 2025, and subsequent adjustments shall be made every fifth year on July 1, or if July 1 is a Saturday or Sunday, the next non-holiday business day following July 1. The Department shall post notice of the adjustments on its website, and the adjusted amount shall become effective as of the date of the posting on the Department's website. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;

d. A capital expenditure by or on behalf of a health care facility that is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;

e. If no capital expenditure is made, the offering of any health service by or on behalf of a health care facility that has not been offered by the facility in the preceding twelve (12) months and for which specific standards or criteria are prescribed in the South Carolina Health Plan; or

f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of two million dollars ($2,000,000). Starting July 1, 2025, and every fifth year thereafter, the Department must determine the increase or decrease in the ratio of the Consumer Price Index for all urban consumers (CPI-U), Medical Care Commodities in the US City Average, for the prior five (5)-year period published by the United States Department of Labor; the dollar threshold for total project cost for the acquisition of medical equipment to be used for diagnosis or treatment pursuant to this item shall be adjusted accordingly, except that the dollar amount shall never be adjusted below two million dollars ($2,000,000). The first adjustment shall be made on July 1, 2025, and subsequent adjustments shall be made every fifth year on July 1, or if July 1 is a Saturday or Sunday, the next non-holiday business day following July 1. The Department shall post notice of the adjustments on its website, and the adjusted amount shall become effective as of the date of the posting on the Department's website.

2. An applicant may not split or combine one (1) expenditure into two (2) or more expenditures for the purpose of avoiding Certificate of Need review, nor may the Department be allowed to combine projects together arbitrarily to bring them under Certificate of Need review.

3. A potential applicant may submit a written request to the Department for a formal determination as to the applicability of the Certificate of Need requirements for a particular project. Such a request shall contain a detailed description of the project, including the extent of modifications, changes in services, and total project costs. Additional information may be requested as may be reasonably necessary to make such applicability determination.

4. These provisions do not apply to acquisitions or changes of ownership of health care facilities, services, and equipment that are already in existence, operational, and providing services in a particular service area, and which have undergone Certificate of Need review and obtained the approval that was appropriate under the law at the time they first entered the relevant service area, so long as the facility or service is not being

relocated. For facilities, services, and equipment that have previously undergone Certificate of Need review, the Certificate of Need must be fulfilled prior to a change of ownership.

SECTION 104. Exemption Determinations.

1. The following are exempt from Certificate of Need review, but prior to undertaking these projects, a written determination from the Department is required:

a. The replacement of like equipment for which a Certificate of Need has been issued and the replacement does not result in a material change in service or a new service~~,~~;

b. The acquisition by a health care facility of medical equipment to be used solely for research, the offering of an institutional health service by a health care facility solely for research, or the obligation of a capital expenditure by a health care facility to be made solely for research if it does not: (a) affect the charges of the facility for the provision of medical or other patient care services other than the services which are included in the research; (b) change the bed capacity of the facility; or (c) substantially change the medical or other patient care service of the facility. FDA research protocol and any applicable Investigational Device Exemption (IDE) policies and regulations must be followed by the facility. A written description of the proposed research project must be submitted to the ~~d~~Department in order for the ~~d~~Department to determine if the above conditions are met. A Certificate of Need is required to continue use of the equipment or service after the equipment or service is no longer being used solely for research; or

c. The permanent reduction in bed capacity, including the permanent closure of a health care facility, or reduction or permanent termination of any health service that has not been offered by the health care facility in the preceding twelve (12) months and for which specific standards or criteria are prescribed in the South Carolina Health Plan.

2. In order to request an exemption, the following information must be provided to the Department in writing, at a minimum:

a. A complete description of the proposed project, including, but not limited to, location of the project, and total project costs~~,~~;

b. Other documentation requested by the Department in order to determine compliance with these regulations; and

c. Additional information as may be reasonably necessary for the Department to make a determination.

3. If an exemption is granted, it is valid for a period of ~~twelve~~eighteen (~~12~~18) months from the date of issuance. If the ~~proposal~~exempted project is not implemented within this ~~twelve~~eighteen-month period, the exemption becomes void and another exemption must be requested in order for the applicant to undertake the ~~proposal~~project. If no evidence of implementation is submitted within eighteen (18) months of issuance, a new exemption request must be submitted to the Department for review.

4. The following projects are exempt from Certificate of Need review ~~but~~and do not require a written determination from the Department: the offices of a licensed private practitioner whether for individual or group practice. This exemption shall not apply to: (1) the construction or other establishment of a new health care facility, as in Section ~~102~~103.1.a; or (2) the acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of ~~six hundred thousand~~two million dollars (~~$600,000~~2,000,000) or adjusted, as in Section ~~102~~103.1.f.

SECTION 105. Determinations of Non-Applicability.

1. Certificate of Need review is not applicable to the following, but prior to undertaking the proposed project, a written determination of non-applicability from the Department is required:

a. Replacement of like equipment with similar capabilities as defined by the Department in Section ~~103.16.~~102; or

b. Acquisition of medical equipment which is to be used for diagnosis or treatment if ~~the total project cost is not in excess of six hundred thousand dollars ($600,000). A written determination of non-applicability is only required when~~ any question exists as to whether ~~or not~~ the total project cost is below ~~the six hundred thousand~~two million dollars (~~$600,000~~2,000,000) or adjusted, as in Section 103.1.f.

2. The following information must be provided to the Department in writing, at a minimum:

a. A complete description of the proposed project, including, but not limited to, location of the project, total project costs, capital and/or operational cost;

b. Other documentation requested by the Department in order to determine compliance with ~~these~~this regulation~~s~~; and

c. Additional information as may be reasonably necessary to make a determination.

3. If a determination of non-applicability is granted pursuant to Section 105.1, it is valid for a period of ~~twelve~~eighteen (~~12~~18) months from the date of issuance. If the ~~proposal~~project is not implemented within this ~~twelve~~eighteen (~~12~~18) month period, the non-applicability determination becomes void and another determination must be requested in order to undertake the ~~proposal~~project. If no evidence of implementation is submitted within eighteen (18) months of issuance, a new non-applicability request must be submitted to the Department for review.

4. Certificate of Need review is not applicable to the following projects and a written non-applicability determination from the Department is not required prior to undertaking these projects:

a. Health care facilities owned and operated by the federal government;

b. Any federal health care facility sponsored and operated by this State;

c. Educational and penal institutions maintaining infirmaries for the exclusive use of their respective student bodies and inmate populations; or

d. Facilities owned and operated by the South Carolina Department of Mental Health and the South Carolina Department of Disabilities and Special Needs, except an addition of one (1) or more beds to the total number of beds of the departments' health care facilities existing on July 1, 1988~~;~~.

5. Certificate of Need review is not applicable to the following projects and a written non-applicability determination from the Department is not required. However, written notification shall be provided to ~~DHEC Division of Health Facilities Construction~~the Department prior to undertaking the following projects:

a. An expenditure by or on behalf of a health care facility for non-medical projects, such as refinancing existing debt, parking garages, laundries, roof replacement, computer systems, telephone systems, and heating and air conditioning systems; or

b. The upgrading of medical facilities, which do not involve additional square feet to the facility or additional health services~~;~~.

SECTION 106. South Carolina Health Plan.

1. With the advice of the health planning committee, the Department shall prepare a South Carolina Health Plan for use in the administration of the Certificate of Need Program. The plan, at a minimum, must include:

a. an inventory of existing health care facilities, beds, specified health~~,~~ services, and equipment~~.~~;

b. projections of need for additional health care facilities, beds, health services, and equipment;

c. standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of service, and proper planning of health care facilities; and

d. a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications for each type of facility, service, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment, may outweigh the adverse affects caused by the duplication of any existing facility, service, or equipment.

2. The South Carolina Health Plan must address and include projections and standards for specified health services and equipment which have a potential to substantially impact health care cost and accessibility. Nothing in this provision shall be construed as requiring the Department to approve any project which is inconsistent with the South Carolina Health Plan.

3. Upon approval by the health planning committee, the South Carolina Health Plan must be submitted at least once every two (2) years to the Board for final revision and adoption. Once adopted by the Board, the Plan may later be revised through the same planning and approval process, public review and comment, including four (4) regional public hearings before adoption or revision of the Plan. Prior to revising the plan, the Department will publish a notice in the State Register, announcing a period for public comments and scheduling public hearings to receive public comments.

CHAPTER 2
APPLICATION PROCEDURES

SECTION 201. Public Notification.

1. Within twenty (20) calendar days prior to submission of an application, the applicant shall publish notification that an application is to be submitted to the Department in the legal section of a daily newspaper serving the area where the project is to be located for three (3) consecutive days. The notification must contain at least the following information:

~~1)~~a. that a Certificate of Need is being applied for;

~~2)~~b. a description of the scope and nature of the project; and

~~3)~~c. the estimated project capital cost.

2. No application may be accepted for filing by the ~~d~~Department unless accompanied by documentation from the newspaper that publication has been made for three (3) consecutive days within the prior twenty (20) day period.

~~SECTION 202. Application.~~

~~1. Two copies of the application shall be forwarded to the Department in the following format and shall contain the following information as applicable. The application will be on 8 ½ × 11-inch paper, one side only, and 3-hole punched on the left side.~~

~~2. Application~~

~~a. Proposal Page and Part A. Questionnaire (See Appendix)~~

~~b. Part B. Additional Information~~

~~(1) Document that the applicant has published notification of this project in a local newspaper as required by Section 201 of these Regulations.~~

~~(2) Describe the project setting forth the proposed change in services or facilities in as much detail as possible. State whether the project will change the existing licensed or survey bed capacity, will encompass the development of a new service, or result in the discontinuance of an existing service. If a new facility is proposed, list all services to be provided.~~

~~(3) Provide the total cost of the project, indicating design fees, land cost, interest cost, construction cost, equipment cost, and any other cost involved in the project. Provide an estimate of the construction cost from a licensed architect or engineer; in the case of equipment, valid/current estimate from a vendor is acceptable.~~

~~(4) State the specific location of the facility or service and/or equipment, including, where applicable, specific areas of an existing facility to be affected by the project. Provide room numbers of all patient rooms affected. Sufficient detail should be provided to allow the Department to visually inspect the site. The number of private and semi-private patient rooms shall be identified.~~

~~(5) Provide details regarding any proposed construction and/or renovations. Discuss alternatives to new construction and why these alternatives were rejected. For a multi-floor project, construction and/or renovation must be described, by floor, to include any additions and/or deletions made to each floor. Provide evidence that the applicant has adequately planned for any temporary move or relocation of any department, facility, or services, which may be necessary during the construction period. Document that plans exist to assure adequate protection (from fire, noise, dust, etc.) and continuation of all services during the proposed construction period.~~

~~(6) If a replacement facility or ancillary service is being constructed, describe plans for disposition of the existing facility or ancillary service area upon completion of the project.~~

~~(7) Provide a timetable for development and completion of the project to include, at a minimum, the date of site acquisition, date of architectural contract, architectural design schedule, date of closing for financing, date of valid construction contract, date that all necessary permits (grading, building, sewer, etc.)~~

will be obtained, and date of start of construction. The timetable shall be presented in one month increments commencing with the month following receipt of the Certificate of Need and ending with the execution of a contract or purchase order for equipment only projects.

(8) Provide the following ownership information:

(a) Proposed name of facility;

(b) Name and address of licensee or prospective licensee. (Note: The licensee is defined as the legal entity who, or whose governing body, has the ultimate responsibility and authority for the conduct of the facility or service; the owner of the business. The licensee must be the entity to whom the Certificate of Need is issued.)

(c) Complete title of the licensee's governing body.

(d) Name, title and mailing address of presiding officer of the governing body.

(e) Name and mailing address of all persons and/or legal entities having any ownership interest or owner's equity of the licensee to include a schedule of percent and type ownership claim of each.

(f) Name and mailing address of all persons and/or legal entities claiming liabilities of the licensee or of the facility or service for which this Certificate of Need is requested to include a schedule of percent and type of claim of each.

(g) Provide a listing which identifies all officers of the licensee.

(h) Is the land and/or building on/in which the proposed facility or service is to be conducted owned by the applicant. _____ YES _____ NO. If no, provide information on the land and building similar to that required in (b) through (g) above.

(i) Has the licensee engaged an entity other than an employee of the licensee to manage or operate the facility or service? _____ YES _____ NO. If yes, provide information similar to that required in (b) through (g) above.

(j) Is there any agreement, contract, option, understanding, intent or other arrangement that will effect a change in any of the information requested and/or provided in (b) through (g) above. _____ YES _____ NO. If yes, provide information similar to that required in (b) through (g) above.

(k) Provide a complete listing of all existing licensed health care facilities and/or services and Certificates of Need in which the proposed licensee currently has an ownership interest, to include names and addresses of each facility or service. In the cases of Certificates of Need for undeveloped facilities and services, provide the name, address, and telephone number of a contact person representing the authority which issued the Certificate of Need.

(*l*) Should the licensee be a subsidiary corporation, provide a diagram of the licensee's relationship to the parent corporation and list the name and address of the parent corporation as well as the corporation which has ultimate control. In addition, please provide the name and mailing address of all persons and/or legal entities having ownership interest of five percent or more or any person with any agreement, contract, option, arrangement, or intent to acquire ownership interest of five percent or more, of all corporations in the corporate organizational structure which have ultimate control of the licensee.

(9) Provide documentation that the applicant has sought cooperative agreements such as transfer agreements with other facilities, as applicable.

(10) Indicate the means by which a person will have access to the facility's services (i.e. physician referral, self admission, etc). Identify the specific facilities or agencies the applicant expects to receive referrals from (i.e. hospitals, home health agencies, etc). Describe any limitations placed on admissions.

(11) Demonstrate that the proposed project is needed or projected as necessary to meet an identified need of the public. This shall address at a minimum: identification of the target population; the degree of unmet need; projected utilization of the proposed facility or service; utilization of existing facilities and services; past utilization of existing similar services within the facility; and justification that the proposed project will not unnecessarily duplicate existing entities. The applicant must show all assumptions, data sources, and methodologies used. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.

(12) Discuss alternative facilities and/or services considered including the advantages and disadvantages of each alternative. Include a statement as to why this project alternative was adopted.

(13) Discuss any serious problems, such as costs, availability, or accessibility in obtaining care of the type proposed, experienced by patients in the absence of this project.

(14) Where a project affects an increase or decrease in bed capacity, provide annual occupancy rates for the facility based on licensed beds, for the past three years by category (i.e. general acute, psychiatric, obstetric, nursing home, etc.).

(15) Identify the method of financing the cost of the project, including the start-up costs. Provide documentation that the applicant can obtain such financing. Alternative sources and/or methods of financing must be identified and the method chosen demonstrated to be the most feasible option.

(16) For an addition to an existing facility or service, provide a current annual budget and at least a three fiscal year projected budget for both the overall facility and the proposed project. The projections must be developed by an accountant. For a new facility or service, provide a projected annual budget for not less than three fiscal years following the completion of the proposed project. The projections must be attested to by an accountant. These budgets must at a minimum include how proposed charges, proposed cost of service, utilization, depreciation, reimbursement rates and contractual adjustments were calculated. Any assumptions made in the application must be specifically noted.

(17) Provide a list of proposed charges for the project. The charges provided may be used for comparison with the average charges in the final completion report as required in Section 607.3.b.

(18) Document that the proposed project is economically feasible, both immediately and long term. In the case of existing facilities, indicate what impact the proposed project will have on patient charges and cost per unit of service.

(19) State how the project will foster cost containment and improve quality of care through the promotion of such services as ambulatory and home health care, preventive health care, promotion of shared services, economies of scale, and design and construction economies.

(20) In the case of projects involving additional long-term care beds, discuss how the plans of other agencies, organizations, or programs responsible for providing and financing long-term care have been considered.

(21) Provide a three-year projected manpower budget in full-time equivalents (FTE's) detailing the existing and proposed nursing, other professional, and non-professional personnel required for the staffing of the new project.

(22) Provide the number of existing and proposed medical staff by specialty, to include physicians employed by, or with admission privileges to, the facility. Include the name of the Chief of the Medical Staff, if available.

(23) Indicate those physicians who have expressed a willingness to utilize the proposed services or to refer patients to the facility for the provision of services.

(24) Discuss the availability of health manpower resources for the provision of the proposed services, including the contemplated program and plan for recruiting and training personnel.

(25) Describe the previous experience of the applicant in the proposed health care field. If the applicant has no prior experience, specify the anticipated sources of technical assistance, either from specific individuals or organizations.

(26) Discuss the impact of the project on the clinical training programs of health professional schools, particularly the extent to which these schools will have access to the services for training.

(27) Provide documentation of policies and procedures to assure the quality of healthcare services by addressing patient safety and quality indicators, as applicable. Documents may include, but are not limited to, measures of patient care, patient safety, healthcare-acquired infections and the following of best practices established by recognized organizations. Applicable quality standards in the South Carolina Health Plan must be addressed.

(28) Provide any additional information that would assist the department in evaluating this project.

c. Part C. Programmatic Documents

Provide adequate programmatic documents in support of the various elements of the proposed project. These documents will include as appropriate:

(1) An Indigent Care Plan as required by the Board of Health and Environmental Control. It shall address at a minimum, the following:

(a) The existing and proposed admission and treatment policies of the facility or agency with regard to race, sex, creed, national origin, and ability to pay.

(b) The proposed admission and treatment policies of the facility or agency with respect to admission and care of indigent patients including those patients unable to pay at the time of admission and those whose benefits expire while in the care of the facility or agency.

(c) In existing facilities or agencies, provide the amount, in dollars and percent of gross revenues, that the facility or agency provided in indigent care during the past three fiscal years. NOTE: Indigent care does not include bad debt; contractual adjustments; or care which is reimbursed by a governmental program (Medicare, Medicaid, county indigent program), church, or philanthropic organization.

(d) Provide the proposed amount of indigent care the facility or agency projects to provide during the existing fiscal year and next fiscal year. This projection should be expressed in both dollars and a percent of gross revenues.

(e) A discussion of why the above figures are adequate or inadequate for the needs of the community; the need of indigent care within the proposed service area; and any solutions, remedial plans or proposals by the facility or agency to better address the indigent care problem in the service area. Include any initiatives or undertakings the facility or agency has begun to address the indigent care problem in the proposed service area.

(f) Describe any Board or Advisory Board established to implement or control the indigent problem at the facility or agency. Include the Board's functions, responsibilities, and limitations.

(2) A map of sufficiently large scale to be meaningful, indicating the location of the project site and its geographical area.

(3) A plot plan of the project site showing existing buildings, roads, parking areas, walks, service and entrance courts, existing utilities (electricity, telephone, water, railroads, sewer, gas, etc.) and other natural land features necessary for adequate analysis of site conditions.

(4) A legal description of the project site indicating its physical characteristics and existing easements.

(5) A square foot program of space and/or equipment elements, and scale drawings describing the existing space and proposed alterations and additions.

(6) Documentation from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use.

(7) Documentation from appropriate sources that utilities supplied to the site are adequate for the project to include electricity, gas, water, and sewerage.

(8) Endorsement from the community that the project is desirable. This may include but is not limited to members of the medical community, citizen's groups, governmental elected officials, and other health and social service disciplines in the community.

(9) Documentation that the proposed project has been approved by the health facility's planning committee and governing body.

(10) For the facilities or services not licensed by the Department of Health and Environmental Control, provide documentation of coordination and support from the appropriate licensing agency.

d. Part D. Assurances

The applicant must furnish written assurance of each of the following where applicable:

(1) That the applicant has or will have a fee simple title or such other estate or interest in the site including necessary easements and rights-of-way, sufficient to assure use and possession for the purpose of the construction and operation of the facility.

(2) That approval by the department of the final drawings and specifications, which will be prepared by an architect and/or engineer legally registered under the laws of the State of South Carolina, will be obtained.

(3) That the applicant will submit to the Department for prior approval, changes that substantially alter the scope of work, function, utilities, major items of equipment, safety or cost of the facility during construction.

(4) That the applicant will cause the project to be completed in accordance with the Certificate of Need application.

(5) That the applicant will cause the project to be completed in accordance with approved plans and specifications by maintaining competent and adequate architectural and engineering services throughout the construction administration phase of the project. That, at the completion of the project, the architect of record shall be required to issue a statement that to the best of his knowledge and belief, based upon available records, supplemental documents, and periodic observation of the work, the project was constructed according to those documents approved by the Department.

(6) That the facility will be operated and maintained in accordance with the standards prescribed by law and regulations for the maintenance and operation of such facilities.

(7) That the applicant understands that the Certificate of Need shall become void at the end of the specified time period from the date of issuance unless otherwise extended under Chapter 6 of these regulations.

(8) That the Department or its authorized representatives may at any time during the course of construction and upon the completion of the project make an on-site inspection of the construction and equipment to check for compliance of the construction in accordance with the application for which the Certificate of Need was issued.

(9) That the controlling interest in any health care facility shall not be sold or leased or otherwise disposed of unless the Certificate of Need has been fulfilled.

(10) That the applicant will notify the Department in writing that the contractual agreement has been completed. For a construction project, the letter shall indicate that a construction contract specifying the beginning and completion dates of the project, has been signed by both parties. For services projects, the letter must indicate that equipment purchase orders with estimated delivery dates have been properly negotiated.

(11) That the applicant will notify the Department in writing of the date that a new or expanded service has been implemented, completed or terminated.

(12) That the applicant will provide monthly progress reports and a final completion report which contain the information required by Section 607 of these regulations.

CHAPTER 3
DISPOSITION OF APPLICATION

SECTION 301. Submission of Application.

1. The application shall be submitted utilizing the web-based application available on the Department's website or by such other means the Department may provide.

~~Two copies of the application along with a~~ 2. A non-refundable filing fee of five hundred dollars ($500) shall be ~~forwarded to~~received by the Bureau of ~~Health Facilities and Services Development~~Planning and Construction, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC, 29201, within twenty (20) calendar days of the public notification pursuant to Section 201 and the Certificate of Need application pursuant to Section 301.1.

3. Applicants are encouraged to involve the Department in the development of proposed projects prior to the submission of an application.

SECTION 302. Additional Information.

~~1. After receipt of an application with proof of publication in a local newspaper and the five hundred dollars ($500) non-refundable filing fee, the Department shall publish in the State Register a notice that an application has been accepted for filing. The Department shall notify the applicant in writing when the application is not acceptable for filing.~~

~~2~~1. Within thirty (30) calendar days from acceptance of an application, the Department ~~will~~may request any additional information pertinent to the project as may be deemed necessary to make the application complete. Should additional information be required for an application to be considered complete, the applicant will have thirty (30) calendar days from the date of the request to submit the requested information. If the applicant does not submit the requested information within thirty (30) calendar days, the application will be deemed ~~to have been~~ withdrawn.

~~3~~2. Should the applicant within such thirty (30) calendar-day period submit incomplete additional information, the Department will have thirty (30) calendar days in which to request further information. If the information requested is not received by the Department within thirty (30) calendar days of this second request, the application will be deemed ~~to have been~~ withdrawn.

~~4~~3. If any deadline provided for in this section falls on a weekend or State holiday, the deadline will be extended until the next calendar day that is not a weekend or State holiday.

SECTION 303. Payment of Filing and Application Fees.

1. When the application is determined to be complete, the Department shall invoice the applicant, by certified mail, for the ~~c~~Certificate of ~~n~~Need application fee. The applicant shall have fifteen (15) calendar days from the date of receipt of the invoice to pay the fee by valid check or credit card made payable to the S.C. Department of Health and Environmental Control. Should the application fee not be received from the applicant within fifteen (15) calendar days from receipt of the Department's invoice ~~by the applicant~~, the application will be considered withdrawn.

2. The application fee is one half of one percent (.5%, .005) of the total project cost (as defined in Section 102), which is payable when the application is deemed complete. The application fee shall not exceed seven thousand dollars ($7,000).

~~2~~3. If any deadline provided for in this section falls on a weekend or State holiday, the deadline ~~must~~will be extended until the next calendar day that is not a weekend or State holiday.

SECTION 304. Relative Importance Criteria.

1. Upon determination by the Department that an application is complete, the Department shall notify the applicant, by certified mail, of the relative importance of the project review criteria to be used in reviewing the application. The applicant will have thirty (30) calendar days from the date of receipt of this notice to submit any additional information. If, subsequent to this notice, the Department determines that the relative importance of the review criteria has changed, the Department must again notify the applicant by certified mail. The applicant will have thirty (30) calendar days from receipt of the revised notice to submit any additional information.

2. The staff may reorder the relative importance of the project review criteria no more than one (1) time ~~during the review period~~. The staff's reordering of the relative importance of the project review criteria does not extend the review period.

3. When an application has been appealed, the Department may not change the weight of the importance of the project review criteria.

SECTION 305. Review Time Frames.

1. Upon determination by the Department that the application is complete, ~~and receipt of the application fee,~~ the Department shall publish in the State Register a notice that the review cycle for the project has begun. Any affected person who has notified the Department in writing that they desire to be notified of the beginning of the review period will be sent a copy of the notification.

2. The Department will make a decision on the complete application no earlier than thirty (30) calendar days but no later than one hundred twenty (120) calendar days of the date of publication in the State Register unless a public hearing is held. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than one hundred fifty (150) calendar days from the date the affected persons are notified that the application is complete. Notice of a Department decision must be sent by certified mail, return receipt requested, to the applicant and affected persons who have requested in writing to be notified. Affected persons may request in writing to be notified by regular mail or electronic mail in lieu of certified mail.

~~a. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than 150 calendar days from the date the affected persons are notified that the application is complete.~~

~~b. [Reserved]~~

SECTION 306. Public Hearing.

A public hearing must be requested in writing by an "affected person" as defined in ~~these~~this regulation~~s~~ within thirty (30) calendar days of the notification of the beginning of a review. Where such a hearing is requested, prior notice of the hearing will be provided to "affected persons." The written notification of the hearing shall include the proposed schedule for the review, time, date, and place of such hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

SECTION 307. Department Review.

1. The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan as described in this regulation, project review criteria, and other provisions in this regulation~~s~~ which must be identified by the Department. The Department may refuse to issue a Certificate of Need even if an application is in compliance with the South Carolina Health Plan but is

inconsistent with project review criteria or ~~departmental~~other provisions in this regulation~~s~~. The Department must identify any provisions in this regulation that is used as a basis for denying an application that is in compliance with the South Carolina Health Plan.

2. In the case of competing applications, the Department shall award a Certificate of Need, if appropriate, on the basis of which, if any, most fully complies with the requirements, goals, and purposes of the Certificate of Need program, South Carolina Health Plan, project review criteria, and any provisions in this regulation~~s developed by the Department~~.

SECTION 308. Department Decision.

On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need.

SECTION 309. Certificate of Need Issuance Fee.

Approved ~~P~~projects with a total project cost greater than one million four hundred thousand dollars ($1,400,000) will require payment of a Certificate of Need issuance fee of seven thousand five hundred dollars ($7,500) ~~upon the granting of the certificate of need. An invoice will be enclosed with the certificate which will be sent by certified mail.~~ The Department must receive payment from the applicant within fifteen (15) calendar days from receipt of the certificate ~~by the applicant~~ for the ~~c~~Certificate of ~~n~~Need to remain valid.

SECTION 310. Project Changes During Review Period.

If an applicant amends ~~his~~the application during the review process, the Department will determine whether or not the amendment is substantial and constitutes a new application. If the change is not substantial and results in an increase in total project cost, the fees will be adjusted accordingly.

SECTION 311. Validity of Certificate of Need Issued.

The Certificate of Need, if issued, is valid only for the project described in the application including location, beds, and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with ~~these~~this regulation~~s~~. Implementation of the project or operation of the facility or medical equipment that is not in accordance with the Certificate of Need application or conditions subsequently agreed to by the applicant and the Department may be considered a violation of this ~~R~~regulation.

SECTION 312. Prohibited Contact.

1. After a Certificate of Need application has been filed with the Department, state and federal elected officials are prohibited from communicating with the Department with regard to the Certificate of Need application at any time. This prohibition does not include written communication of support or opposition to an application. Such written communication must be included in the administrative record.

2. From the date of publication of notice in the local newspaper that an application is being filed and until the date final review is requested under Section 401 of ~~these~~this regulation~~s~~:

a. members of the Board and persons appointed by the Board to hold a final review conference on staff decisions may not communicate directly or indirectly with any person in connection with the application; and

b. no person shall communicate, or cause another to communicate, as to the merits of the application with members of the Board and persons appointed by the Board to hold a final review conference on staff decisions.

CHAPTER 4
APPEALS

SECTION 401. Appeal of Decision.

1. A Department decision involving the issuance, denial, or revocation of a ~~c~~Certificate of ~~n~~Need may be appealed by an affected person ~~with standing~~ pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.

2.~~ Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.~~ A person may not file a request for final review in opposition to the staff decision on a Certificate of Need unless the person provided written notice to the Department during the staff review that they are an affected person and specifically states their grounds for opposition to the application under review.

~~**SECTION 402. [Reserved]**~~

CHAPTER 5
GENERAL PROVISIONS

~~**SECTION 501. Findings of the Department.**~~

~~In the case of any proposed new institutional health service for the provision of health services to inpatients, the Department shall not grant a Certificate of Need, or otherwise make a finding that such proposed new institutional health service is needed, unless:~~

~~1. The capital and operating costs of the proposal and their potential impact on patient charges are reasonable;~~

~~2. Superior alternatives to such services in terms of cost, efficiency, or appropriateness do not exist and that the development of such alternatives is not practicable;~~

~~3. In the case of new construction, alternatives to new construction (e.g., modernization or sharing arrangements) have been considered;~~

~~4. Patients will experience serious problems in terms of costs, availability or accessibility, or such other problems as may be identified by the Department, in obtaining care of the type proposed in the absence of the project; and~~

~~5. In the case of a proposed addition of beds for the provision of nursing care service, the addition is consistent with the plans of other State agencies responsible for provision and financing of long-term care (including home health) services.~~

SECTION ~~502~~501. Periodic Reports.

For the purpose of health planning, health care facilities and others who provide services that require a Certificate of Need or who have been exempted, shall on an annual basis submit information requested on the applicable Joint Annual Report.

~~**SECTION 503. Distribution of Procedures Criteria**~~

~~The Department shall distribute copies of its proposed and adopted review procedures and criteria, and proposed revisions to statewide health agencies and organizations, any agency which establishes rates for health care facilities in the state, and other persons upon request.~~

SECTION ~~504~~502. Review Under Applicable Plan.

All decisions on Certificate of Need applications shall be made based on the currently approved South Carolina Health Plan in effect at the time such application is accepted. Should a new plan be adopted during any phase of the review or appeals process, the applicant shall have the option of withdrawing the application and resubmitting under the newly adopted plan or continuing the review or appeal process under the plan in use when the application was submitted. In cases where applications are withdrawn and resubmitted under the newly adopted South Carolina Health Plan within forty-five (45) calendar days of the date of withdrawal, no additional filing fee shall be required.

CHAPTER 6
VOIDANCE AND EXTENSION OF CERTIFICATES OF NEED

SECTION 601. Voidance and Extension Procedures.

1. The Certificate of Need shall become void twelve months (one year) from the date of issuance unless implemented as described in this subsection or a timely extension request is received pursuant to Section 602. The Department may void a Certificate of Need if requested by the applicant~~, or if the Department determines that the Certificate of Need has not fully implemented within one year from the date issued~~. Implementation may be evidenced by, but not limited to, a properly negotiated valid construction contract or appropriate purchase order for service projects.

2. A Certificate of Need must be issued with a timetable submitted by the applicant, and approved by the Department, to be followed for completion of the project. The holder of the Certificate of Need must submit quarterly progress reports documenting compliance with the aforementioned timetable. Failure to meet the timetable will result~~s~~ in the revocation of the Certificate of Need by the Department unless the Department determines that extenuating circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay. If the applicant has not met the approved timetable, documented evidence that extenuating circumstances beyond the control of the holder of the Certificate of Need should be provided to the Department. This information can also be included in a request for an extension as provided in Section 602.

3. The Department may grant up to two (2) extensions of up to nine (9) months each. In order to obtain an extension, the applicant must have demonstrated substantial progress and must either be complying with the approved timetable or have submitted documentation satisfactory to the Department that extenuating circumstances beyond the control of the applicant have prevented compliance with the timetable. After the nine (9) month extension period, the Certificate of Need will expire and become void.

4. However, the Board may grant further extensions of the Certificate of Need of up to nine (9) months each if it determines that substantial progress has been made. A request to the Board must be made at least three (3) months prior to the expiration of the Certificate of Need and must contain justification for such extension.

SECTION 602. Extension Request.

1. A Certificate of Need extension shall be requested in writing by the applicant at least thirty (30) calendar days before the expiration date ~~and shall contain such information as the Department may reasonably require~~of the Certificate of Need.

2. ~~This information~~The written request for an extension shall include at least the following:

a. A detailed description of any changes in the configuration, costs, services, or scope of the project.

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.

c. An estimated timetable for commencement and completion of all remaining components of the project.

d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstance beyond the control of the applicant if the timetable was not met.

SECTION 603. Criteria for Extension.

The following criteria shall be used to determine whether substantial progress has been made by the applicant:

1. Site procurement: The applicant should have made definitive progress toward permanent acquisition of the intended site. Such progress may include purchase of property previously under option or consummation of long-term lease agreements.

2. Architectural Progress: The facility architect should have been employed and definitive progress should be made toward development of final drawings.

3. Financial Status: ~~t~~The applicant should document definitive progress toward finalizing any necessary loans or lease-purchase arrangements.

4. The applicant should provide reasonable assurance that the project will be under construction or implemented within the requested extension time frame.

SECTION 604. ~~Non-Transferability~~Nontransferability of Certificate of Need.

1. A Certificate of Need is nontransferable. A Certificate of Need or rights there under may not be sold, assigned, leased, transferred, mortgaged, pledged, or hypothecated, and any actual transfer or attempt to make a transfer of this sort will result~~s~~ in the immediate voidance of the Certificate of Need. Any of the aforementioned transactions involving an entity directly or indirectly holding a Certificate of Need before fulfillment of the Certificate of Need will result~~s~~ in the transfer and the subsequent voidance of the Certificate of Need. ~~Fulfillment of the Certificate of Need occurs, although not limited to, the submission~~

~~of an adequate final completion report as determined by the Department~~. ~~Anyone having their Certificate of Need voided shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval.~~

2. The sale or transfer of the controlling interest or majority ownership in a corporation, partnership, or other entity holding, either directly or indirectly, a Certificate of Need, will result in the transfer and voidance of a Certificate of Need.

3. Fulfillment of the Certificate of Need occurs upon the submission of an adequate final completion report pursuant to Section 607.3.

SECTION 605. Project Changes After Receipt of Certificate of Need.

If an applicant amends or alters ~~his~~their project after receipt of a Certificate of Need, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project.

SECTION 606. Total Project Cost.

In issuing a Certificate of Need, the Department shall specify the approved total project cost. A project is only approved for the amount specified in the Certificate of Need. The Department will review cost overruns on an individual basis.

SECTION 607. Periodic Reporting of Certificate of Need Implementation.

1. The applicant is required to submit a quarterly progress report that corresponds with the timetable included in the Certificate of Need application beginning ninety (90) calendar days after receipt of the Certificate of Need. Failure to meet the timetable will result~~s~~ in the revocation of the Certificate of Need by the Department unless a determination is made by the Department that circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay.

2. The applicant shall report on, if applicable: (1) costs incurred on the project; (2) construction activity; (3) program or service activity; and (4) any deviations from the submitted application with supporting documentation.

3. After the project has been fully implemented, the applicant shall provide the Department with a final completion report that contains, at a minimum:

a. An audited cost report that shows all expenditures on the approved project;

b. A list of average charges and costs for the services approved in the application and documented by affidavit, certification, or other proof;

c. A registered architect's or engineer's signed statement of final construction costs;

d. An equipment listing and inventory for the project;

e. A program and/or service narrative describing the final project configuration; ~~and~~

f. An explanation of any deviation from the approved application with justification, or a signed statement from the applicant that the project was implemented as outlined in the application~~.~~; and

g. A listing of non-capital costs.

4. Records relating to the project shall be maintained by the applicant for seven (7) years following the completion of the project and these records shall be made available to the Department's auditors for inspection as needed.

5. The Department may audit any project for consistency with the information provided in the Certificate of Need application. Undertaking a project that is not in accordance with the approved application or conditions or amendments subsequently agreed to by the applicant and the Department may be considered a violation of this article.

CHAPTER 7
PENALTIES FOR NON-COMPLIANCE

SECTION 701. Penalties.

Undertaking any activity requiring ~~c~~Certificate of ~~n~~Need review, ~~as defined in~~pursuant to Section ~~102~~103 of ~~these~~this regulation~~s~~, without prior approval of the Department or failing to comply with any of the above stated regulations shall be grounds for the denial, suspension, or revocation of the Certificate of Need, or other penalties, under the provisions of ~~Sections 44-7-320 through 44-7-340 of the Code of Laws of South Carolina~~the State Certification of Need and Health Facility Licensure Act, S.C. Code Ann. Sections 44-7-110 *et seq.*, as amended. ~~Any violation of this regulation is subject to provisions set forth in the statute.~~

~~**SECTION 702. [Reserved]**~~

CHAPTER 8
PROJECT REVIEW CRITERIA

SECTION 801. Applicability and Weighting.

1. The criteria listed in Section 802 are to be used in reviewing all projects under the Certification of Need program. These criteria have been grouped under the following general categories:

Need for the Proposed Project (Section 802.1 through 802.4)

Economic Consideration (Section 802.5 through 802.~~1~~9)

Health System Resources (Section 802.~~20~~10 through 802.~~25~~14)

Site Suitability (Section ~~802.26 through~~ 802.~~30~~15)

Special Consideration (Section 802.~~31~~16 through 802.~~33~~18)

2. The Department shall notify the applicant of the relative importance of the project review criteria to be used in reviewing the application. The relative importance assigned to each specific criterion is established by the Department depending upon the importance of the criterion applied to the specific project. The relative importance must be consistent for competing projects.

3. A project does not have to satisfy every criterion in order to be approved, but no project may be approved unless it is consistent with the South Carolina Health Plan. A project may be denied if the Department determines that the project does not sufficiently meet one (1) or more of the criteria.

SECTION 802. Criteria for Project Review.

1. Need:

The proposal shall not be approved unless it is in compliance with the South Carolina Health Plan.

2. Community Need Documentation:

a. The target population should be clearly identified as to the size, location, distribution, and socioeconomic status (if applicable).

b. Projections of anticipated population changes should be reasonable and based upon accepted demographic or statistical methodologies, with assumptions and methodologies clearly presented in the application. The applicant must use population statistics consistent with those generated by the ~~state demographer, State Budget and Control Board~~South Carolina Revenue and Fiscal Affairs Office.

c. The proposed project should provide services that meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and based on a reasonable approach as judged by the reviewing body. Any deviation from the population projection used in the South Carolina Health Plan should be explained.

d. In the case of a reduction, relocation, or elimination of a facility or service, the applicant should address the need that the population presently has for the service, the extent to which that need will be met by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other underserved groups, to obtain needed health care.

e. Current and/or projected utilization should be sufficient to justify the expansion or implementation of the proposed service.

3. Distribution (Accessibility):

a. Duplication and modernization of services must be justified. Unnecessary duplication of services and unnecessary modernization of services will not be approved.

b. The proposed service should be located so that it may serve medically underserved areas ~~(~~or an underserved population segment~~) and should not unnecessarily duplicate existing services or facilities in the proposed service area~~.

~~c. The location of the proposed service should allow for the delivery of necessary support services in an acceptable period of time and at a reasonable cost.~~

~~d~~c. The proposed facility should not restrict admissions. If any restrictions are applied, their nature should be clearly explained.

~~e~~d. The applicant must document the means by which a person will have access to its services (e.g.~~,~~ outpatient services, admission by house staff, admission by personal physician).

~~f~~e. The applicant should address the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other medically underserved groups, are likely to have access to those services being proposed.

~~g~~f. The facility providing the proposed services should establish provisions to ~~insure~~ensure that individuals in need of treatment as determined by a physician have access to the appropriate service, regardless of ability to pay.

~~h~~g. Potential negative impact of the proposed project upon the ability and/or resources of existing providers to serve medically underserved groups must be considered.

4. Acceptability:

a. The proposal and applicant should have the support of ~~"~~affected persons~~"~~ (including local providers and the target population). The lack of opposition should not be considered support for the purposes of these criteria.

b. Where documented opposition exists to a proposal, such opposition will be considered along with the application.

c. Possible transfer agreements should be confirmed and an intent to negotiate these arrangements should be documented by all parties.

~~d. The applicant should document the initiation of any other required reviews or agency check-offs.~~

~~5. Financial Entries and Assumptions:~~

~~All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of this financial information.~~

~~6. Projected Revenues:~~

~~a. The proposed charges should be comparable to those charges established by other facilities for similar services within the service area or state. The applicant should document how the proposed charges were calculated.~~

~~b. The projected levels of utilization should be reasonably consistent with those experienced by similar facilities in the service area and/or state. In addition, projected levels of utilization should be consistent with the need level of the target population.~~

~~c. The projected collection and reimbursement rates should be reasonably consistent with those experienced/utilized by similar facilities.~~

~~d. Failure to provide contingency plans for any known factor which would jeopardize the stability of the revenue projections shall be grounds for rejection of the budget.~~

~~7. Projected Expenses:~~

~~Projections of construction costs, start-up costs, operating costs, debt service, depreciation, manpower costs, etc. should be consistent with those experienced by similar facilities offering a similar level and scope of services (with proper consideration given to such factors as inflation, cost of capital, etc.).~~

~~8. Beginning Cash Flow:~~

~~The applicant must have documented the availability of resources or sources of funds sufficient to cover capital requirements and start-up costs. The schedule of utilization and net revenues must be detailed with assumptions explicitly present.~~

~~9. Net Income:~~

~~The project should show an improvement in its net revenue position over time, especially the first three years, until a steady, positive net income trend is attained. Any projected deviations from this pattern should be explained.~~

~~10. Debt Service:~~

~~a. Debt service (interest cost plus payment toward principal) should not be so large as to cause a negative net income.~~

~~b. Characteristics of the debt (interest, prepayment arrangements, etc.) should be consistent with those arrangements used by other health service entities in the State and consistent with accepted good business practices in terms of assumption and retirement of debt.~~

~~c. The applicant must document the impact the project will have on the facility's proposed level of patient charges.~~

~~11. Methods of Financing:~~

~~a. Possible alternatives should be identified.~~

~~b. Reasons for the selection of the proposed funding method should be stated and reasonable.~~

~~12. The applicant should demonstrate an ability to obtain the desired capital. The applicant must provide at least conditional commitment from an appropriate institution.~~

~~13~~5. Record of the Applicant (Owner and/or Administrator):

a. The applicant's record should be one of successful operation with adequate management experience.

b. The applicant should have a demonstrated ability to obtain necessary capital financing.

c. If the applicant has no prior experience, sources of assistance should be specified (i.e.~~,~~ technical assistance from specific individuals or organizations).

d. The applicant's record or ~~his~~their representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.

~~14~~6. Ability to Complete the Project:

a. The applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application.

b. The financial schedules and time frames contained in the application should be consistent with those usually experienced in the development of similar facilities or services.

~~15~~7. Financial Feasibility:

a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures.

b. All financial entries and assumptions contained in the application must be provided by an accountant who attests to the reliability of this financial information.

c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three (3) years of operation.

d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing, if necessary.

e. The impact of the project upon the applicant's cost to provide services and the applicant's net patient charges must be reasonable.

~~16. Cost Containment (Minimizing Costs):~~

~~a. The applicant should have identified and sought alternative sources and/or methods of funding and demonstrated that the method chosen was the most feasible option.~~

~~b. If the applicant had the option of lease or purchase, with all other factors being equal, he should demonstrate that his choice is the least costly in the long run.~~

~~c. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges should be reasonable. The impact of the project upon the cost and charges of other providers of similar services should be considered if the data are available.~~

~~17~~8. Efficiency:

The proposed project should improve efficiency by avoiding duplication of services, promoting shared services, and fostering economies of scale or size.

~~18. Physical Design:~~

~~The proposed project should foster economies of design by use of design characteristics such as improved access and circulation within the facility, the relationship of services within the facility, and the use of shared space for centralized supply, storage, and common activities.~~

~~1~~9. Alternative Methods:

a. The applicant should have considered any available or more effective alternatives which exist to the proposed service such as the use of less costly alternatives, outpatient services, shared services, or extended hours of service.

b. For new construction projects, modernization of existing facilities should be considered as an alternative, and the rejection of this alternative by the applicant should be justified.

~~20~~10. Staff Resources:

a. The applicant should have a reasonable plan for the provision of all required staff (physicians, nursing, allied health and support staff, etc.).

b. The applicant should demonstrate that sufficient physicians are available to ~~insure~~ensure proper implementation (e.g.~~,~~ utilization and/or supervision) of the project.

c. If the applicant presently owns existing facilities or services, ~~he/she~~they should demonstrate a satisfactory staffing ~~"track record."~~history.

d. Alternative uses of resources for the provision of other health services should be identified and considered.

~~21~~11. Support Services and Equipment:

a. Support services and equipment necessary to implement and sustain the proposed service should be identified, accessible~~,~~ and of sufficient capacity.

b. Where possible, projects should utilize equipment already available and accessible to the population to be served.

~~22~~12. Distribution:

The existing distribution of the health service(s) should be identified and the effect of the proposed project upon that distribution should be carefully considered to functionally balance the distribution to the target population.

~~23~~13. Adverse Effects on Other Facilities:

a. The impact on the current and projected occupancy rates or use rates of existing facilities and services should be weighed against the increased accessibility offered by the proposed services.

b. The staffing of the proposed service should be provided without unnecessarily depleting the staff of existing facilities or services or causing an excessive rise in staffing costs due to increased competition.

~~24~~14. Adverse Effects on Training Programs:

a. The proposed delivery of health services should not adversely affect the ability of local health professional training programs to meet their clinical needs.

~~25. Access:~~

b. If the proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools in the area will have access to the services for training purposes should be clearly delineated in the proposal.

~~26~~15. ~~Zoning~~Site and Building Suitability:

a. The proposed site must comply with local zoning regulations. Documentation should be provided from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use.

b. The proposed facility should not be located on a site where environmental conditions would either create a health hazard or aggravate an existing health condition in individuals served by the facility.

c. Documentation should be provided that all of the property intended for use is available to the applicant. Consideration may also be given to the suitability of the proposed site for any expansion of services included in the applicant's long-range plans.

~~27. Utilities:~~

~~The utilities necessary for the facility to operate should be available on site or the application should state provisions made for bringing these utilities on site or providing alternatives such as wells or sewage treatment plants. Applicants should document the availability of needed utilities. The cost of such provisions should be detailed in the financial section of the application.~~

~~28. Site Size:~~

~~Documentation should be provided that all of the property intended for use is available to the applicant. Consideration may also be given to the suitability of the proposed site for any expansion of services included in the applicant's long-range plans.~~

~~29. Environmental Hazard:~~

~~The proposed facility should not be located on a site where environmental conditions would either create a health hazard or aggravate an existing health condition in individuals served by the facility.~~

~~30. Square Footage:~~

~~Space allocations should conform to applicable local, state, and federal regulations or minimum standards. For all projects, state or other applicable licensing standards must be met by the proposal.~~

~~31~~16. Medically Underserved Groups:

a. The applicant should address the contribution of the proposed service in meeting the health needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (e.g.~~,~~ low income persons, racial and ethnic minorities, women, the elderly, and handicapped persons), particularly those needs identified in the applicable South Carolina Health Plan as deserving of priority.

b. The extent to which medically underserved populations currently use the applicant's services should be considered in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved.

c. Consideration of the documented performance of the applicant in meeting its obligation, if any, under any applicable Federal regulations requiring provision of uncompensated care, indigent care plan, community service, or access by minorities and handicapped persons to programs receiving Federal

financial assistance (including the existence of any civil rights access complaints against the applicant) should be given.

d. Consideration should be given to the extent to which Medicare, Medicaid, and medically indigent patients are served by the applicant.

~~32. Other Entities:~~

~~Consideration should be given to the special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers.~~

~~33~~17. Elimination of Safety Hazards:

The Department shall issue a Certificate of Need for a proposed capital expenditure if it is required to eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations; or to comply with State Licensure standards, or to comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State Plan for medical assistance approved under Title XIX of that Act, provided the Department has determined that the facility or service for which the capital expenditure is proposed is needed and the obligation of the capital expenditure is consistent with the South Carolina Health Plan. Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with licensure, certification, or accreditation standards shall be reviewed against each of the applicable criteria for project review.

18. Quality of Care:

Applicants should describe metrics or benchmarks of quantitative quality metrics, if any, for the proposed facility, service, or equipment requiring a Certificate of Need. If the applicant is an existing provider, it should provide data on such metrics or benchmarks. If the applicant is a proposed provider, it should provide a plan on how it will meet such metrics or benchmarks.

~~APPENDIX:~~

~~APPLICATION FOR CERTIFICATION OF NEED FOR A HEALTH FACILITY OR SERVICE~~

~~Proposal Prepared By:~~

~~Name:_____ Title:_____~~

~~Organization:_____~~

~~Address:_____~~

~~City:_____ State:_____ Zip Code:_____~~

~~Telephone Number_____~~

~~Email:_____ Fax Number:_____~~

The Applicant hereby certifies that the information contained in this Application, including all assurances and attachments, are correct to the best of his knowledge and belief.

Applicant's Signature:_____

Date:_____

Forward to:

Bureau of Health Facilities and Services Development
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, S.C. 29201

NOTE: A "complete" application shall include a written narrative report by the applicant (Regulation 61-15, Section 202).

PART A – QUESTIONNAIRE		
1. Name of Facility		
2. Address, City, County, State, Zip Code		
3. Type of Facility (Circle)		
A. Hospital	B. Nursing Home	C. Psychiatric Facility
D. Rehabilitation Facility	E. Substance Abuse Facility	F. Ambulatory Surgery Facility
G. Other (Specify)		

4. Purpose of Review (Circle)		
A. New Facility	B. Change of Licensure	C. Addition to Existing Facility
D. Renovation of Existing Facility		E. Change of Services
F. Other (Specify)		

5. Management		
A. Name of Administrator	B. Address, City, State, Zip Code	
C. Telephone:	D. Fax Number	E. Email
-		

6. Licensee
A. Name of Licensee
B. Address, City, State, Zip Code

7. Ownership or Control of the Facility
(Attach a list of names and addresses of the owners of the facility, indicating percent of ownership of each owner, the person responsible for the proposal, and the attorney(s) representing the proposal). Circle the appropriate information regarding ownership.
A. Individual B. Partnership C. Corporation D. Proprietary
E. Non-Profit F. Government (Specify)
G. Other: (Specify)

8. Proposed Site of the Property	
A. Owned	B. Leased
C. Length of Site Lease	

~~D. Option~~	~~E. Length of Option~~
~~F. Name and Address of Owner(s) of Real Property~~	

~~9. Total Bed Capacity for Which Application is Made~~

-	~~Existing Facilities~~			
-	~~New Facility Only~~	~~Existing Beds~~	~~# Gained or Lost~~	~~Bed Total~~
~~Type of Beds~~	-	-	-	-
~~A. Medical/Surgical~~	-	-	-	-
~~B. Obstetrics~~	-	-	-	-
~~C. Pediatrics~~	-	-	-	-
~~D. Substance Abuse~~	-	-	-	-
~~E. Psychiatric~~	-	-	-	-
~~F. Rehabilitation~~	-	-	-	-
~~G. Nursing Care~~	-	-	-	-
~~H. RTFs~~	-	-	-	-
~~I. ICU/CCU~~	-	-	-	-
~~J. Other~~	-	-	-	-
~~K. TOTAL~~	-	-	-	-

~~10. Construction and Site~~

~~A. Type of Construction~~	~~B. Number of Buildings Pertaining to Project~~
~~C. Number of Stories Pertaining to Project~~	~~D. Size of the Site in Acres~~
~~E. Size of the Project Site in Acres~~	~~F. Square Footage of the Project~~
~~G. Anticipated Date of Beginning Construction~~	~~H. Anticipated Date of Licensing or Project Completion~~
~~I. Anticipated Date for Submission of Final Completion Report~~	-

~~11. Zoning of Construction Site~~

~~12. Costs~~ ~~(Provide Estimated Signed Cost Statement from Either the Architect or Engineer)~~

~~A. Land Cost~~	~~B. Construction Cost~~
~~C. Architect's/Engineer's Fee~~	~~D. Equipment Costs (to include taxes)~~
-	-
-	-
-	~~1) Fixed Equipment~~
-	~~2) Movable Equipment~~
~~E. Financing Cost During Construction~~	~~F. Other Costs (Specify)~~
~~G. Total Project Cost~~	~~H. Construction and Equipment Cost~~
-	-
-	~~1) Per Square Foot~~
-	~~2) Per Bed~~

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-340

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-15, *Certification of Need for Health Facilities and Services*. Interested persons may submit written comments to the Office of Policy and Communications, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Healthcare Quality Public Comment Form at https://forms.office.com/g/9VMEXLWtq0. To be considered, the Department must receive comments no later than 5:00 p.m. on July 25, 2022, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to S.C. Code Sections 44-7-110 through 44-7-340, the Department promulgates substantive and procedural regulations considered necessary by the Department and approved by the S.C. Board of Health and Environmental Control to carry out the Department's Certificate of Need duties. The Department proposes amending R.61-15 for consistency with statutory requirements, to enable an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing, and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. The amendments may also revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review.

The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-15*, Certification of Need for Health Facilities and Services*

As of the July, 25, 2022, close of the Notice of Drafting comment period:

Name	Section
Maryann Connors	General
Comment: I support a full repeal of SC's Certificate of Need laws. **Department Response:** Acknowledged. The Department is carrying out its obligations as required by state law.	
Name	**Section**
Sara Sears, Self Regional Healthcare	General
Comment: Eliminate the CON requirement for adding general hospital beds to existing hospital if the facility has maintained at least a 75% capacity threshold for previous year. For acute care beds, the increase cannot exceed the greater of 10% of the current beds or 50 beds. For all other bed types, the increase in is restricted to 10% of the current capacity of the licensed bed type. Eliminate the CON requirement for adding skilled nursing facility beds to existing health care facilities. **Department Response:** Not adopted. This comment requires statutory and State Health Plan changes. The Department is carrying out its obligations as required by state law.	
Name	**Section**
Candace Carroll, Americans for Prosperity-SC	General
Comment: On behalf of Americans for Prosperity activists in South Carolina, I am submitting comments in support a full repeal of South Carolina's Certificate of Need (CON) Regulations. AFP activists engage friends and neighbors on key issues and encourage them to take an active role in building a patient-centered health care system that lowers costs, increase choices, and improves access for millions of people seeking relief. In 1971, lawmakers established the CON program to evaluate building plans and medical equipment purchases to determine which services are needed to address community medical needs and which services are unnecessary. However, the agency overseeing the program, the Department of Health and Environmental Control, routinely blocks new health care providers from offering essential health services across the state, especially in rural and underserved communities. Research from George Mason University shows CON laws have dramatically reduced the availability of health care in South Carolina. The authors of the study found that these policies have decreased the number of hospitals by 30 percent and decreased the number of ambulatory surgery centers by 14 percent. South Carolina's CON laws also reduce access to important medical equipment, including magnetic resonance imaging (MRI) scanners and positron emission tomography (PET) scanners. Analysis conducted by the nonpartisan Mercatus Center estimates that these barriers reduce the supply of MRIs by 34 percent and PET scanners by 65 percent. Americans for Prosperity Foundation issued a report last year entitled "Permission to Care" highlighting that over $30 million in health care investment has been denied in SC. The biggest barrier for health care entrepreneurs navigating South Carolina's CON process is the ability of competitors to intervene. In addition to potentially swaying a CON decision against the applicant, competitors can add years and thousands of legal fees to the application process. In at least two recently resolved cases in South Carolina, legal challenges to CON decisions delayed the openings of much needed hospitals in	

two counties by over a decade. One of the first Executive Orders Gov. Henry McMaster issued when COVID-19 hit SC was a temporary suspension of SC's CON program. He has since expressed an eagerness for a full repeal of CON bill to come to his desk. This support of repeal of CON was echoed by the SC Senate who voted overwhelmingly (35-6) to end the program. This committee has a tremendous opportunity before you to join Gov. McMaster and the SC Senate in ensuring more families receive essential health services by allowing medical providers to open new facilities and offer new service outside of South Carolina's restrictive CON laws. We thank you for the opportunity to address this critical issue and we look forward to continue working with the Committee to craft real solutions that expand access to affordable and high-quality health care for all South Carolinians.

Department Response:

Acknowledged. DHEC is carrying out its obligations as required by state law.

Name	Section
Dr. Marcelo Hochman	General

Comment:

Considering the above and the documented fact that the CON process and requirement has been a failure over the last 40 years, we respectfully ask DHEC to:

1. Use all the Agency's powers and discretion to void enforcement of existing regulations pertaining to the CON process
2. Use all the Agency's powers and discretion to liberalize the CON process so that new entrants and applications are not at the mercy of incumbent CON holders whose intent is to prevent entry into their space.
3. Use all the Agency's powers and discretion to remove any thresholds that 'trigger a CON review' since these are artificial and serve only to perpetuate the flawed system. It is our desire to unencumber the Agency from a lengthy, costly process which is contrary to the needs of the people of South Carolina so that it may focus on more productive activities.

Department Response:

Acknowledged. DHEC is carrying out its obligations as required by state law.

Name	Section
Dr. Cleave Ham, Charleston County Medical Society	General

Comment:

As CCMS supports full CON repeal, we also recognize that there will need to be an associated appropriate regulatory and licensure framework in place, to produce a freely innovating, competitive healthcare system in S.C. Such a framework is present in other sectors of our economic system and has provided the highest standard of living in the world. As examples, an associated healthcare regulatory framework might include such items as transparency requirements, quality metrics, ensuring healthcare accessibility to quality care for all members of society, among others. As DHEC reviews CON regulations, please note that this issue should not be thought of as an irreconcilable conflict between hospital systems and physicians who wish to provide care independently – indeed, hospitals and physicians must work together on behalf of patient care; neither can exist without the other. The common ground we need and seek on behalf of patient care and the physician/patient relationship can only be reached by "levelling the playing field" via CON repeal and incentivizing all components of S.C. healthcare to work together to more effectively provide accessible, quality care at a reasonable cost. Of interest, elimination of non-compete clauses for S.C. physicians as a condition of employment should be an integral part of this goal as well – indeed, such was recommended in the Legislative Audit Council review of CON regulations during the 2022 S.C. legislative session.

Department Response:

Acknowledged. DHEC is carrying out its obligations as required by state law.

Name	Section

Timothy Rogers, SC Home Care & Hospice Association	General

Comment:
SCHCHA asks that, while we believe any consideration of eliminating home health from CON would, in our opinion, require a statutory change, as DHEC reviews and prepares changes and modifications to Regulation 61-15, it is our position CON should be preserved for home health agencies and that DHEC make revisions and changes consistent with the preservation of CON for home health agencies.

Department Response:
Acknowledged. DHEC is carrying out its obligations as required by state law.

Name	Section
Bruce Bailey, Tidelands Health	General

Comment:
At Tidelands Health, a not-for profit health care provider that has served the Grand Strand for more than 70 years, we believe it is time to modernize the CON program. Although the majority of needed reforms require statutory changes and cannot be implemented through changes to Regulation 61-15, we encourage SC DHEC to pursue revisions to the regulation as proposed by SCHA, including:
·Updating 61-15 §102(1)(c) and (f) to increase the threshold for capital expenditures to at least $5 million and the threshold for medical equipment to at least $2 million. We agree these thresholds should be subject to an inflationary adjustment every five years using the U.S. city average of the Medical Care Commodities Index. Such adjustments would help ensure these thresholds keep pace with the market for medical equipment and capital expenditures.
· Development of an electronic application process, which would eliminate waste and streamline the application process for both the Department and applicants.
· Maintaining or enhancing requirements within the Regulation associated with indigent care. Like other health care systems across the state, Tidelands Health serves as a vital backbone within our region by providing needed health care services regardless of an individual's ability to pay. Specialty care providers must do their part by also providing care to underinsured and uninsured individuals in need. Absent such a requirement, specialty care providers will provide only profitable services to commercially insured patients, stripping away revenue used by hospitals to cover the costs of providing care to uninsured or underinsured individuals. Such an imbalance would threaten the viability of hospitals, particularly those in rural and underserved areas, and likely lead to cuts in services and vital community health programs.

Department Response:
Adopted. The proposed regulation increases the thresholds. The proposed regulation is amended to align with implementation of the electronic application process. The Department acknowledges the importance of maintaining requirements associated with indigent care and is not recommending any changes in the proposed regulation.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	General

Comment:
In favor of continued efforts to modernize the CON application and review process, Spartanburg Regional Healthcare System recommends the Department make as much of the application process electronic as possible.

Department Response:
Adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Vicki Young, SC Primary Healthcare Association	General

Comment:

I write today on behalf of the SC Primary Health Care Association, our Community Health Center (or Federally Qualified Health Center) membership, and the more than 400,000 South Carolinians they serve each year to ask that, as part of your review and revision to Reg. 61-15, you delete the threshold requirement for equipment purchases, thereby exempting equipment from the requirement of obtaining a certificate of need.

If a complete exclusion of equipment is not possible through the regulation revision process, we would then ask for either a substantial increase of the threshold on equipment amounts; or a change in the formula to include only the cost of the equipment when applying the threshold, not the cost of renovations or construction required as part of the purchase.

It is our belief that allowing our centers to obtain necessary equipment more readily will directly and immediately benefit the South Carolinians we serve and provide a better, more thorough level of care for a sometimes-underserved population that experiences an array of health care needs.

Department Response:

Partially adopted. The Department proposes increasing thresholds in the proposed regulation.

Name	Section
Ed Bender, SCHA	General

Comment:

SCHA appreciates DHEC's desire to use some reform proposals offered by the Legislative Audit Council ("LAC") in its February 2022 report. Dr. Simmer's agency response letter is an excellent guidepost for what LAC recommendations the Department has authority to address in this regulatory review.

For many years, SCHA has championed CON reform because CON plays a critical role in South Carolina healthcare, but the system needs reform. However, many of the reform measures proposed by SCHA and the LAC require statutory revision and are not germane to this process. The most material reform measure available in this process is to raise the dollar thresholds for capital expenditures and medical equipment contained in S.C. Code Ann. Regs. 61-15(1)(c) & (f).

SCHA proposes revising S.C. Code Ann. Regs. 61-15 §102(1)(c) & (f). Specifically, SCHA proposes these thresholds be increased from $2,000,000 to at least $5,000,000 for capital expenditures and from $600,000 to at least $2,000,000 for medical equipment. These thresholds were last updated in 1993 and the cost of health care equipment and construction have increased dramatically in the intervening twenty-nine years. As a result, SCHA believes these figures need to be updated to reflect the current market for capital expenditures and medical equipment.

If possible, SCHA would also suggest tying both thresholds to the Medical Care Commodities Index ("MCCI"), which is a subset of the Medical Care Consumer Price Index. SCHA believes the MCCI most accurately reflects the type of expenditures covered by §§102(1)(c) and 102(1)(f). Furthermore, SCHA would suggest making the inflationary adjustment every five years using the U.S. city average of the MCCI because MCCI is a narrow index, so including a broad geographic region and consumer base will provide the most reliable inflationary number.

Department Response:

Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Ed Bender, SCHA	General

Comment:

In addition to dollar threshold increases, the LAC made seven recommendations to DHEC to improve CON. Of those seven, these three are appropriate for revision in the regulation:

• Standardize information required in the CON process to ensure consistency in evaluations;

• Require CON applicants to provide information on net patient charges where appropriate in the evaluation process; and

• Require CON applicants to include non-capital expenditures in the final CON report.

SCHA is generally supportive of incorporating these recommendations into 61-15, however, it will withhold specific comments until the Department publishes the proposed regulation.

Department Response:

Adopted. The Department incorporated the LAC recommendations within the Department's regulatory authority to implement.

Name	Section
Ed Bender, SCHA	General

Comment:

SCHA feels compelled to use this forum to identify two LAC recommendations DHEC is precluded from addressing in this process.

First, the LAC recommended the General Assembly should exclude any CON "review of low-cost facilities and equipment such as MRI machines and ambulatory surgical centers." As the Department is aware, much of the CON law is prescribed by statute, such as the inclusion of ambulatory surgical centers ("ASC") in the definition of "health care facility." S.C. Code Ann. § 447-130(10). Construction of new health care facilities, including ASCs, requires a CON. S.C. Code Ann. § 44-7-160(1). Removing ASCs from the CON regulation would be a direct conflict with the CON statute and would be invalid. See, Brooks v. S.C. State Bd of Funeral Serv., 247 S.E.2d 820, 823, 271 S.C. 457 (S.C. 1978) (holding a regulation is invalid if it conflicts with a governing statute).

Second, the LAC recommended the General Assembly restrict "certain anti-competitive practices in the healthcare industry, such as non-compete agreements." While DHEC did not indicate plans to address this recommendation in 61-15, SCHA is compelled to point out doing so would certainly exceed the Department's statutory authority. A regulation is invalid if it exceeds the authority conferred by statute. See, Calhoun Life Ins. v. Gambrell, 140 S.E.2d 774, 776, 245 S.C. 406 (S.C. 1965). The purpose of the CON Act is to promote cost containment and prevent duplication of health care facilities and services. S.C. Code Ann. § 44-7-120. Regulating private contractual matters between sophisticated parties certainly exceeds DHEC's stated purpose and the intent of the General Assembly when creating CON. Since eliminating ASCs and regulating non-competes would likely be invalid, SCHA encourages the Department to refrain from addressing these during this process. Moreover, any attempt by the Department to address these issues would be duplicative because on July 15, 2022, the Centers for Medicare and Medicaid Services submitted a proposed rule for outpatient and ASC reimbursement that, among other things, solicits comments on healthcare transparency and competitiveness.

Department Response:

Acknowledged. DHEC is carrying out its obligations as required by state law.

Name	Section
Ed Bender, SCHA	General

Comment:

SCHA appreciates the Department's inclusion of indigent care plans in the CON application and would encourage DHEC to preserve and potentially augment these requirements in the regulation. South Carolina hospitals provide vital care for those uninsured and underinsured citizens in need. SCHA wants to ensure other provider types are also doing their part to care for these citizens and this provision helps accomplish that goal. In the absence of such requirements, or in the event CON is repealed, South Carolina hospitals will continue to provide indigent care while specialized providers will skim-off profitable services and provide them exclusively for patients with the best health insurance. This would undermine the financial viability of South Carolina hospitals and threaten hospitals' ability to ensure continued access to care for rural and disadvantaged communities, while maintaining the high-level of care South Carolinians receive today. Accordingly, SCHA would like to ensure the indigent care plans are preserved or even strengthened remain part of the Regulation 61-15.

Department Response:

Acknowledged. The Department acknowledges the importance of maintaining requirements associated with indigent care and is not recommending any changes in the proposed regulation.

Name	Section
Ed Bender, SCHA	General

Comment:
SCHA also encourages DHEC to develop an electronic application process. The current paper application process is both cumbersome and wasteful. The Department and CON applicants would greatly benefit from transitioning to an electronic application process. The CON Act clearly provides DHEC with the authority to establish the form of CON application by regulation. S.C. Code Ann. § 447200(A). Accordingly, SCHA respectfully requests the Department pursue an electronic application process.

Department Response:
Adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Holly Pisarik, SCMA	General

Comment: Although we believe that the only method for addressing the fundamental flaws of the State's Certificate of Need laws is to repeal, to the extent the agency plans to amend the Regulation, we recommend the following:
Implement the recommendations by the LAC that can be accomplished through amendment to the Regulation.

Increase the monetary threshold for purchase of medical equipment - Currently, there is a threshold of $600,000 for purchase of medical equipment. We recommend increasing that to $5 million and provide for the annual adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index.

Increase the monetary threshold for capital expenditures - Currently, there is threshold of $2 million for capital expenditures by or behalf of healthcare facilities. We recommend increasing that to $10 million and provide for the annual adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index.

Eliminate Certain Services to which CON Applies - Any service currently outlined in the State Health Plan that can be performed in an Ambulatory Surgery Center should be removed from the State Health Plan and exempt from CON.

Implement Transparency and Benchmarking - According to DHHS, 'lack of transparency in prices, quality and cost is considered an important contributor to excess health care spending in the US.' In an effort to provide transparency and monitor costs, the department should require hospitals and ASFs to file transparency reports (including but not limited to - charity care reports (based on costs, not charges) by hospitals and ASFs, number of outpatient procedures performed, payor mix, hospital profits, collection efforts through the GEAR program by hospitals, outreach efforts by ASFs to serve the underinsured and uninsured, quality data, CEO and other executive salary, bond ratings, among other things considered relevant by the department.

Department Response:
Partially adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years. The comment to eliminate certain services does not pertain to this regulation but pertains to the State Health Plan. The Department acknowledges the importance of maintaining requirements associated with indigent care and is not recommending any changes in the proposed regulation.

Name	Section
Sara Bacik, MUSC	General

Comment:
MUSC Health supports the Department's development and use of a reliable, transparent, and efficient electronic application process to reduce administrative burdens on both the regulated community and Department staff.

Department Response:
Adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	General

Comment: In favor of continued efforts to modernize the CON application and review process, Spartanburg Regional Healthcare System recommends the Department make as much of the application process electronic as possible.

Department Response:
Adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	General

Comment: Spartanburg Regional Healthcare System strongly disagrees with the recommendation to give consideration to regulating or placing additional restrictions on non-compete agreements. Courts already require all employers to satisfy a five-part test in order for non-compete agreements to be enforceable in South Carolina pursuant to a well-established body of law. Any challenges to the legitimate interests of hospitals, physician practices and other healthcare employers should be made through existing and effective remedies. Not only is Recommendation 12 the only one that would extend into a private employment contract wholly unrelated to CON, but it also deviates from all of the other twelve (12) recommendations in a critical respect. Each and every one of the other recommendations are specific tactics driving significant potential efficiency and program performance improvements either by (a) modifying the scope of the CON program; or (b) enhancing the administration and oversight of the CON program. Recommendation 12 is the lone outlier that would not appear to drive either of these two focused program improvement strategies. While not addressed in the Report, Spartanburg Regional Healthcare System would appreciate consideration being given to the following comments related to sections of Regulation 61-15 to create efficiencies within the program.

Department Response:
Not adopted. This comment is not within the regulatory authority of the Department.

Name	Section
Malcolm Isley, Prisma	General

Comment:
Prisma believes the CON process could be further streamlined and improved to be less onerous and time consuming for both health care providers and Department staff; however, Prisma realizes that many changes would require legislative action and cannot be accomplished through amendment of the regulations. For example, Prisma believes home health agencies should be exempt from CON review.

Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	General

Comment:
Furthermore, Prisma believes that the bed need calculation methodology for inpatient psychiatric hospitals can be improved. Upgrades to medical facilities that include the addition of square footage could be exempt, provided that the additional square footage is limited to a certain percentage of the facility's current square footage.

Department Response:

Not adopted. This is addressed in the State Health Plan.

Name	Section
Malcolm Isley, Prisma	General

Comment:
Also, the burden on providers and Department staff could be lessened if project progress reports were required to be submitted on a semi-annual rather than a quarterly basis.
Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	General

Comment:
Although bed need is calculated in connection with the publication of the South Carolina Health Plan, Prisma asks the Department to consider ways to improve the hospital bed need calculation methodology to more accurately reflect the providers' actual needs. For example, the calculation could include utilization of observation beds. To the extent the regulations can be amended to reflect a more refined approach to calculating bed need, Prisma would respectfully request the Department consider such amendments.
Joint annual reports ("JAR") are fundamental to the calculation of need for beds, services, and equipment and are vital to health care providers internal planning; yet, some providers do not timely submit accurate JAR data, as required by the CON Act. Prisma recommends that the Department consider amending the regulations to require timely submission of JARs and to penalize providers who fail to comply.
Department Response:
Not adopted. This is addressed in the State Health Plan and state licensing regulations for health facilities and services.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	General

Comment: Chapter 2: Necessity of CON Laws on Low-Cost Facilities and Services ([LAC Report] Page 20)
The auditors concluded that the Certificate of Need requirements be eliminated for Home Health, narcotic treatment programs, and opioid treatment programs. Spartanburg Regional Healthcare System fully supports the recommendation to eliminate CON for home health. However, the recommendation to remove CON requirements from narcotic treatment programs and opioid treatment programs cannot be implemented unless the CON Statute is changed.
Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	101

Comment: Section 101: While the purposes of the CON program are established in the CON Act, Prisma believes the CON regulations could expound upon and clarify those purposes to better reflect modern health care operations and alternative delivery care models. In that regard, Prisma recommends Section 101 be amended as follows:
The purpose of these Regulations is to promote cost containment and effective utilization of health care facilities and services. In addition, the Regulations should guide the establishment of new, and redistribution of existing, health care facilities and services which will best improve the health of populations of South Carolina citizens while preventing unnecessary duplication.
Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Sara Bacik, MUSC	102

Comment: Chapter 1, Section 102. Applicability
▪ §102(1)(c) Increase capital expenditure threshold to not less than $5 million, adjusted to the Medical Care Commodities Index component of the Medicare Consumer Price Index.
▪ §102(1)(f) Increase dollar amount threshold to not less than $2 million, adjusted to the Medical Care Commodities Index component of the Medicare Consumer Price Index.
▪ Delete §102(3) to eliminate confusion regarding the exemption and non-applicability determination process.
Department Response:
Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years. The Department clarified the language in Section 102.3 (now in 103.3) to eliminate confusion.

Name	Section
Shelley Pifer, Lexington Medical Center	102

Comment: 1. c - Lexington Medical Center proposes to raise the threshold for expenditures by a health care facility from $2,000,000 to $5,000,000.
1. f - Lexington Medical Center proposes to raise the threshold of acquisition of medical equipment which is to be used for diagnosis and treatment from $600,000 to $2,000,000. This $2,000,000 threshold would only be applied to the equipment itself- not the entire project. (Note: The state of North Carolina recently increased the equipment threshold for major medical equipment from $750,000 to $2,000,000.)
Department Response:
Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Malcolm Isley, Prisma	102

Comment: Prisma believes it is vitally important for health care systems to have the flexibility to utilize CON approved beds in a manner that effectively allows them to meet the fluctuating needs of their patient base. Prisma recommends the Department consider revising Section 102.1.b to allow health care systems to transfer CON approved beds between facilities within the same health care system provided that the facilities are located in the same health care inventory region or in adjacent counties. Allowing intersystem transfers without CON approval would give providers the ability to promptly and cost-effectively meet the need for additional beds at a facility with high-utilization when the needs at another facility within the same system may not be as great. To accomplish this purpose, Prisma recommends Section 102.1.b be amended as follows:
1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:
b. A change in the existing bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds; however, the transfer of beds, which have already been CON approved, between facilities in the same health care system shall not be considered a change to either facility's existing bed complement, provided that the facility transferring the beds and the facility receiving the beds are located within the same health care inventory region, as defined in the South Carolina Health Plan, or in counties adjacent to one another.
Department Response:
Not adopted. The Department is obligated to carry out its statutory requirements.

Name	Section
Malcolm Isley, Prisma	102

Comment: Section 102.1.c: Prisma recommends the Department consider raising the threshold expenditure triggering CON review for capital projects to at least $5 million.
Section 102.1.f: Prisma recommends the Department consider raising the threshold expenditure triggering CON review for the purchase of equipment to at least $2 million.
Department Response:

Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
James Hiott, Colleton Medical Center	102

Comment:
Colleton Medical Center supports a simplified system that removes the requirements for a CON for all but new healthcare facility construction and new service introduction. This would be the most effective, timely and reasonable way to reduce the cost of CON. This would allow providers to make decisions regarding the additions of beds, services and equipment in a more timely and cost-effective manner to best respond to community needs and to provide the highest possible quality of care for the patients.

Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
James Hiott, Colleton Medical Center	102

Comment:
If DHEC insists on maintaining thresholds, we recommend that the threshold for the acquisition of medical equipment be increased to $5 million and that the capital expenditure threshold for the addition or substantial expansion of a health service for which standards are prescribed in the State Health Plan be increased to $10 million.

Department Response:
Partially adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
James Hiott, Colleton Medical Center	102

Comment:
One of the most important considerations is not to create inequity among healthcare facilities when eliminating or revising CON criteria.

Department Response:
Acknowledged. The Department reduced the number of project review criteria by almost half.

Name	Section
Christina Oh, Trident Health	102

Comment:
Trident Health supports a simplified system that removes the requirements for a CON for all but new healthcare facility construction and new service introduction. This would be the most effective, timely and reasonable way to reduce the cost of CON. This would allow providers to make decisions regarding the additions of beds, services and equipment in a more timely and cost-effective manner to best respond to community needs and to provide the highest possible quality of care for the patients.

Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Christina Oh, Trident Health	102

Comment:
If DHEC insists on maintaining thresholds, we recommend that the threshold for the acquisition of medical equipment be increased to $5 million and that the capital expenditure threshold for the addition or substantial expansion of a health service for which standards are prescribed in the State Health Plan be increased to $10 million.

Department Response:
Partially adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Christina Oh, Trident Health	102

Comment:
One of the most important considerations is not to create inequity among healthcare facilities when eliminating or revising CON criteria.
Department Response:
Acknowledged. The Department reduced the number of project review criteria by almost half.

Name	Section
Mark Sims, Grand Strand Medical Center	102

Comment:
Grand Strand Medical Center supports a simplified system that removes the requirements for a CON for all but new healthcare facility construction and new service introduction. This would be the most effective, timely and reasonable way to reduce the cost of CON. This would allow providers to make decisions regarding the additions of beds, services and equipment in a more timely and cost-effective manner to best respond to community needs and to provide the highest possible quality of care for the patients.
Department Response:
Acknowledged. The Department is obligated to carry out its statutory requirements.

Name	Section
Mark Sims, Grand Strand Medical Center	102

Comment:
If DHEC insists on maintaining thresholds, we recommend that the threshold for the acquisition of medical equipment be increased to $5 million and that the capital expenditure threshold for the addition or substantial expansion of a health service for which standards are prescribed in the State Health Plan be increased to $10 million.
Department Response:
Partially adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Mark Sims, Grand Strand Medical Center	102

Comment:
One of the most important considerations is not to create inequity among healthcare facilities when eliminating or revising CON criteria.
Department Response:
Acknowledged. The Department reduced the number of project review criteria by almost half.

Name	Section
Jeff Taylor, Summerville Medical Center	102

Comment:
Summerville Medical Center supports a simplified system that removes the requirements for a CON for all but new healthcare facility construction and new service introduction. This would be the most effective, timely and reasonable way to reduce the cost of CON. This would allow providers to make decisions regarding the additions of beds, services and equipment in a more timely and cost-effective manner to best respond to community needs and to provide the highest possible quality of care for the patients.
Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Jeff Taylor, Summerville Medical Center	102

Comment:

If DHEC insists on maintaining thresholds, we recommend that the threshold for the acquisition of medical equipment be increased to $5 million and that the capital expenditure threshold for the addition or substantial expansion of a health service for which standards are prescribed in the State Health Plan be increased to $10 million.

Department Response:

Partially adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Jeff Taylor, Summerville Medical Center	102

Comment:

One of the most important considerations is not to create inequity among healthcare facilities when eliminating or revising CON criteria.

Department Response:

Acknowledged. The Department reduced the number of project review criteria by almost half.

Name	Section
Shelley Pifer, Lexington Medical Center	103

Comment: 16. The definition of like equipment with similar capabilities should be changed to read as follows: "Like equipment with similar capabilities means medical equipment in which functional and technological capabilities are similar to the equipment being replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use: and does not constitute a material change in service or a new service."

Department Response:

Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Sarah Bacik, MUSC	103

Comment: Eliminate definitions already contained in CON Act as well as unnecessary/outdated/obsolete definitions. Add a specific definition of “implemented/implementation” consistent with Section 44-7-230 of the CON Act and Section 607 of the Regulations.

Department Response:

Partially Adopted. The Department revised many definitions for clarity. The Department further clarified implementation in the proposed regulation.

Name	Section
Malcolm Isley, Prisma	103

Comment: Section 103.24: Prisma recommends that the Department consider eliminating the inclusion of land costs in the total project costs when the project consists solely of the purchase of fixed or movable equipment as such costs are not relevant to those types of projects.

24. Total project cost is the estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect’s fee, financing cost, and other capital costs properly charged under generally accepted accounting ~~principals~~ principles as a capital cost. The determination of project costs involving leased equipment of buildings will be calculated based on the total value (purchase price) of the equipment or building being leased. Notwithstanding the foregoing, the cost of land is not included in calculating the total project costs for projects which solely involve the purchase of either fixed or movable equipment.

Department Response:

Not Adopted. The Department revised many definitions for clarity.

Name	Section
Malcolm Isley, Prisma	103

Comment: Section 103.9: Rural health care providers are essential to ensuring access to care for all South Carolina citizens, but these providers often operate on small budgets with thin profit margins. Limiting the costs associated with CON approval for these vital health care providers would assist in ensuring their long-term viability and continued access to care for some of South Carolina's most vulnerable populations. For this reason, Prisma recommends the Department consider exempting rural health care providers from payment of CON fees.

9. Fees means the Department may charge and collect fees to cover the cost of operating the program. The fees for review of certificate of need projects include: (a) initial filing fee; (b) application fee; and (c) issuance fee, which are defined below; however, rural health care providers are exempt from and shall not be subject to these fees.

Department Response:
Not Adopted. The Department is carrying out its obligations under state law.

Name	Section
Mark Sims, Grand Strand Medical Center	104

Comment:
It is recommended that Section 104.1.a. regarding the replacement of like equipment for which a CON has been issued and does not result in a material change in service or a new service not require a written determination from the Department.
Section 104.4 will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment to be used for diagnosis or treatment to align with amounts in Section 102.

Department Response:
Adopted. The Department proposed to increase the monetary threshold amounts.

Name	Section
Malcolm Isley, Prisma	104

Comment: As with CON approved projects, the implementation of projects that are exempt from CON review is sometimes delayed. For this reason, Prisma recommends the Department consider implementing a protocol to allow providers who have received a CON exemption to obtain an extension of that exemption beyond the 12 month period provided for in the regulations.

Department Response:
Adopted. The Department proposed to increase the expiration of exemption period.

Name	Section
James Hiott, Colleton Medical Center	104

Comment:
It is recommended that Section 104.1.a. regarding the replacement of like equipment for which a CON has been issued and does not result in a material change in service or a new service not require a written determination from the Department.
Section 104.4 will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment to be used for diagnosis or treatment to align with amounts in Section 102.

Department Response:
Adopted. The Department proposed to increase the monetary threshold amounts.

Name	Section
Sarah Bacik, MUSC	104

Comment: Chapter 1, Section 104. Exemption Determinations
▪ §104(1) Delete (a) and (b) and cross-reference §44-7-170(A).

Department Response:
Not adopted. The Department does not propose deleting these sections because they provide clarification for the regulated community on projects requiring a written exemption from the Department.

Name	Section

Christina Oh, Trident Health	104

Comment:
It is recommended that Section 104.1.a. regarding the replacement of like equipment for which a CON has been issued and does not result in a material change in service or a new service not require a written determination from the Department. Section 104.4 will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment to be used for diagnosis or treatment to align with amounts in Section 102.

Department Response:
Adopted. The Department proposed to increase the monetary threshold amounts.

Name	Section
Jeff Taylor, Summerville Medical Center	104

Comment:
It is recommended that Section 104.1.a. regarding the replacement of like equipment for which a CON has been issued and does not result in a material change in service or a new service not require a written determination from the Department. Section 104.4 will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment to be used for diagnosis or treatment to align with amounts in Section 102.

Department Response:
Adopted. The Department proposed to increase the monetary threshold amounts.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	104

Comment: 1.1: SRHS recommends that the Department remove the requirement that written determination from the Department is required in order to replace like equipment for which a Certificate of Need has been issued and the replacement does not result in a material change in service or a new service. By virtue of the previous issuance of a Certificate of Need, the Department has determined that the equipment is necessary.

Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	105

Comment: If CON review is inapplicable to a proposed project, there should be no reason for a written non-applicability determination to expire. For this reason, Prisma recommends the Department consider eliminating Section 105.3 of the regulations, which voids the Non applicability determination if the project is not implemented within 12 months. Alternatively, as with written exemptions, the Department should consider implementing a protocol to allow providers who receive non-applicability determinations to obtain an extension.

Department Response:
Adopted. The timeframe was changed from 12 to 18 months.

Name	Section
Mark Sims, Grand Strand Medical Center	105

Comment: Section 105.1.b. will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment which is to be used for diagnosis or treatment to align with previously stipulated amounts.

Department Response:
Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
James Hiott, Colleton Medical Center	105

Comment: Section 105.1.b. will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment which is to be used for diagnosis or treatment to align with previously stipulated amounts.

Department Response:

Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Christina Oh, Trident Health	105

Comment: Section 105.1.b. will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment which is to be used for diagnosis or treatment to align with previously stipulated amounts.

Department Response:

Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Sarah Bacik, MUSC	105

Comment: Chapter 1, Section 105. Determinations of Non-Applicability

▪ §105(1) Delete (a) and (b) and cross-reference §44-7-170(B).

Department Response:

Not Adopted. The Department does not propose deleting these sections because they provide clarification for the regulated community on projects requiring a written non-applicability determination from the Department.

Name	Section
Jeff Taylor, Summerville Medical Center	105

Comment: Section 105.1.b. will need to be revised to eliminate or increase the threshold amount for the acquisition of medical equipment which is to be used for diagnosis or treatment to align with previously stipulated amounts.

Department Response:

Adopted. The Department proposes increasing thresholds in the proposed regulation with inflationary cost consideration every five years.

Name	Section
Shelley Pifer, Lexington Medical Center	106

Comment: Lexington Medical Center recommends that the Department must review and update the South Carolina Health Plan annually, including standards by which need is determined for health services and health care facilities.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	106

Comment: Thresholds for Equipment and Capital Expenditures ([LAC Report] Page 27)

The current spending thresholds were enacted in 2001. The auditors note with the increase in healthcare costs, these amounts are now obsolete. The regulated community as well as DHEC agree that the thresholds are too low and should be updated. Furthermore, the auditors recommend that the thresholds for both capital expenditures and equipment be increased and indexed for inflation using the Medical Care Index component of the Consumer Price Index. Spartanburg Regional Healthcare System fully supports these recommendations to increase the capital expenditure threshold to at least $5,000,000; the equipment threshold to at least $2,000,000; and index both for inflation.

Department Response:

Adopted. The Department proposed to increase the monetary threshold amounts.

Name	Section
Shelley Pifer, Lexington Medical Center	201

Comment: Publishing a notification in the legal section of a daily newspaper is an antiquated requirement of the Certificate of Need regulation. Perhaps consider a location on the DHEC website where the applicant can post the project description and costs prior to submitting the application.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	201

Comment: Prisma recommends that the Department revise Section 201 of the regulations to allow the required public notification to be made via an online newspaper serving the area.

Within twenty days prior to submission of an application, the applicant shall publish notification that an application is to be submitted to the Department in the ~~legal section of a~~ printed newspaper or online news service serving the area where the project is to be located for three consecutive days. . . .

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Shelley Pifer, Lexington Medical Center	202

Comment:

2. b. Part B. Additional Information - LMC proposes removing the following questions from Part B. Additional Information:

- B.5 - Construction Details - All renovation and construction details are already provided to DHEC's Bureau of Health Facilities and Construction. Any information provided in this question is duplication within the Department.
- B.6 - Replacement Facility- This information is usually addressed in the project description if applicable to the project.
- B.8 - Ownership Information - This information is relevant but seldom changes. This information can be completed on-line initially and updated as needed.
- B.13 - Accessibility to Service - This information can be covered in Question B.11, within the need for the project.
- B.14 - Historical Occupancy - This information, if necessary to the project at all, can be provided in Question 8.11, within the need for the project.
- 8.25 - Previous Experience of the Applicant - This information can be covered in Question B.11, within the need for the project.

2. c. Part C. Programmatic Documents - LMC proposes removing the following documents that are required in this section because it is excessive information that is not necessary to make a decision on a CON application.

- C.3 - Plot plan of the project site - This question is very similar to the previous question C.2, a map of the project site and its geographical area. This question is also not applicable to most CON applications.
- C.4 - Legal description - This question is also not applicable to most CON applications.
- C.8 - Community letters of support- These tend to be a paper exercise due to form letters

Department Response:

Adopted. The Department removed these questions from the proposed regulation.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	202

Comment: Community support is important when considering a new project. However, the support letter process does not achieve its intended goal when form letters are simply signed and included as part of

the CON application. Presently, it is a paper exercise; most support letters do not add to the value of a CON application. SRHS recommends that community letters of support be removed from CON application requirements.

Department Response:

Partially adopted. The Department removed these questions from the proposed regulation.

Name	Section
Malcolm Isley, Prisma	202

Comment: Prisma recommends the Department consider eliminating the need for CON applicants to submit certain routine, repetitive information (e.g., transfer agreements, previous experience, etc.). The Department can request additional information after the application has been filed if the Department believes the information is necessary for review. Additionally, Prisma recommends the Department consider eliminating the need for support letters, which are generally generic, form letters and provide little value to the Department's review of a project.

The application ~~shall be forwarded to the Department in the following format and~~ shall contain the following information as applicable. The application ~~will be~~ may be filed with the Department either (i) electronically by email or other means developed by the Department or (ii) on 8 ½ x 11-inch paper, one sided only, and 3-hole punched on the left side.

Department Response:

Partially adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Malcolm Isley, Prisma	301

Comment: ~~Two copies of t~~The application along with a non-refundable filing fee of five hundred dollars ($500) shall be ~~forwarded to~~ filed with the Bureau of Health Facilities and Services Development, either electronically via email or other electronic means developed by the Department or by delivering two paper copies to S.C. Department of Health and Environmental Control, 2600 Bull Street, SC 29201. Applicants are encouraged to involve the Department in the development of proposed projects prior to submission of the application.

Department Response:

Adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Jeff Taylor, Summerville Medical Center	302

Comment: Summerville Medical Center believes that standardization in the evaluation process is vital to the proper administration of the CON program. If not already in place, internal review policies and procedures that ensure consistency in the CON application review are critical and should be developed and provided to CON applicants. For example, the Department could develop a template of information/documentation required for each CON application in general, as well as information required for a specific type of service or equipment. The Department can also ensure that submitted CON applications contain the information requested in each section of the CON application, and follow up with the applicant in writing if certain sections of the CON application have not been addressed without explanation.

Although the time frames for evaluation of a CON application are set by statute, Summerville Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. We recommend that Section 302 be amended to require the Department to deem an application complete within 30 days of its receipt if no additional information is being requested from the applicant and that notice to affected persons be immediately published in the next State Register. This would ensure that the review period is timely implemented for CON applications when no additional information is required from the applicant.

Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Christina Oh, Trident Health	302

Comment: Trident Medical Center believes that standardization in the evaluation process is vital to the proper administration of the CON program. If not already in place, internal review policies and procedures that ensure consistency in the CON application review are critical and should be developed and provided to CON applicants. For example, the Department could develop a template of information/documentation required for each CON application in general, as well as information required for a specific type of service or equipment. The Department can also ensure that submitted CON applications contain the information requested in each section of the CON application, and follow up with the applicant in writing if certain sections of the CON application have not been addressed without explanation.

Although the time frames for evaluation of a CON application are set by statute, Trident Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. We recommend that Section 302 be amended to require the Department to deem an application complete within 30 days of its receipt if no additional information is being requested from the applicant and that notice to affected persons be immediately published in the next State Register. This would ensure that the review period is timely implemented for CON applications when no additional information is required from the applicant.

Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
James Hiott, Colleton Medical Center	302

Comment: Colleton Medical Center believes that standardization in the evaluation process is vital to the proper administration of the CON program. If not already in place, internal review policies and procedures that ensure consistency in the CON application review are critical and should be developed and provided to CON applicants. For example, the Department could develop a template of information/documentation required for each CON application in general, as well as information required for a specific type of service or equipment. The Department can also ensure that submitted CON applications contain the information requested in each section of the CON application, and follow up with the applicant in writing if certain sections of the CON application have not been addressed without explanation.

Although the time frames for evaluation of a CON application are set by statute, Colleton Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. We recommend that Section 302 be amended to require the Department to deem an application complete within 30 days of its receipt if no additional information is being requested from the applicant and that notice to affected persons be immediately published in the next State Register. This would ensure that the review period is timely implemented for CON applications when no additional information is required from the applicant.

Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Mark Simms, Grand Strand Medical Center	302

Comment: Grand Strand Medical Center believes that standardization in the evaluation process is vital to the proper administration of the CON program. If not already in place, internal review policies and procedures that ensure consistency in the CON application review are critical and should be developed and provided to CON applicants. For example, the Department could develop a template of information/documentation required for each CON application in general, as well as information required for a specific type of service or equipment. The Department can also ensure that submitted CON

applications contain the information requested in each section of the CON application, and follow up with the applicant in writing if certain sections of the CON application have not been addressed without explanation.

Although the time frames for evaluation of a CON application are set by statute, Grand Strand Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. We recommend that Section 302 be amended to require the Department to deem an application complete within 30 days of its receipt if no additional information is being requested from the applicant and that notice to affected persons be immediately published in the next State Register. This would ensure that the review period is timely implemented for CON applications when no additional information is required from the applicant.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	302

Comment: If the Department determines that no additional information is required to complete the application, the Department shall deem the application complete immediately following thirty (30) calendar days from the day the application was accepted for filing and shall publish notice to affected persons that the application has been deemed complete in the next regularly scheduled publication of the State Register.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Christina Oh, Trident Health	304

Comment: Trident Medical Center recommends that Section 304.1 be revised to add a requirement that within five (5) days of a determination by the Department that an application is complete, the Department shall notify the applicant by certified mail of the relative importance of the project review criteria to be used in reviewing the application.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	304

Comment: 1. Within five (5) calendar days of a ~~upon~~ determination by the Department that an application is complete, the Department shall notify the applicant, by email or by certified mail, of the relative importance of the project review criteria to be used in reviewing the application. . . .

Department Response:

Partially adopted. The Department is carrying out its obligations under state law.

Name	Section
Mark Sims, Grand Strand Medical Center	304

Comment: Grand Strand Medical Center recommends that Section 304.1 be revised to add a requirement that within five (5) days of a determination by the Department that an application is complete, the Department shall notify the applicant by certified mail of the relative importance of the project review criteria to be used in reviewing the application.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
James Hiott, Colleton Medical Center	304

Comment: Colleton Medical Center recommends that Section 304.1 be revised to add a requirement that within five (5) days of a determination by the Department that an application is complete, the Department

shall notify the applicant by certified mail of the relative importance of the project review criteria to be used in reviewing the application.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Jeff Taylor, Summerville Medical Center	304

Comment: Summerville Medical Center recommends that Section 304.1 be revised to add a requirement that within five (5) days of a determination by the Department that an application is complete, the Department shall notify the applicant by certified mail of the relative importance of the project review criteria to be used in reviewing the application.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Malcolm Isley, Prisma	305

Comment: The Department will make a decision on the complete application no earlier than thirty (30) calendar days but no later than 120 calendar days of the date of publication in the State Register unless a public hearing is held. Notice of a Department decision must be sent by email or by certified mail, return receipt requested to the applicant and affected persons who have requested in writing to be notified.

a. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than 150 calendar days from the date the affected persons are notified that the application is complete.

b. ~~[Reserved]~~ If no affected persons have provided written notice of their opposition to an application, the Department must render its decision to approve or deny the application no later than sixty (60) calendar days from the date of publication in the State Register that the application has been deemed complete.

Department Response:

Partially adopted. The Department is carrying out its obligations under state law.

Name	Section
Christina Oh, Trident Medical Center	305

Comment: Although the time frames for evaluation of a CON application are set by statute, Trident Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. It is recommended that Section 305 be amended to require the Department to issue a determination to approve or deny a CON application within 60 days of the CON application being deemed complete as published in the State Register if the application is not opposed by affected persons within the first 30 days of the review period.

It is recommended that the following time frame be added to Section 305:

If no affected persons have provided written notice of their opposition to an application, the Department must render its decision to approve or deny the application no later than sixty (60) calendar days from the date of publication in the State Register that the application has been deemed[.]

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Mark Sims, Grand Strand Medical Center	305

Comment: Although the time frames for evaluation of a CON application are set by statute, Grand Strand Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. It is recommended that Section 305 be amended to require the Department to issue a determination to approve or deny a CON application within 60 days of the CON application being deemed complete as published in the State Register if the application is not opposed by affected persons within the first 30 days of the review period.

It is recommended that the following time frame be added to Section 305:

If no affected persons have provided written notice of their opposition to an application, the Department must render its decision to approve or deny the application no later than sixty (60) calendar days from the date of publication in the State Register that the application has been deemed[.]

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
James Hiott, Colleton Medical Center	305

Comment: Although the time frames for evaluation of a CON application are set by statute, Colleton Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. It is recommended that Section 305 be amended to require the Department to issue a determination to approve or deny a CON application within 60 days of the CON application being deemed complete as published in the State Register if the application is not opposed by affected persons within the first 30 days of the review period.

It is recommended that the following time frame be added to Section 305:

If no affected persons have provided written notice of their opposition to an application, the Department must render its decision to approve or deny the application no later than sixty (60) calendar days from the date of publication in the State Register that the application has been deemed[.]

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Jeff Taylor, Summerville Medical Center	305

Comment: Although the time frames for evaluation of a CON application are set by statute, Summerville Medical Center believes that there are amendments that can be made to the CON Regulations to streamline the process. It is recommended that Section 305 be amended to require the Department to issue a determination to approve or deny a CON application within 60 days of the CON application being deemed complete as published in the State Register if the application is not opposed by affected persons within the first 30 days of the review period.

It is recommended that the following time frame be added to Section 305:

If no affected persons have provided written notice of their opposition to an application, the Department must render its decision to approve or deny the application no later than sixty (60) calendar days from the date of publication in the State Register that the application has been deemed[.]

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Sarah Bacik, MUSC	305

Comment: Chapter 3, Section 305. Review Time Frames

▪ Add language that Department must automatically notify and provide the applicant with a copy of any correspondence (FOIA Requests, Affected Persons Letters, Opposition, etc.) related to the project.

Department Response:

Not adopted. The proposed regulation is amended to align with implementation of the electronic application process.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	305

Comment: Chapter 4: Examples of CON Process Deterring Applicants for New or Expanded Facilities and Services ([LAC Report] Page 60) While the LAC report notes that the CON program can cause frustration or reluctance for new or expanded facilities and services, it acknowledges that it is only a deterrent for some providers or potential providers. As a result, the auditors recommend that ambulatory surgery centers be removed from certificate of need review.

Department Response:

Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Sarah Bacik, MUSC	502

Comment: Chapter 5, Section 502. Periodic Reports
▪ Add language that a CON application cannot be deemed complete unless the prior year JARs have been submitted.
Department Response:
Not adopted. The Department is carrying out its obligations under state law.

Name	Section
Shelley Pifer, Lexington Medical Center	607

Comment: 3. LMC recommends simplifying the final completion report. The final completion report should include:

a. Total expenditures on the project;
b. Signed statement of final construction costs;
c. Project narrative

Department Response:
Not adopted. The Department needs this data to ensure the project aligns with the application.

Name	Section
Sarah Bacik, MUSC	607

Comment: Chapter 6, Section 607. Periodic Reporting of Certificate of Need Implementation
▪ Revise quarterly reporting requirements as follows:
o Require quarterly reports until project has been implemented.
o Do not require quarterly reports during construction period, except as otherwise required with respect to project changes under Section 605.
o Required final report when project is completed/fully implemented
Department Response:
Not adopted. The Department needs this data to ensure the project aligns with the application.

Name	Section
Elizabeth Fletcher, Spartanburg Regional	607

Comment: Spartanburg Regional Healthcare System strongly disagrees with the recommendation to remove Certificate of Need requirements for both procedural and quality concerns. In Chapter 7, Article 3, Section 44-7-130 of the SC Code of Laws, Ambulatory Surgery Centers are included in the definition of a Health Care Facility. Section 44-7-160(1) requires a person or health care facility as defined in this article to obtain a Certificate of Need from the department before undertaking the construction or other establishment of a new health care facility. The recommendation to remove CON requirements from Ambulatory Surgery Centers cannot be implemented unless the CON Statute is changed. While ambulatory surgery centers are a lower cost alternative to hospitals, as with any healthcare facility, patient safety and quality care are of the utmost concern. Traditionally ambulatory surgery centers do not require the same staffing ratios nor equipment as hospitals. With the rapid evolution of minimally invasive surgeries, it is important that new or expanded facilities undergo a rigorous and thoughtful review process to ensure that the proposed procedures are appropriate for the setting and that there will be adequate staff in place to support the surgical procedures. It is unclear why the LAC report would remove this specific service when other, less invasive treatments remain under the CON program. An ambulatory surgery provider focused on high quality should welcome a thorough review process to ensure the safety of its patients. Also in this section, the LAC report recommends that consideration should be given to regulating or placing restrictions on non-compete agreements.
Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Sarah Bacik, MUSC	701/702

Comment: Chapter 7, Section 701/702. Penalties for Non-Compliance
▪ Consistent with 44-7-150, add specific language establishing uniform procedures and standards for the Department to employ after receiving reports of non-compliance by entities undertaking any activity requiring CON review without prior approval, including but not limited to investigations/inspections procedures.
Department Response:
Acknowledged. The Department is carrying out its obligations under state law.

Name	Section
Christina Oh, Trident Medical Center	802

Comment: Trident Medical Center believes the CON review process could be streamlined by eliminating many of the project review criteria ("PRC"). Several of the PRC included in the CON Regulations are routinely deemed most important in the review of applications, while numerous others are rarely considered or rarely considered in depth. Trident Medical Center believes the following PRC are most important for review and should remain in effect:
Need (802.1), Community Need Documentation (802.2), Distribution (Accessibility) (802.3), Acceptability (802.4), Financial Entries and Assumptions (802.5), Projected Revenues (802.6), Projected Expenses (802.7), Beginning Cash Flow (802.8), Net Income (802.9), Debt Service (802.10), Financial Feasibility (802.15), Cost containment (802.16), Adverse Effects on Other Facilities (802.23), Medically Underserved Groups.
Trident Medical Center further recommends that PRC 802.5, 802.6, 802.7, 802.8, 802.9, 802.10, 802.15, and 802.16 could be collapsed into one PRC addressing financial feasibility and cost containment:
Financial Feasibility:
a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal, based upon accepted accounting procedures.
b. All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of the information.
c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three years of operation.
d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing if necessary.
e. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges must be reasonable.
The PRC that are not referenced in this section should be eliminated. If the number of PRC are reduced, the Department should consider all remaining PRC in the review of every application.
Department Response:
Adopted. This comment was incorporated into the proposed regulation.

Name	Section
James Hiott, Colleton Medical Center	802

Comment: Colleton Medical Center believes the CON review process could be streamlined by eliminating many of the project review criteria ("PRC"). Several of the PRC included in the CON Regulations are routinely deemed most important in the review of applications, while numerous others are rarely considered or rarely considered in depth. Colleton Medical Center believes the following PRC are most important for review and should remain in effect:
Need (802.1), Community Need Documentation (802.2), Distribution (Accessibility) (802.3), Acceptability (802.4), Financial Entries and Assumptions (802.5), Projected Revenues (802.6), Projected Expenses (802.7), Beginning Cash Flow (802.8), Net Income (802.9), Debt Service (802.10), Financial Feasibility (802.15), Cost containment (802.16), Adverse Effects on Other Facilities (802.23), Medically Underserved Groups.

Colleton Medical Center further recommends that PRC 802.5, 802.6, 802.7, 802.8, 802.9, 802.10, 802.15, and 802.16 could be collapsed into one PRC addressing financial feasibility and cost containment:
Financial Feasibility:
a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal, based upon accepted accounting procedures.
b. All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of the information.
c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three years of operation.
d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing if necessary.
e. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges must be reasonable.
The PRC that are not referenced in this section should be eliminated. If the number of PRC are reduced, the Department should consider all remaining PRC in the review of every application.

Department Response:

Adopted. This comment was incorporated into the proposed regulation.

Name	Section
Jeff Taylor, Summerville Medical Center	802

Comment: Summerville Medical Center believes the CON review process could be streamlined by eliminating many of the project review criteria ("PRC"). Several of the PRC included in the CON Regulations are routinely deemed most important in the review of applications, while numerous others are rarely considered or rarely considered in depth. Summerville Medical Center believes the following PRC are most important for review and should remain in effect:
Need (802.1), Community Need Documentation (802.2), Distribution (Accessibility) (802.3), Acceptability (802.4), Financial Entries and Assumptions (802.5), Projected Revenues (802.6), Projected Expenses (802.7), Beginning Cash Flow (802.8), Net Income (802.9), Debt Service (802.10), Financial Feasibility (802.15), Cost containment (802.16), Adverse Effects on Other Facilities (802.23), Medically Underserved Groups. Summerville Medical Center further recommends that PRC 802.5, 802.6, 802.7, 802.8, 802.9, 802.10, 802.15, and 802.16 could be collapsed into one PRC addressing financial feasibility and cost containment:
Financial Feasibility:
a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal, based upon accepted accounting procedures.
b. All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of the information.
c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three years of operation.
d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing if necessary.
e. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges must be reasonable.
The PRC that are not referenced in this section should be eliminated. If the number of PRC are reduced, the Department should consider all remaining PRC in the review of every application.

Department Response:

Adopted. This comment was incorporated into the proposed regulation.

Name	Section

Mark Simms, Grand Strand Medical Center	802

Comment: Grand Strand Medical Center believes the CON review process could be streamlined by eliminating many of the project review criteria ("PRC"). Several of the PRC included in the CON Regulations are routinely deemed most important in the review of applications, while numerous others are rarely considered or rarely considered in depth. Grand Strand Medical Center believes the following PRC are most important for review and should remain in effect:

Need (802.1), Community Need Documentation (802.2), Distribution (Accessibility) (802.3), Acceptability (802.4), Financial Entries and Assumptions (802.5), Projected Revenues (802.6), Projected Expenses (802.7), Beginning Cash Flow (802.8), Net Income (802.9), Debt Service (802.10), Financial Feasibility (802.15), Cost containment (802.16), Adverse Effects on Other Facilities (802.23), Medically Underserved Groups. Summerville Medical Center further recommends that PRC 802.5, 802.6, 802.7, 802.8, 802.9, 802.10, 802.15, and 802.16 could be collapsed into one PRC addressing financial feasibility and cost containment:

Financial Feasibility:

a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal, based upon accepted accounting procedures.

b. All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of the information.

c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three years of operation.

d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing if necessary.

e. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges must be reasonable.

The PRC that are not referenced in this section should be eliminated. If the number of PRC are reduced, the Department should consider all remaining PRC in the review of every application.

Department Response:

Adopted. This comment was incorporated into the proposed regulation.

Name	**Section**
Malcolm Isley, Prisma	802

Comment: Section 802: Prisma believes the CON review process could be streamlined by eliminating many of the project review criteria ("PRC"). Several of the PRC included in the CON Regulations 5 are routinely deemed most important in the review of applications, while numerous others are rarely considered or rarely considered in depth. Prisma believes the following PRC are most important for review and should remain in effect:

o Compliance with the State Health Plan (802.1)
o Community Need Documentation (802.2)
o Distribution (Accessibility) (802.3)
o Acceptability (802.4)
o Financial Entries and Assumptions (802.5)
o Projected Revenues (802.6)
o Projected Expenses (802.7)
o Beginning Cash Flow (802.8)
o Net Income (802.9)
o Debt Service (802.10)
o Financial Feasibility (802.15)
o Cost containment (802.16)
o Adverse Effects on Other Facilities (802.23)
o Medically Underserved Groups

Furthermore, Prisma recommends the Department collapse PRC 802.5, 802.6, 802.7, 802.8, 802.9, 802.10, 802.15, and 802.16 into a single PRC addressing financial feasibility and cost containment:
Financial Feasibility:
a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal, based upon accepted accounting procedures.
b. All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of the information.
c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three years of operation.
d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing if necessary.
e. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges must be reasonable.
The PRC that are not referenced in this section should be eliminated. If the number of PRC are reduced, the Department should consider all remaining PRC in the review of every application.
Department Response:
Adopted. This comment was incorporated into the proposed regulation.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 8, 2022

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

From: Bureau of Radiological Health

Re: Notice of Proposed Regulation Amending R.61-64*, X-rays (Title B)*.

I. Introduction

The Bureau of Radiological Health proposes the attached Notice of Proposed Regulation amending R.61-64, *X-rays (Title B)*, for publication in the September 23, 2022, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 13-7-40 et seq., which requires the Department to promulgate, amend, and repeal regulations relating to the control of ionizing and nonionizing radiation, the qualifications of operators applying ionizing or nonionizing radiation to humans, and registration of radiation sources or devices or equipment utilizing these sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. Pursuant to S.C. Code Sections 13-7-40 et seq., the Department promulgates, amends, and repeals regulations relating to the control of ionizing and nonionizing radiation, the qualifications of operators applying ionizing or nonionizing radiation to humans, and registration of radiation sources or devices or equipment utilizing these sources. The Department proposes comprehensive amendment to R.61-64, *X-Rays (Title B)*. General areas of this revision include, but are not limited to, clarifying and simplifying the regulation, adding new definitions as required, deleting requirements that are no longer applicable, and ensuring the regulation is in alignment with the current statute. The Department may also amend requirements regarding registration, inspections, violations, enforcement, equipment, and mammography. The proposed amendments will also update vendor classes, add requirements for personnel security screening systems using x-ray, and clarify, organize, and update the Radiation Safety Officer requirements. The Department may also include changes such as corrections for readability, grammar, punctuation, codification, and other such regulatory text improvements.

2. The Department had a Notice of Drafting published in the February 25, 2022, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from fourteen (14) parties by the March 28, 2022, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

3. Healthcare Quality held a virtual stakeholder meeting on March 16, 2022. Staff considered stakeholder feedback in formulating the proposed amendments herein.

4. Appropriate Department staff conducted an internal review of the proposed amendments on July 13, 2022.

5. The Technical Advisory Radiation Control Council currently has no active members, however, organizations with designated representation on the council will be contacted directly with information on how to participate in this regulation promulgation process.

III. Request for Approval

The Bureau of Radiological Health respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 23, 2022, *State Register*.

Susan Jenkins
Director
Bureau of Radiological Health

Gwen Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the February 25, 2022, *State Register*
C. Summary of Public Comments Received and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-64, *X-rays (Title B)*

September 8, 2022

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

61-64. X-rays (Title B).

Preamble:

Pursuant to S.C. Code Sections 13-7-40 et seq., the Department of Health and Environmental Control ("Department") promulgates, amends, and repeals regulations relating to the control of ionizing and nonionizing radiation, the qualifications of operators applying ionizing or nonionizing radiation to humans, and registration of radiation sources or devices or equipment utilizing these sources. The Department proposes comprehensive amendment to R.61-64, X-Rays (Title B). General areas of this revision include, but are not limited to, clarifying and simplifying the regulation, adding new definitions as required, deleting requirements that are no longer applicable, and ensuring the regulation is in alignment with the current statute. The Department may also amend requirements regarding registration, inspections, violations, enforcement, equipment, and mammography. The proposed amendments will also update vendor classes, add requirements for personnel security screening systems using x-ray, and clarify, organize, and update the Radiation Safety Officer requirements. The Department may also include changes such as corrections for readability, grammar, punctuation, codification, and other such regulatory text improvements. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the February 25, 2022, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
Entire Regulation	Reorganization/Revision	Amended numbering in regulation for correct codification and clarity.
Entire Regulation	Technical Correction	Amended to correct grammatical errors, punctuation, and capitalization.
Entire Regulation	Technical Correction	Amended to correct references.
Entire Regulation	Technical Correction	Amended to use text and numerical symbols when any number is utilized. Amended to clarify deadlines in calendar days.

Entire Regulation	Technical Correction	Amended "these regulations" to "this regulation" for grammatical correctness.
Entire Regulation	Technical Correction	Amended to add "RHB" when referencing parts of this regulation.
Statutory Authority	Addition	To clarify appropriate S.C. Code of Laws authority.
Table of Contents	Reorganization/Revision	To reflect proposed organization and title amendments in regulation text.
1.2. Prohibited Use.	Addition/Revision	Amended to add exemptions for Hand-held Intraoral Equipment and Personnel Security Screening Systems. Amended language for licensed practitioner to be consistent with revised definition.
1.3. Inspections.	Addition/Revision	Amended to provide clarity related to records requests and added reference to the Atomic Energy and Radiation Control Act.
1.4 Test and Surveys.	Technical Correction	Amended to provide clarity for instrument calibrations.
1.6 Additional Requirements.	Revision/Reorganization	1.6.3 Amended to provide clarity and recodify equipment not covered in regulation. 1.6.4 was recodified to 3.3.
1.7 Corrective Action Plan.	Revision/Reorganization/Addition	Title amended for consistency with other Departmental regulations. Prior 1.7.1 was recodified to 1.8.2 and prior 1.7.4 was recodified to 1.13.2. Added clarification for determination of response adequacy.
1.8 Enforcement.	Revision/Deletion/Reorganization	Amended for consistency with other Departmental regulations.
1.10 Records.	Revision	Amended to provide clarity regarding records and inventory.
1.11 Records and Reports of Misadministration.	Revision/Addition	Amended title in 1.11.1 and added language regarding

		records based on stakeholder comments.
1.12 Material False Statements	Deletion	Title was amended to provide clarity and prior 1.12.1 was deleted.
1.13 Fines and Penalties	Revision/Deletion/Reorganization	Title amended for consistency with other Departmental regulations. Former 1.13.1 was recodified to 1.7.4. Former 1.13.2 was amended to provide clarity regarding the categories of severity levels. Former 1.13.2.2 – 1.13.4.3 were deleted as the sections reflect Department operating procedures and not regulatory language. (OGC please review) Former 1.7.4 recodified to 1.13.2 and penalty matrix was clarified. Former 1.13.4.2 recodified to 1.13.3 and clarified.
2.3 Application and Review Fees.	Revision	2.3.2 Amended to provide clarity regarding the current required fee. 2.3.3 amended to provide clarity regarding notice of vendor registration.
2.4 Facility Registration Approval.	Revision	Amended to provide clarity regarding facility registration approval for in-state facilities and out-of-state facilities prior to installation of x-ray producing machines.
2.5 Equipment Registration Requirements, User of X-ray Machines.	Revision/Deletion	2.5.2 and 2.5.3 were deleted and recodified to new 2.6.
2.6 Report of Change	Reorganization/Revision/ Addition/Deletion	Prior 2.5.2 and 2.5.3 recodified and amended to provide clarity regarding the reporting of changes to the Department.
2.7 Registration Requirements – Servicing and Services (VENDOR).	Revision/Addition/Technical Correction	2.7.1 Amended to provide clarity regarding vendor registration and registration exemptions. 2.7.2 Amended to correct grammatical errors, and provide clarity regarding registration application

		requirements, applicant certification, and application signature requirements. 2.7.4 and 2.7.5 Amended to add clarity regarding vendor registration. 2.7.6 Amended for consistency with this and other parts, and to provide clarity regarding vendor classification and services. 2.7.7 Amended to provide clarity regarding reporting changes to registration. 2.7.8 Amended to provide clarity regarding vendor classification and services, training and education requirements, and for consistency with other parts. 2.7.9 Amended to update reference to regulation.
2.8 Vendor Obligation.	Revision	2.8.1 Amended to provide clarity regarding sales and installation notifications. 2.8.2 Amended to provide clarity regarding vendor obligation to meet requirements. 2.8.3 Amended to provide clarity regarding maintenance and contents of records. 2.8.4 Amended to provide clarity regarding quality of records. 2.8.5 Amended to change "must" to "shall" for consistency.
RHB 2.9 Out of State Facilities.	Addition/Revision	2.9.1 Amended to provide clarity regarding requirements for out-of-state facility registration. 2.9.2 Amended to reference form provided by the Department.
RHB 2.11 Annual Fees.	Revision/Reorganization/Addition	2.11.1 Amended to clarify the assessment of the annual registration fee. Prior 2.10.4 regarding the instruction for payment recodified here. Amended to clarify the due date for payment of the fee. Amended to clarify the date the late fee will be required.

		Amended to clarify the date on which the registration will be revoked. Amended to change "suspended" to "revoked" for consistency. 2.11.2 Amended to change "machine" to "equipment" for consistency with other parts of the regulation. 2.11.3 amended to add new equipment types (X-ray Gauge and Personnel Security Screening System) to the fee schedule and update reference.
3.1 Scope.	Revision	Amended to provide clarity and consistency with other Departmental regulations.
3.2 Implementation.	Technical Correction	Added text indicating text of an abbreviation.
3.3 Authority and Responsibility for the Radiation Protection Programs.	Reorganization/Revision	Amended to ensure compliance with the regulation. Revised 3.3.3 to clarify radiation protection program requirements. Recodified prior 1.6.4 to 3.3.4. Renumbered remainder of section.
3.5 Compliance with Requirements for the Summation of External and Internal Doses.	Addition	Added a word for title clarity.
3.8 Dose to an Embryo/Fetus.	Revision	Amended to reflect CRCPD suggested state regulations.
3.9 Dose Limits for Individual Members of the Public.	Deletion	Deleted retrofit allowance because it is no longer relevant.
3.11 Surveys.	Revision	Revised timeframe for instrument calibration for consistency.
3.12 Personnel Monitoring.	Revision/Addition	3.12.3 Amended to allow RSO evaluation of exposure of badges, updated "lead apron" to "protective apron," and clarified monitoring periods and documentation requirements. 3.12.3 Added reference to fetal dosimeters. 3.12.5 Amended to reflect CRCPD suggested state

		regulations, as indicated in public comments. Amended to clarify periodic checks to quarterly checks.
3.15 Caution Signs.	Revision	Amended to provide clarity of the radiation symbol.
3.18 Records of Radiation Protection Programs.	Revision	Amended requirement to five years for consistency with the regulation.
3.19 Records of Surveys.	Addition	Added "instrument" for clarification.
3.20 Determination and Records of Prior Occupational Dose.	Addition/Deletion	Added "attempt" to obtain records of prior occupational exposure. Deleted "telegram" as it is no longer relevant.
3.22 Records of Individual Monitoring Results	Deletion	Deleted sentence regarding effective date of these regulations as it is no longer relevant.
3.24 Notification of Incidents	Revision/Addition	Amended to delete forms of notification no longer applicable and add current forms of notification.
3.29 Storage and Control of Radiation Sources	Revision	Amended to reflect intent of CRCPD Suggested State Regulations.
3.30 Reports of Stolen, Lost, or Missing Radiation Sources	Addition	Added reporting includes abandoned radiation machines.
4.2 General Safety Provisions	Revision/Deletion/Addition	4.2.2 Added direct for clarification of supervision and amended for grammatical purposes. 4.2.6 and 4.2.8 Amended for clarity, grammar and replaced lead with protective apron. 4.2.9 Added exemption for hand placement. 4.2.10 Deleted requirement for patient shielding and added collimation requirement. 4.2.12 Deleted references. 4.12.13 Amended for clarity on ESE requirements and handheld dental equipment. 4.2.15 Amended to clarify x-ray log.

		4.2.16 Clarified SID. 4.2.17 Deleted procedures because no longer applicable.
4.3 General Requirements for all Diagnostic X-ray Systems	Revision	Amended throughout to correct grammatical use of x-ray and clarify units of measurement.
4.4 Shielding	Revision/Reorganization/ Addition	4.4.1 Amended to clarify the person/persons responsible for ensuring changes are reviewed by the appropriate class vendor. Amended to clarify the form to be utilized and the required fees. Amended to reduce timeframe for the requirement of a shielding plan for space utilized as a radiation area. Prior 4.4.2.3 regarding requirement for shielding plan deleted and reorganized to 4.4.1.3 for clarity. 4.4.2 Amended to clarify which replacement type does not require a shielding plan. Amended to delete vendor class for consistency with RHB 2.7.6. Amended to clarify timeframe to notify the Department. Amended to include form to be utilized for notification. Amended to change "machine" to "system" for consistency. Amended to clarify when a shielding plan is required. Amended to delete vendor class for consistency with RHB 2.7.6. Prior 4.4.2.3 deleted and reorganized to 4.4.1.3. 4.4.3 Amended to clarify when equipment may be installed or operated. Amended to clarify adherence to the accepted shielding plan. 4.4.4 Amended to clarify and allow for the use of the current version of the

		appropriate national Council of Radiation Protection and Measurements Reports. Amended to include adherence to Part IV, Appendix C. 4.4.6 Amended to add/delete vendor classes for consistency with RHB 2.7.6. Amended to clarify requirements for the area survey. Amended to clarify the form to be utilized for submission of the area survey. 4.4.7 Amended to clarify the content of the “as-built” drawings and added vendor classes for consistency. Timeframe deleted and reorganized to 4.4.7.1.1. Addition to clarify the timeframe for submission of “as-built” drawings, the required content of the drawings, and the form to be utilized for submissions. 4.4.7 Amended to add vendor class for consistency with RHB 2.7.6. 4.4.8 Title amended to include Transportable Installations. Amended to create heading for Bone Density and Mammography installations section. Amended to add vendor class for consistency with RHB 2.7.6. Amended to include form to be utilized for notification. Added requirements for Transportable Installations. Added requirements for area survey for Transportable Installations. Added form to be utilized for notification and reference to existing requirement for review fees in RHB 2.3.2

4.5 Intraoral Dental Radiographic Systems	Revision/Reorganization	Amended to provide clarity regarding applicability of part. 4.5.4 Amended to provide clarity regarding x-ray control location. 4.5.9 – 4.5.10 Amended for grammatical purposes. 4.5.12 Amended to provide clarity on use of patient shielding. 4.5.13 Recodified from 4.6.4.
4.6 Extraoral Dental Radiographic Systems	Revision/Reorganization	Amended to provide clarity regarding applicability of part. 4.6.1 Amended to provide clarity regarding cephalometric equipment requirements. 4.6.2 Amended to provide clarity regarding panoramic equipment requirements. 4.6.3 Amended to provide clarity regarding dental CT equipment requirements. 4.6.4 Recodified to 4.5.13.
4.7 Medical Radiographic Systems	Revision/Addition/Deletion	Amended to provide clarity regarding applicability of part. Added "transportable" to clarify its inclusion for this requirement. Added "RHB" to applicable regulation numbers throughout this Part. 4.7.1 Amended to provide clarity on included equipment and correct grammatical errors. 4.7.2 Amended to clarify equipment specification. 4.7.3 Amended for grammatical purposes. 4.7.4 Amended for clarity and to grammatical purposes. 4.7.8 Deleted sentence as it is no longer relevant.
4.8 Mobile Radiographic Systems	Revision/Deletion	Amended to provide clarity regarding applicability of part. 4.8.4 Amended for grammatical purposes.

		4.8.6 Amended for grammatical purposes. 4.8.8 Amended to clarify intent of requirement. 4.8.10 Requirement deleted from this Part. Requirement is specified in Part III. 4.8.11 Renumbered to 4.8.10. 4.8.12 Renumbered to 4.8.11.
4.9 Fluoroscopic X-ray Systems	Revision/Addition/Deletion	Amended to provide clarity regarding applicability of part. Added "transportable" and "direct digital receptor" to clarify inclusion for this requirement. Added "RHB" to applicable regulation numbers throughout this Part. 4.9.1 Added "transportable" to clarify inclusion to this requirement. 4.9.4 Amended for grammatical purposes and to delete the current requirement of 4.9.4.3.7 as the requirement is covered in another part of this regulation. 4.9.10 Amended to clarify intent of requirement.
4.10 Bone Densitometry Systems	Revision/Addition	Amended to provide clarity regarding applicability of part Added "RHB" in front of regulation number in 4.10.2.2
4.11 Computed Tomography (CT) X-ray Systems	Revision/Addition/Deletion	Amended to provide clarity regarding applicability of part. 4.11.1 Amended to provide clarity regarding Computed Tomography systems, and to clarify references to subsections. 4.11.2 Amended for grammatical purposes. 4.11.3 Amended to clarify regarding routine equipment quality control and equipment performance testing. 4.11.5 Amended to provide clarity regarding cone beam

		computed tomography systems.
4.12 Veterinary Systems	Revision/Technical Correction	Amended to provide clarity regarding applicability of part. 4.12.1 Amended to provide clarity on qualified users and remove reference. 4.12.7 Amended for grammatical purposes. 4.12.9 – 4.12.19 Amended for grammatical purposes. 4.12.21 Amended to clarify regarding applicable provisions. 4.12.22 Amended to clarify regarding training for operators.
4.13 Medical Specimen Systems	Revision/Technical Correction	Amended to provide clarity regarding applicability of part.
Part IV – Appendix A	Revision/Technical Correction	Amended throughout to correct grammatical use of "x-ray", and to update terminology
Part IV – Appendix B	Revision/Addition	1. Amended to provide clarity regarding the operator's location and occupancy of adjacent areas. 4. Amended to require the date of the plan and the signature.
Part IV – Appendix C	Revision/Technical Correction	Amended throughout to clarify the operator's location. 1. Amended to correct grammar. 3. Amended to provide clarity regarding the placement of x-ray controls for various x-ray systems. 4. Amended to provide clarity regarding the design of the viewing system, and for grammatical purposes.
Part IV – Appendix D	Revision/Technical Correction	Amended to provide clarity regarding dose limits to patients, and for grammatical purposes.

Part IV – Appendix E	Revision/Technical Correction	Amended to provide clarity regarding the exemption qualification, and for grammatical purposes.
Part IV – Appendix F	Revision/Deletion/Technical Correction	Amended to provide clarity regarding optional equipment testing, techniques to be used for dose testing, and CT equipment testing requirements. Removed requirement to document adherence to shielding plan. Amended to update references.
Part V Quality Standards and Certification Requirements for Facilities Performing Mammography	Technical Correction	Amended to updated references throughout this Part.
5.1 Scope	Deletion/Technical Correction	5.1.1 Amended to delete requirements for submitting changes to the Department regarding Appendix A approval. 5.1.2 Amended to correct grammar for consistency.
5.3 Revocation of Accreditation	Reorganization	Recodified and reorganized from prior 5.23 for better subject matter flow. Following sections are renumbered.
5.4 Certificates	Technical Correction	Amended to change “must” to “shall” for consistency.
5.5 Suspension or Revocation of Certificates	Reorganization	Recodified and reorganized from prior 5.24. Amended and updated to comply with state statute regarding the appeals process.
5.7 Adverse accreditation or reaccreditation decisions	Revision/Deletion	Amended section title. Since this Agency does not play a role in accreditation/reaccreditation decisions, this section was amended to direct appeals of adverse accreditation/reaccreditation decisions to the Food and Drug Administration (FDA).

5.9 Personnel Requirements	Addition	5.9.2 Amended subsection title to be consistent with other personnel subsections.
5.12 Quality Assurance Requirements	Reorganization/Deletion	5.12.2 Amended and reorganized for clarity. Prior 5.10.2.3 deleted to remain in compliance with FDA mammography inspection policies.
5.13 Equipment Quality Assurance Tests	Technical Correction/Addition	5.13.5 Amended heading of table to correct spelling. Amended to change "half-value layer" to HVL for consistency. Amended to include requirement for average glandular dose.
5.14 Surveys	Deletion	Prior 5.12.5 deleted to comply with FDA mammography inspection policies.
Prior 5.23 Revocation of Accreditation	Reorganization	Recodified and reorganized to 5.3 for better subject matter flow.
Prior 5.24 Suspension or Revocation of Certificates	Reorganization	Recodified and reorganized to 5.5 for better subject matter flow.
5.25 Mammography Units Used for Localization or Stereotactic Breast Biopsy Procedures	Revision/Deletion	5.25.3 Amended to change "Accreditation Program Overview" to "QC Manual". Amended to delete requirement for the medical physicist survey report and corrective action to be sent to the Department within 10 days. Amended to add requirement for the medical physicist survey and corrective action to be maintained for Departmental review.
5.28 Notification Requirements for Mobile Mammography Facilities Certified by Another Certifying Agency	Addition	5.28.1 Amended to include the requirement for the submission of the operating schedule. 5.28.3 Amended to include reference to the existing requirements for Out-of-State application fees and Out-of-State facility requirements.

6.1 Scope	Revision	Amended for clarity and to be consistent with CRCPD Suggested State Regulations.
6.3 General Provisions for All Therapeutic Equipment	Revision/Addition/Deletion	6.3.1 Amended for clarity 6.3.2 Amended to delete unnecessary reference to Nuclear Regulatory Commission. 6.3.3 Amended to clarify requirements and be consistent with CRCPD Suggested State Regulations. Also amended to specify required level of supervision. 6.3.5 Added 6.3.5.5 for consistency with CRCPD SSRs.
6.4 Therapeutic X-ray Systems of Less than 1 MeV	Revision/Addition/Deletion	Amended to correct chart format and to delete references to the wording "effective date of these regulations" and add the specific date of requirement.
6.5 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above	Revision	Amended to correct use of incorrect word "normal" with correct word "nominal."
6.6 Operational Requirements for X-ray and Electron Therapy Systems with Energies of 1 MeV and Above	Amended	Amended to allow operational flexibility and to add "RHB" to applicable regulation numbers throughout this Part.
7.1 Scope	Technical Correction	Amended for grammatical purposes.
7.4 General Requirements for all Analytical X-ray Equipment	Revision/Technical Correction	7.4.4 Amended for grammatical purposes. 7.4.5 Amended to provide clarity on safety device documentation. 7.4.7 – 7.4.9 Amended for grammatical purposes.
7.5 Additional Requirements for Open Beam Configuration X-ray Equipment	Revision/Technical Correction	7.5.8 Amended to provide clarity regarding type of equipment for which training requirements pertain and for grammatical purposes.

7.6 Additional Requirements for Enclosed Beam X-ray Equipment	Revision	Amended to provide clarity regarding applicability of part.
7.7 Area Requirements for All Analytical X-ray Equipment	Revision/Technical Correction	7.7.2 Amended to provide clarity regarding dose limits and for grammatical purposes. 7.7.3 Amended to provide clarity regarding radiation area surveys and use of area monitors. 7.7.4 Amended and partially moved to 7.7.5. 7.7.5 Moved from 7.7.4 and amended to provide clarity regarding maintenance of records.
7.9 Minimum Personnel Radiation Safety Training Requirements for Radiation Safety Officers and Operators	Revision/Technical Correction	Amended to provide clarity regarding training for personnel. 7.9.1 Amended to clarify reference to part, and for grammatical purposes.
7.10 Operating Procedures	Revision/Technical Correction	7.10.1 Amended to provide clarity regarding contents of operating procedures and for grammatical purposes.
8.1 Scope	Technical Correction	Amended for grammatical purposes.
8.2 Locking of X-ray Machines	Revision	Amended to provide clarity regarding surveillance by adequately trained individual.
8.5 Warning Devices	Addition	Added to require the presence of warning devices and labels on equipment.
8.7 Posting Requirements	Deletion	Partially deleted to remove redundancy.
8.8 Minimum Personnel Radiation Safety Requirements for Radiation Safety Officers, Radiographers, and Operators	Revision/Technical Correction	Amended to provide clarity regarding personnel training requirements, and for grammatical purposes.
8.9 Operating and Emergency Procedures	Technical Correction	Amended for grammatical purposes.
8.11 Personnel Monitoring	Revision	Amended to provide clarity regarding use of personnel monitoring devices.

8.12 Minimum Subjects to be Covered in Training Radiation Safety Officers and Radiographers	Revision/Technical Correction	Amended to provide clarity regarding personnel training requirements, and for grammatical purposes.
8.13 Special Requirements for Certain Industrial Radiographic Techniques	Revision/Deletion/Technical Correction	Amended for grammatical purposes, to update references to subsections, to provide clarity regarding instrument calibration frequency, shielded room radiography, and field radiography, and to remove exemptions for certain industrial radiographic techniques.
Part IX	Addition/Reorganization	Former Part IX was recodified to Part X. Proposed Part IX added requirements for Personnel Security Screening Systems Using X-Ray.
Part X	Addition/Deletion/Revision/Reorganization	Former Part X was recodified to Part XI. Deleted definitions no longer relevant or referenced in regulation. Added and amended definitions for clarity and to reflect CRCPD Suggested State Regulations.
Part XI	Deletion/Reorganization	Former Part XI was deleted in its entirety. Former Part X was recodified to Part XI.
11.1 Scope	Revision	Amended to be consistent with other scopes listed in these regulations.
11.2 Posting of Notices to Workers	Revision/Reorganization/Technical Correction	11.2.1 – 11.2.3 Amended to provide clarity regarding postings. 11.2.4 – 11.2.5 Amended for grammatical purposes, and to update reference.
11.3 Instructions to Workers	Revision/Technical Correction	Amended to provide clarity regarding requesting exposure records. Amended for grammatical purposes, and to update reference.

11.4 Notification and Reports to Individuals	Revision/Technical Correction	11.4.1 Amended to provide clarity regarding notification responsibilities of the registrant, and appropriate identifying information. 11.4.2 Amended to update reference. 11.4.3 Amended for grammatical purposes. 11.4.4 Amended to update references, and to provide clarity regarding timely notification.
11.5 Prescence of Registrants and Workers During Inspections	Revision/Technical Correction	11.5.2 Amended to provide clarity regarding consulting with workers, and to update reference. 11.5.4 Amended to provide clarity regarding workers' representatives, for grammatical purposes, and to update reference.
11.6 Consultation with Workers During Inspection	Revision/Technical Correction	11.6.1 – 11.6.2 Amended to provide clarity regarding consulting with workers, for grammatical purposes, and to update reference. 11.6.3 Amended to update references.
11.7 Request by Workers for Inspections	Revision/Technical Correction	11.7.1 Amended to provide clarity regarding the form to be used, and to update reference. 11.7.2 Amended to provide clarity regarding inspections., and to update reference. 11.7.3 Amended for grammatical purposes.
11.8 Inspections not Warranted	Revision/Reorganization	Amended title to provide clarity regarding revised content. Recodified RHB 10.8.1 to RHB 11.8, and amended to provide clarity regarding inspection with respect to a complaint.
11.9 Right to Inspect and Investigate	Technical Correction	Amended for grammatical purposes.

Notice of Public Hearing and Opportunity for Public Comment:

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 the comment(s) by 5:00 p.m. on September 26, 2022, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 8, 2022, 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. 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. Public hearing procedures are subject to change in response to COVID-19 protocols. If applicable, the Department will provide notice of these changes twenty-four (24) hours in advance of the public hearing.

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/.

Preliminary Fiscal Impact Statement

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

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: 61-64, X-rays (Title B)

Purpose: The Department proposes comprehensive amendment to R.61-64, X-Rays (Title B). General areas of this revision include, but are not limited to, clarifying, and simplifying the regulation, adding new definitions as required, deleting requirements that are no longer applicable, and to ensure the regulation is in alignment with the current statute. The Department proposes to amend requirements regarding registration, inspections, violations, enforcement, equipment, patient shielding, and mammography. The proposed amendments will also update vendor classes, allow for the use of and add requirements for personnel security screening systems using x-ray, and clarify, organize, and update the radiation safety officer requirements. The proposed revisions also include changes such as corrections for readability, grammar, punctuation, codification, and other such regulatory text improvements.

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. The proposed revisions related to the new NCRP recommendations are a substantial change to the long-standing, traditional practice of gonadal shielding, therefore, the Department will provide the regulated community

and the public with weblinks to information resources including implementation guidance and frequently asked questions. 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 necessary to update provisions with current practices and standards and to improve the overall effectiveness of the regulation.

The proposed revisions allow and set forth requirements for the use of x-rays on humans for the purposes of security screening. This is a result of the increasing interest in the use of security screening using x-rays in prisons, correctional facilities, detention centers, and jails to improve safety. Such use is currently prohibited by regulation and is being approved through the exemption process. It is reasonable to apply radiation to humans for purposes other than healing arts and research if there is determined to be a greater benefit to the public. The proposed requirements for such use are derived from the American National Standards Institute (ANSI) publication ANSI/HPS N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation." Proposed requirements for establishing a radiation safety program, appointing a Radiation Safety Officer (RSO), and providing RSO and operator training will help to assure safe operation. Radiation dose limits for screened individuals are substantially lower than the established standards for members of the public.

The proposed regulation will no longer implicitly or explicitly require the use of patient gonadal shielding (GS) during x-ray examinations based on the National Council on Radiation Protection and Measurement's (NCRP) January 12, 2021, Statement No. 13 - NCRP Recommendations for Ending Routine Gonadal Shielding During Abdominal and Pelvic Radiography concluding "that in most circumstances GS use does not contribute significantly to reducing risks from exposure and may have the unintended consequences of increased exposure and loss of valuable diagnostic information." The NCRP is a trusted source among radiation protection professionals.

The proposed revision will also require the use of thyroid shielding for patients when it will not interfere with the diagnostic image based on the 2019 NCRP Report No. 177 - Radiation Protection in Dentistry and Oral & Maxillofacial Imaging.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these proposed amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any requirements of these amendments.

The installation and use of personnel security screening equipment will no longer require an application requesting exemption saving significant time and effort for registrants. Equipment registration fees for personnel security screening equipment will be added to the list of annual registration fees equal to the amount that is currently being assessed under the fee category of "Other."

Equipment registration fees for x-ray gauge equipment will be added to the list of annual registration fees equal to the amount that is currently being assessed under the fee category of "Diffraction."

Some members of the regulated community may incur minimal costs. Registrants who perform dental x-rays and do not possess thyroid shields for patients may need to obtain one or more shields depending on patient load and patient flow. A thyroid shield can be purchased for approximately $35.00, based on unit

pricing. Patients will be better protected from the harmful effects of radiation and will benefit from updated requirements based on current science.

UNCERTAINTIES OF ESTIMATES:

The cost of obtaining thyroid shields will vary among registrants. The cost savings related to ending routine gonadal shielding for patients will vary among registrants.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments to R.61-64 seek to support the Department's goals of protecting workers and the public from the harmful effects of ionizing radiation from x-rays while continuing to allow for their beneficial use. Proposed revisions related to routine gonadal shielding may result in an increase in the disposition of protective aprons by many registrants. The Department encourages the proper disposal or recycling of protective aprons constructed with lead to reduce any potential negative impact on the environment. The use of thyroid shields during certain x-ray examinations will limit unnecessary radiation exposure to the radiosensitive thyroid gland.

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

There is no anticipated detrimental effect on the environment. If the proposed amendments are not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(h):

A thorough review of regulatory requirements and language, recent statements and publications by the National Council on Radiation Protection and Measurements, increasing interest in the use of security screening using x-rays, and comments from the regulated community led staff to propose revisions to R.61-64.

The following statements and reports were relied upon in developing the proposed amendments:

National Council on Radiation Protection and Measurement (NCRP) "Statement No. 13 - NCRP Recommendations for Ending Routine Gonadal Shielding During Abdominal and Pelvic Radiography" dated January 12, 2021;

National Council on Radiation Protection and Measurement (NCRP) "Report No. 177 - Radiation Protection in Dentistry and Oral & Maxillofacial Imaging" dated 2019;

American Dental Association's Council on Scientific Affairs and the U.S. Food and Drug Association co-publication "Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation Exposure" dated 2012;

American National Standards Institute (ANSI) publication "ANSI/HPS N43.17-2009, Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation" dated 2009; and

Conference of Radiation Control Program Directors, Inc. Suggested State Regulations dates vary based on last amendment.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-64. X-Rays (Title B).

Statutory Authority: S.C. Code Sections 13-7-40 et seq.

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PART I
GENERAL PROVISIONS

RHB 1.1. Scope.

Except as otherwise specifically provided, ~~these~~this regulation~~s~~ appl~~y~~ies to all persons who receive, possess, use, transfer, own, or acquire any x-ray producing machine. The provisions of ~~these~~this regulation~~s~~ shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis, analysis, or therapy by persons licensed to practice one (1) or more of the health professions within the authority granted to them by statute or regulation.

RHB 1.2. Prohibited Use.

1.2.1 It shall be unlawful to operate or maintain fluoroscopic devices for fitting or selling footwear.

1.2.2 It shall be unlawful to intentionally apply radiation to human beings except by, or under the direct supervision of, persons licensed to practice the health professions and authorized to use such radiation except as provided in Part IX.

1.2.3 It shall be unlawful to use, receive, own, or possess x-ray equipment unless the facility is registered with the Department and is operated in compliance with all applicable provisions.

1.2.4 It shall be unlawful to use hand-held non-image intensified fluoroscopic screens.

1.2.5 It shall be unlawful to use plastic pointed position indicating devices on intraoral dental systems.

1.2.6 The use of any source of radiation may be prohibited when it is determined by the Department to be detrimental to public health and safety.

1.2.7 It shall be unlawful to use hand-held radiographic or fluoroscopic imaging devices, or hand-held therapy units, except for hand-held intraoral equipment operated according to Part IV and contact therapy ~~units~~equipment operated according to Part VI of ~~these~~this regulation~~s~~.

1.2.8 It shall be unlawful to use fluoroscopy for positioning a patient for radiographic imaging, except when done by a licensed practitioner ~~of the healing arts~~, or except for radiation therapy simulators.

1.2.9 It shall be unlawful for a person other than a licensed practitioner ~~of the healing arts as defined by the South Carolina Department of Labor, Licensing, and Regulation~~ to use fluoroscopy when the licensed practitioner ~~of the healing arts~~ is not physically present in the room, except during therapy simulations, maintenance activities, and training courses.

1.2.10 It shall be unlawful to use direct exposure x-ray film (without intensifying screens) for all radiological imaging other than intraoral dental radiography, therapeutic portal imaging, and industrial radiography.

1.2.11 It shall be unlawful to use a mammographic imaging system not specifically designed by the manufacturer for imaging of the breast.

1.2.12 It shall be unlawful to intentionally expose a human to electronically produced ionizing radiation except for healing arts purposes, personnel security screening performed in accordance with Part IX, or as part of a research protocol authorized by an institutional review board conforming to 45 CFR 46, 21 CFR 50, and 21 CFR 56.

1.2.13 No person shall make, sell, lease, transfer, lend, repair, or install x-ray equipment or the supplies used in connection with such equipment unless such supplies or equipment, when properly placed in operation and properly used will meet the requirements of ~~these~~this regulation~~s~~. This includes, but is not limited to, such items as cones, filters, adequate timers, and fluoroscopic shutters (where applicable). Also, such persons shall be registered with the Department in accordance with RHB ~~2.6~~2.7.

RHB 1.3. Inspections.

1.3.1 Each registrant shall afford, at all reasonable times, the Department or its duly authorized representative the opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

1.3.2 Each registrant shall make available to the Department or its authorized representative for inspection, upon ~~reasonable notice~~request, records maintained pursuant to ~~these~~this regulation~~s~~.

1.3.3 The Department shall have the right to enter at all reasonable times upon any private or public property, except property under the jurisdiction of the federal government, for the purpose of determining whether there is compliance with the provisions of the Atomic Energy and Radiation Control Act (Act) and regulations issued by the Department pursuant thereto.

1.3.4 The Department is authorized by law to enter and inspect property in order to determine compliance with Department regulations. Such entry and inspection falls under the health oversight activities exception of the Health Information Portability and Accountability Act (HIPAA). Therefore, when protected health information is necessary for determining compliance with Department regulations, protected health information may be used and disclosed to the Department without the subject's authorization.

RHB 1.4. Test and Surveys.

1.4.1 Each registrant shall make or cause to be made such surveys as are necessary ~~for him~~ to comply with ~~these~~this regulation~~s~~.

1.4.2 Each registrant shall perform, upon instructions from the Department, or shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

1.4.2.1 Sources of radiation;

1.4.2.2 Facilities wherein sources of radiation are used or stored;

1.4.2.3 Radiation detection and monitoring instruments; and

1.4.2.4 Other equipment and devices used in connection with utilization or storage of sources of radiation.

1.4.3 Results of such tests and surveys shall be submitted to the Department upon request.

1.4.4 Radiation Survey Instruments

1.4.4.1 The radiation survey instrument used shall have a minimum operation range consistent with the radiation field being measured.

1.4.4.2 Each radiation survey instrument shall be maintained annually.

1.4.4.2.1 Each radiation survey instrument used for equipment performance testing and radiation area surveys shall be calibrated at intervals not to exceed twenty-four (24) months and after ~~each instrument~~any servicing that may have affected its accuracy.

1.4.4.2.2 Each radiation survey instrument shall be calibrated such that the accuracy is within ~~20~~twenty percent (20%) or within the manufacturer specifications, whichever is less, and traceable to a national standard that can be demonstrated.

1.4.4.2.3 Each radiation survey instrument shall be calibrated at two (2) or more widely separated points, other than zero (0), on each scale.

1.4.4.2.4 Records of these instrument calibrations shall be maintained for inspection by this Department.

1.4.4.3 The manufacturer's instructions of the survey instrument shall be made available to the instrument users. This shall include any restrictions of the operating techniques required for the proper operation of the instrument.

1.4.4.3.1 The registrant shall adhere to the manufacturer's instructions in all respects.

1.4.4.3.2 The user shall be able to demonstrate familiarity and competence with these instructions.

1.4.4.3.3 The operator shall check each survey instrument with a dedicated check source each day of use to ensure the instrument is operating properly.

1.4.4.4 Calibration radiation measurements required by Part VI shall be performed using a dosimetry system:

1.4.4.4.1 Having a calibration factor traceable to a national standard;

1.4.4.4.2 Calibrated within the preceding twenty-four (24) months and after any servicing that may have affected its calibration; and

1.4.4.4.3 Calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system~~; and~~.

RHB 1.5. Exemptions.

1.5.1 The Department may, upon application by any user, or upon its own initiative grant such exemptions from the requirements of ~~these~~this regulation~~s~~ as it determines are authorized by law, and will not result in undue hazard to health, life, or property. Applications for exemptions shall specify why such exemption is necessary.

1.5.2 Before granting an exemption, the Department shall determine that there is reasonable and adequate assurance that:

1.5.2.1 The occupational dose to any individual adult will not exceed those specified in RHB 3.4.

1.5.2.2 The dose to an individual member of the public will not exceed those specified in RHB 3.9.

1.5.2.3 There is no significant hazard to life or property.

RHB 1.6. Additional Requirements.

1.6.1 The Department may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in ~~these~~this regulation~~s~~ as it deems appropriate or necessary to minimize danger to public health and safety or property.

1.6.2 The Department is authorized to inspect and investigate the premises~~, and~~ operations, and personnel of any radiation installation, whether or not such installation is required to be registered by the Department, for the purpose of studying and evaluating the health hazard(s) caused by the use and operation of such machines and material.

1.6.3 Equipment Not Covered In Regulations. ~~Prior to the sale and operation of x-ray producing equipment not specifically covered in these regulations, the seller shall submit for review and approval to the Department a listing of manufacturer's specifications for the equipment, an analysis of exposure rates for the equipment, independent peer reviewed radiation safety studies of the equipment, training materials in the use of the equipment, and verification of compliance with the United States Food and Drug Administration. In addition, the seller shall provide the written operating procedures and user's manual of the equipment. Guidance documents regarding new modalities may be found on the Department's website.~~X-ray producing equipment not specifically covered in this regulation shall not be sold or operated until the Department approves the equipment.

1.6.3.1 Prior to the sale and operation of x-ray producing equipment not specifically covered in this regulation, the seller shall submit for review and approval to the Department:

1.6.3.1.1 A listing of manufacturer's specifications for the equipment;

1.6.3.1.2 An analysis of exposure rates for the equipment;

1.6.3.1.3 Independent radiation safety studies of the equipment;

1.6.3.1.4 Training materials in the use of the equipment;

1.6.3.1.5 Verification of compliance with the U.S. Food and Drug Administration, if applicable;

1.6.3.1.6 Written procedures for use of the equipment;

1.6.3.1.7 User's manual of the equipment; and

1.6.3.1.8 A completed application using the current version of the forms provided by the Department.

1.6.3.2 Facilities who install, purchase, and/or utilize equipment that was approved according to RHB 1.6.3 shall adhere to the guidelines of use document issued by the Department at the time of the unit's approval.

~~1.6.4 Radiation Safety Officer. The registrant shall designate an individual who will be responsible for radiation protection at the facility. Such individual shall:~~

~~1.6.4.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the equipment for which he is responsible;~~

~~1.6.4.2 Develop and implement a program of radiation safety for effective compliance with the applicable requirements of these regulations;~~

~~1.6.4.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the equipment;~~

~~1.6.4.4 Ensure that surveys are made, procedures are carried out, and radiation safety instructions are given as required by these regulations.~~

RHB 1.7. ~~Violations~~Corrective Action.

~~1.7.1 The Department may obtain an injunction or other court order prohibiting any violation or any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine or imprisonment or both, as provided by the Act.~~

~~1.7.2~~1.7.1 Any person found in violation of any regulation shall notify the Department, in writing, with respect to action that has been taken or planned to correct the violation.

~~1.7.2.1~~1.7.1.1 Mammography Violation Response

~~1.7.2.1.1~~1.7.1.1.1 If the MQSA (Mammography Quality Standards Act) report results in a Level 1, repeat Level 1, or repeat Level 2 finding, a written Corrective Action Plan shall be provided to the Department within fifteen (15) calendar days of the date of citation.

~~1.7.2.1.2~~1.7.1.1.2 If the MQSA report results in a Level 2 or repeat Level 3 finding, a written Corrective Action Plan shall be provided to the Department within thirty (30) calendar days of the date of citation.

~~1.7.2.2~~1.7.1.2 All Other Violation Response

~~1.7.2.2.1 A written Corrective Action Plan shall be provided in writing within twenty (20) calendar days from the date of citation with respect to action that is planned to correct the violation.~~

~~1.7.2.2.2~~1.7.1.2.1 All violations shall be adequately corrected within sixty (60) calendar days from the date of citation. The Department shall be notified in writing of all action taken to correct the violations.

1.7.1.2.2 As the Department deems necessary, the registrant shall also submit to the Department in writing within sixty (60) calendar days from the date of citation an acceptable comprehensive plan of action detailing processes implemented to prevent recurrence of the violation.

1.7.1.2.3 The Department determines the adequacy of each violation response.

~~1.7.3~~1.7.2 The Department is authorized to hold public hearings, compel attendance of witnesses, make findings of fact and determinations, and to assess fines and civil penalties relating to violations of the provisions of the Act or any regulation, temporary or permanent order, or final determination of the Department.

~~1.7.4 The Department may impose a civil penalty not to exceed Twenty-five Thousand Dollars ($25,000) on a person who violates a provision of the Act, rules, regulations, or orders issued. Each day of continued violation shall constitute a separate offense in computing the civil penalty. Civil penalties shall be assessed as specified in RHB 1.13.~~

RHB 1.8. Enforcement.

~~1.8.1 Upon determination by the Department that the Act or these regulations have been violated or that a public health risk exists, the Department will:~~

~~1.8.1.1 Provide written notification to the non-compliant facility as soon as possible after violations are noted which:~~

~~1.8.1.1.1 Cites each section of the Act or regulations violated.~~

~~1.8.1.1.2 Specifies the manner in which the registrant failed to comply.~~

~~1.8.1.1.3 Requires submission of a timely and comprehensive corrective action plan, including a time schedule for completion of the plan.~~

~~1.8.1.1.4 Establishes a firm time schedule within which a corrective action plan must be submitted. The Department will approve the plan and proposed time schedule for its completion if the plan is adequate.~~

~~1.8.1.2 In cases where the registrant fails to comply with the conditions of the written notification, the Department will seek further enforcement action, appropriate penalties and direct remedial relief.~~

~~1.8.1.3 If the registrant fails to comply with the requirements of the Regulations within ten days, or in cases where there is an imminent hazard to human health and safety, the Department will take one or a combination of the following steps:~~

~~1.8.1.3.1 Issue an administrative order which:~~

~~1.8.1.3.1.1 Imposes an appropriate civil penalty; or~~

~~1.8.1.3.1.2 Requires corrective action; or~~

~~1.8.1.3.1.3 Impounds or orders the impounding of sources of radiation in accordance with the Act;~~

~~1.8.1.3.1.4 Revokes the facility's registration in accordance with Part II; or~~

~~1.8.1.3.2 Requests the Department attorney or the attorney general to seek court action to enjoin violations and seek conviction for a simple misdemeanor; or~~

~~1.8.1.3.3 Take enforcement action that the Department feels appropriate and necessary and is authorized by law.~~

~~1.8.2 Under an actual or potential condition posing a risk to any individual comparable to a Major severity level violation, the Department may immediately impound or order the impounding of sources of radiation in accordance with the Act.~~

1.8.1 In assessing a fine or penalty, or suspending or revoking a registration or certification, the Department may consider, but is not limited to considering, the following factors:

1.8.1.1 The degree of harm to the public health or safety which has resulted or might result from such violations;

1.8.1.2 The degree of exceedance of a radiation level as set forth in applicable law and regulation;

1.8.1.3 The duration of the violation; and

1.8.1.4 Any prior violations of statutes, rules, orders, regulations, or registration conditions.

1.8.2 The Department may obtain an injunction or other court order prohibiting any violation or any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine or imprisonment or both, as provided by the Act.

RHB 1.9. Impounding.

~~1.9.1~~ The Department may immediately impound or order the impounding of sources of radiation in the possession of any person who fails to comply with ~~these~~this regulation~~s~~ or provisions of the Act, or when the Department deems a situation to constitute an emergency.

RHB 1.10. Records.

1.10.1 Each registrant shall keep records showing the receipt, transfer, use, storage, and disposal of all sources of radiation and major components, including, but not limited to, controls, tubes, tables, cassette holders, and transformers. ~~These records~~The registrant shall ~~be~~ maintain~~ed by the registrant~~these records until disposal is authorized by the Department. Such authorization shall be made in writing. All records shall be readily available at the facility for Departmental review. Additional record requirements are specified elsewhere in ~~these~~this regulation~~s~~.

1.10.2 The registrant shall maintain the following information for each x-ray system for inspection by the Department:

1.10.2.1 Model and serial numbers of all tubes, controls, and beam limiting devices;

1.10.2.2 Tube rating charts and cooling curves, for units certified by the U.S. Food and Drug Administration, and for units regulated under Part IV and Part V;

1.10.2.3 Aluminum equivalent filtration of the useful beam, including any routine variation for units regulated under Part IV and Part V;

1.10.2.4 Records of surveys, tests, equipment performance tests, maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. Records shall be maintained for five (5) years; until the next Department inspection; or until the registrant no longer possesses the equipment~~.~~; and

1.10.2.5 A copy of all correspondence with the Department regarding that x-ray system.

1.10.3 Each registrant ~~possessing more than 10 radiation machine controls~~ shall maintain a current inventory listing that indicates the model number, serial number, shielding acceptance number (if applicable), date of last equipment performance test, location and status of each control, and identification of each control or generator installed since the last Departmental inspection including the date of installation. The inventory listing shall be made available to the Department upon request.

1.10.4 All records required by ~~these~~this regulation~~s~~ shall be accurate and true.

1.10.5 Each record required by this Part shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

RHB 1.11. Records and Reports of Misadministration.

1.11.1 Therapy Misadministrations.

When a misadministration involves any therapy procedure, the registrant shall notify the Department, by ~~telephone, fax, or electronic mail~~a means as determined by the Department, no later than twenty-four (24) hours after discovery of the misadministration. The registrant shall also notify the referring physician and the patient of the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant that he or she will inform the patient or that, based on

medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within twenty-four (24) hours, the registrant shall notify the patient as soon as possible thereafter. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

1.11.1.1 The registrant shall submit a written report to the Department within fifteen (15) calendar days after the discovery of the misadministration. The report ~~must~~shall not include the patient's name or other information that could lead to identification of the patient. The written report ~~must~~shall include the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; the action taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian; and if not, why the individual involved was not informed; and if the patient was notified, what information was provided to the patient.

1.11.1.2 The registrant shall furnish the following to the patient within fifteen (15) calendar days after discovery of the misadministration if the patient was notified:

1.11.1.2.1 A copy of the report that was submitted to the Department; or

1.11.1.2.2 A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the registrant.

1.11.1.3 Each registrant shall retain a record of each therapy misadministration for ten (10) years. The record shall contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

1.11.2 Diagnostic Misadministrations. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for ~~the~~ Departmental review, and maintain the record ~~as directed in RHB 1.11.3~~for three (3) years. The record shall contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, and the patient's referring physician), a brief description of the misadministration, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

~~1.11.3 Each registrant shall retain a record of each therapy misadministration for ten (10) years and three (3) years for each diagnostic misadministration. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.~~

~~1.11.4~~1.11.3 Aside from the notification requirement, nothing in RHB 1.11.1 through 1.11.~~3~~2 shall affect any rights or duties of registrants and physicians in relation to each other, registrants, patients, or responsible relatives or guardians.

RHB 1.12. ~~Communications~~Material False Statements.

~~1.12.1 All communications and reports concerning these regulations, and registrations filed thereunder, shall be addressed to the Department at:~~

~~SC Department of Health and Environmental Control~~
~~Bureau of Radiological Health~~
~~2600 Bull Street~~
~~Columbia, South Carolina 29201~~

~~1.12.2 Material False Statements.~~ It shall be unlawful to make a material false statement to the Department regarding information contained in the application for registration, information pertaining to an inspection, or any other information required by any provision of ~~these~~this regulation~~s~~.

RHB 1.13. ~~Administration of Civil Penalties~~Fines and Penalties.

~~1.13.1 Assessment - Assessment of civil penalties shall be based on the following criteria:~~

~~1.13.1.1 the seriousness of the violation(s);~~

~~1.13.1.2 previous compliance history;~~

~~1.13.1.3 the amount necessary to deter future violations;~~

~~1.13.1.4 efforts to correct the violation; and~~

~~1.13.1.5 any other mitigating or enhancing factors.~~

~~1.13.2~~1.13.1 Severity Levels - The ~~seriousness of~~ violations of standards ~~shall be~~are categorized by ~~one of~~ the following severity levels, as determined by the Department.

~~1.13.2.1~~1.13.1.1 ~~Major- Violations that are most significant and have a direct negative impact on occupational or public health and safety, or which represent a significant deviation from the requirements of this regulation.~~ Potential for Harm. The potential for harm shall be determined as major, moderate, or minor as follows:

1.13.1.1.1 Major Potential for Harm. Violations that have significant potential for harm and have a direct negative impact on occupational or public health and safety;

1.13.1.1.2 Moderate Potential for Harm. Violations that have more than minor potential for harm, but if left uncorrected, could lead to more serious circumstances; or

1.13.1.1.3 Minor Potential for Harm. Violations that have minor potential for harm and safety.

1.13.1.2 Extent of Deviation. The extent of deviation from regulatory requirements shall be determined as major, moderate, or minor as follows:

1.13.1.2.1 Major Deviation. The violations represent substantial deviation from the requirements of this regulation resulting in substantial noncompliance;

1.13.1.2.2 Moderate Deviation. The violations represent significant deviation from the requirements of this regulation resulting in significant noncompliance; or

1.13.1.2.3 Minor Deviation. The violations represent a slight deviation from the requirements of this regulation and do not result in substantial or significant noncompliance.

~~1.13.2.2 Moderate- Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances, or which represent a moderate deviation from the requirements of this regulation.~~

~~1.13.2.3 Minor- Violations that are of minor safety significance, or which represent a minor deviation from the requirements of this regulations.~~

~~1.13.2.4 In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.~~

~~1.13.3 Application - Examples of violations in each severity level are given in RHB 1.13.4.3. While examples are given for determining the appropriate severity level for violations, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Department of Health and Environmental Control places on a particular type of violation of state requirements. Adjustments to the values listed in RHB 1.13.4.1 under each severity level may be made for the presence or absence of the following factors:~~

~~1.13.3.1 Prompt Identification and Reporting. Reduction of a civil penalty may be given when a Registrant identifies the violation and promptly reports the violation to the Department. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the Registrant does not take immediate action to correct the problem upon discovery.~~

~~1.13.3.2 Corrective Action to Prevent Recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the Registrant takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty. On the other hand, the civil penalty may be increased if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of Registrant initiative, and comprehensiveness of the corrective action - such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.~~

~~1.13.3.3 Compliance History. Reduction of the civil penalty may be given for prior good performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as previous compliance history in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.~~

~~1.13.3.4 Prior Notice of Similar Events. The civil penalty may be increased for cases where the Registrant had prior knowledge of a problem as a result of a Registrant audit, or specific industry notification, and had failed to take effective preventive steps.~~

~~1.13.3.5 Multiple Occurrences. The civil penalty may be increased where multiple examples of a particular violation are identified during the inspection period.~~

1.13.3.6 The above factors are additive. However, the civil penalty will not exceed twenty five thousand dollars ($25,000) for any one violation. Each day of noncompliance shall constitute a separate violation.

1.13.4 The Department shall issue civil penalties according to the following schedule:

1.13.4.1 Penalty Matrix

Deviation from Requirement: - Potential for Harm:	Major (11-30)	Moderate (4-10)	Minor (1-3)
Major (11-70)	$25,000-5,000	$15,000-5,000	$10,000-2,500
Moderate (6-10)	$10,000-2,500	$7,500-1,000	$5,000-500
Minor (0-5)	$5,000-1,000	$3,000-500	$2,500-250

Calculation of Base Penalty:

Each violation is assigned a relative point value as follows: Potential for Harm- 0-70, with 70 being maximum harm; Deviation from Requirement- 1-30, with 30 being the maximum deviation. Add the two values together, convert to a decimal value (15 to .15, for example), and multiply by the maximum per day per violation per civil penalty ($25,000). This is the base civil penalty per violation. The base penalty may be increased for repeat violations, multi-day penalties, or degree of recalcitrance, willfulness, negligence, or indifference.

Minimum Increase for Repeat Violations Found on Follow-up Inspections or Reinspections

Second Offense (First Follow-up Inspection or First Reinspection)	15%
Third Offense (Second Follow-up Inspection or Second Reinspection)	30%
Fourth Offense (Third Follow-up Inspection or Third Reinspection)	45%
Fifth and Subsequent Offenses	60%

Multi-Day Penalties

Increase penalty 1% to 7% for each day of noncompliance.

Degree of Recalcitrance, Willfulness, Negligence, or Indifference

Increase Penalty 10% to 50%

1.13.4.2 The Department reserves the right to impose a civil penalty up to Twenty-five Thousand Dollars on a person who violates the regulations in such a manner so as to present an imminent hazard to human health and safety. The Twenty-five Thousand ($25,000.00) Dollar civil penalty may be levied for the following:

~~1.13.4.2.1 Two or more incidents of workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.~~

~~1.13.4.2.2 Two or more incidents of members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)~~

~~1.13.4.2.3 Two or more incidents in a one year period of deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (1.2.2)~~

~~1.13.4.2.4 Two or more incidents on two consecutive inspections of failing to perform required equipment performance testing, surveys, tests, or evaluations. (1.4)~~

~~1.13.4.2.5 Four or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without the equipment meeting all applicable regulations when properly placed in operation. (2.7.2)~~

~~1.13.4.2.6 Two or more incidents in a five year period of initiating a healing arts screening program without prior approval from the Department. (4.2.11.2)~~

~~1.13.4.2.7 Two or more incidents on two consecutive inspections of failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.5.1)~~

~~1.13.4.2.8 Two or more incidents on two consecutive inspections of ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.13.2)~~

~~1.13.4.2.9 Operation of a mammography facility without possessing a current, valid certificate issued by the Department, as required by RHB 5.2.~~

~~1.13.4.2.10 Two or more incidents of a registrant failing to ensure that operators of x-ray equipment possess a valid, current certificate from the South Carolina Radiation Quality Standards Association. (4.2.2, 6.3.3.1)~~

~~1.13.4.3 Example of Violations with Potential for Harm~~

~~Major~~

~~Workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.~~

~~Members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)~~

~~Deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (4.2.11)~~

~~Two or more incidents on three consecutive inspections of failing to perform required equipment performance tests, surveys, or evaluations. (1.4)~~

~~Two or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)~~

~~Exposure to an individual for training, demonstration, or other purposes when there are not healing arts requirements or proper prescription provided. (4.2.11.1)~~

~~Two or more incidents on two consecutive inspections of a fluoroscopic system with a source to skin distance less than those specified in RHB 4.9.1.~~

~~Two or more incidents on two consecutive inspections of a fluoroscopic system with an x-ray field exceeding the length or width of the visible area of the image receptor by greater than five percent (5%), or the sum of the excess length and width of greater than six percent (6%). (4.9.2.2)~~

~~Initiating or conducting a healing arts screening program without prior approval from the Department. (4.2.11.2)~~

~~Failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.5.1)~~

~~ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.13.2)~~

~~A fluoroscopic x-ray system with a tabletop entrance exposure rate that exceeds the limits specified in 4.9.4 by more than a factor of 2.~~

~~Two or more incidents on two consecutive inspections of a fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier. (4.9.2.1)~~

~~Two or more incidents on two consecutive inspections where a required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable.~~

~~An x-ray system having a malfunction such that inadvertent exposures could occur, e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.~~

~~Two or more incidents on two consecutive inspections that have a potential for serious overexposure of patients, radiation workers, non-radiation workers, or a member of the public.~~

~~Moderate~~

~~Making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)~~

~~Routine holding of patients or films at a registrant's facility. (4.2.12.4)~~

~~Two or more incidents on two consecutive inspections of a registrant failing to ensure that an x-ray operator receives the training required by RHB 4.2.3.7 or RHB 6.3.3.9.~~

~~Two or more incidents on two consecutive inspections of lack of adequate filtration present in an x-ray machine. (4.3.5)~~

~~Two or more incidents on two consecutive inspections of failure to use exposure reduction devices properly (e.g., collimators, filtration). (4.3.5, 4.7.4.1, 4.7.14)~~

~~Two or more incidents on two consecutive inspections of having a fluoroscopic system with a tabletop entrance exposure rate that exceeds the limits specified in 4.9.4.~~

~~Two or more incidents on two consecutive inspections of ESEs that vary from the average ESE as determined by Appendix D of Part IV. (4.2.13.2)~~

~~Two or more incidents on two consecutive inspections of having a capacitor storage radiographic system such that the standby radiation exceeds the limits specified in RHB 4.3.4 by a factor of 2.~~

~~Two or more incidents on two consecutive inspections of failure to provide appropriate warning devices as required by RHB 7.4.4.~~

~~Two or more incidents on two consecutive inspections of failure to secure unused ports on radiation source housings. (7.4.5.5)~~

~~Two or more incidents on two consecutive inspections of inadequate mechanical support of tube head. (4.3.8)~~

~~Use of mechanical timer. (4.3.11)~~

~~Use of x-ray equipment before submission and approval of a shielding plan. (4.4.3)~~

~~Two or more incidents in two consecutive inspections of failing to meet the x-ray control requirements of RHB 4.5.4.~~

~~Two or more incidents on two consecutive inspections of failure to provide shutters on open-beam configuration x-ray units. (7.5.6.2)~~

~~Two or more incidents on two consecutive inspections of failure to control access to equipment, or failure to control access to restricted areas. (7.5.3)~~

~~Two or more incidents on two consecutive inspections of an intraoral dental x-ray unit capable of operation in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters or which exhibit a minimum SSD less than 18 centimeters. (4.5.1, 4.5.2)~~

~~Two or more incidents on two consecutive inspections of a mobile radiographic system for which the minimum source to skin distance is less than 30 centimeters. (4.8.12)~~

~~Minor~~

~~Two or more incidents on two consecutive inspections of having a capacitor storage radiographic system such that the standby radiation exceeds the limits specified in RHB 4.3.4.~~

~~Repeated violations (Two or more incidents on two consecutive inspections) not covered in a more severe category that have minor safety significance.~~

~~1.13.4.4 Examples of Violations Categorized by Deviation from the Requirement~~

~~Major~~

~~Failure to allow authorized Department personnel access to x-ray facilities or equipment to conduct inspections or investigations. (1.3.1)~~

~~Two or more failures on two consecutive inspections to correct violations within sixty days. (1.7.3)~~

~~Two or more incidents of a person who is not certified by the South Carolina Radiation Quality Standards Association using or exhibiting a title, sign, display or declaration that misleads the public to believe the person is authorized to apply ionizing radiation on humans for diagnostic or therapeutic purposes. (4.2.2.4, 6.3.3.6)~~

~~Continuation of registrant activities after revocation of registration.~~

~~Two or more incidents of making material false statements to the Department. (1.12.2)~~

~~Two or more failures of a person to apply for registration approval prior to beginning operation of an x-ray facility. (2.4)~~

~~Two or more failures of a registrant to register x-ray equipment. (2.1.1)~~

~~Two or more incidents of providing x-ray vendor services without being registered with the Department. (2.6.1)~~

~~Two or more failures on two consecutive inspections of a person to notify the Department in writing within thirty days when he has sold, leased, transferred, lent, assembled, or installed x-ray equipment. (2.5.3)~~

~~Two or more failures of a vendor to notify the Department of installation of equipment. (2.7.1)~~

~~Intentional exposure of a radiation monitoring device to deceptively indicate a dose. (3.12.2)~~

~~Two or more incidents on two consecutive inspections of failure to provide personnel monitoring if required. (3.12)~~

~~Two or more incidents on two consecutive inspections of failing to adhere to the facility's operating conditions.(4.2.3)~~

~~Two or more incidents on two consecutive inspections of management action to discriminate against an employee for attempting to communicate or for actually communicating with the Department. (10.7.3)~~

~~Two or more incidents of operation of an out of state x-ray machine for more than 365 days. (2.8)~~

~~Two or more incidents of a registrant failing to report or record misadministrations. (1.11)~~

~~Moderate~~

~~Two or more incidents on two consecutive inspections of failing to perform a repeat analysis. (4.2.16.4)~~

~~Two or more incidents on two consecutive inspections of failing to perform densitometric and sensitometric testing if required by RHB 4.2.17.2.7.~~

~~Two or more incidents on two consecutive inspections of failing to perform periodic measurements of entrance exposure rates on fluoroscopes. (4.9.4.3.6)~~

~~Failure of a person to register prior to providing or offering to provide x-ray services. (2.6.1)~~

~~Making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)~~

~~Failure of a registrant to display each operator's current certificate from the South Carolina Radiation Quality Standards Association, as required by RHB 4.2.2.6 or RHB 6.3.3.8.~~

~~Failure of a registrant to register x-ray equipment with the Department. (2.1.1)~~

~~Failure of a registrant to notify the Department when he has sold, leased, transferred, lent, assembled, or installed x-ray equipment. (2.5.3)~~

~~Failure to notify the Department prior to operating an out-of-state x-ray machine in South Carolina. (2.8)~~

~~Failure to make notifications as required by RHB 3.25.1.~~

~~Failure of a vendor to notify the Department of installation of equipment. (2.7.1)~~

~~Failure by a registrant to correct violations within sixty days. (1.7.3)~~

~~Failure to report misadministrations to the Department as required. (1.11)~~

~~Two or more incidents in two consecutive inspections of a registrant failing to verify that a person providing x-ray machine services or servicing is registered with the Department. (2.5.4)~~

~~Two or more incidents on two consecutive inspections of a registrant not notifying the Department within 20 days of a violation citation with regards to corrective action taken or planned to correct the violation. (1.7.2)~~

~~Minor~~

~~Failure to maintain required records including, but not limited to, patient logs, utilization logs, and technique charts.~~

~~Failure to post Department notices as required in RHB 10.2.~~

~~Failure to correctly label x-ray equipment.~~

1.13.2 The Department may impose a civil monetary penalty up to twenty-five thousand dollars ($25,000.00) per violation and revoke or suspend a registration or certification if the Department finds the registrant or certificate holder who violates a provision of the Act, rules, regulations, or orders. Each day of noncompliance with any provision of the Act, rules, regulations, or orders shall constitute a separate violation. When imposing a monetary penalty, the Department may utilize the following schedule to determine the dollar amount:

Potential for Harm	**Deviation from Requirements**		
	Major Deviation	Moderate Deviation	Minor Deviation
Major Potential for Harm	$25,000 – 5,000	$15,000 – 5,000	$10,000 – 2,500
Moderate Potential for Harm	$10,000 – 2,500	$7,500 – 1,000	$5,000 – 500

Minor Potential for Harm	$5,000 – 1,000	$3,000 – 500	$2,500 – 250

1.13.3 The Department reserves the right to impose a civil penalty of twenty-five thousand dollars ($25,000.00) on a person or facility who violates the regulation in such a manner so as to present an imminent hazard to human health and safety.

RHB 1.14. Compliance with other Laws.

The registrant shall comply with all other applicable federal, state, and local regulations.

RHB 1.15. Severability.

If any provision of this regulation or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the regulation which can be given effect without the invalid provision or application, and to this end the provisions of the regulation are severable.

RHB 1.16. Appeals.

Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

PART II
REGISTRATION OF X-RAY MACHINES AND SERVICES

RHB 2.1. Scope.

This ~~p~~Part provides for the registration of x-ray machines~~,~~ (controls and tubes)~~,~~ and facilities, and for the registration of persons providing x-ray machine installation, servicing, and/or services.

2.1.1 Except as specifically exempted in RHB 2.2, each person who receives, possesses, uses, or acquires an x-ray machine shall register the control and tubes of such machine with the Department in accordance with the requirements of this Part.

2.1.2 In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of ~~these~~this regulation~~s~~.

RHB 2.2. Exemptions.

2.2.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration requirements of this ~~p~~Part, providing dose equivalent rate averaged over an area of ~~10~~ten square centimeters (10 cm^2) does not exceed one-half millirem (0.5 mrem) per hour at five centimeters (5 cm) from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

2.2.2 Television receivers, video display terminals, and computer monitors, when used without modification to their internal or external construction, are exempt from the requirements of this Part.

2.2.3 Any facility where a federal agency has exclusive jurisdiction is exempt from the requirements of this Part.

2.2.4 X-ray machines while in transit or storage incident thereto are exempt from the requirements of this Part.

RHB 2.3. Application and Review Fees.

2.3.1 Facility Application Fee. Each registrant shall pay a non-refundable application fee of sixty-two dollars and fifty cents ($62.50) upon submission of the initial Facility Registration Approval Request form. A facility registration approval shall not be issued until payment of the application fee.

2.3.2 Shielding Plan or Area Survey (in lieu of Shielding Plan) Review Fee. Each registrant shall pay a non-refundable shielding plan review fee of sixty-two dollars and fifty cents ($62.50) per x-ray control upon submission of any shielding plan. A shielding plan acceptance shall not be issued until payment of the review fee.

2.3.3 Vendor Application Fee. Each vendor shall pay a non-refundable application fee of sixty-two dollars and fifty cents ($62.50) upon submission of the ~~initial~~ Business Registration ~~Approval Request form~~application. A notice of vendor registration ~~approval~~ shall not be issued until payment of the application fee.

2.3.4 Out-of-State Facility Application Fee. Any person proposing to bring an x-ray machine into the ~~S~~state, for any temporary use, shall pay a non-refundable application fee of sixty-two dollars and fifty cents ($62.50) upon submission of the initial Out-of-State Facility Form. An Out-of-State Facility approval shall not be issued until payment of the application fee.

RHB 2.4. Facility Registration Approval.

2.4.1 ~~Fixed Installation Fixed Facility~~In-State Facilities. Any facility planning to install an x-ray producing machine ~~in a fixed location~~ shall ~~meet the provisions of this Subpart~~apply for Facility Registration Approval (FRA) prior to installation.

2.4.1.1 ~~Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit to the Department the following information:~~Applicants for registration shall submit to the Department a completed application on a form prescribed and provided by the Department prior to installation of x-ray producing equipment. The applicant shall ensure the FRA application includes:

2.4.1.1.1 ~~Facility, Location Address, and Mailing Address;~~The full name, location address, business email address, and mailing address of the facility for which the registration is sought;

2.4.1.1.2 The name and signature of the ~~radiation safety officer~~Radiation Safety Officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.1.1.3 ~~Type and make of x-ray equipment to be installed;~~The full names of any partners or co-owners, if applicable, as well as the full name of corporate owners, if applicable;

2.4.1.1.4 ~~A~~ The name, address, registration number, and contact person of the company preparing the shielding plan, if required by RHB 4.4 or ~~8.12.2~~8.13.2;

2.4.1.1.5 The name, address, registration number, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale and/or installation, then the above information shall be provided for all companies involved~~.~~; and

2.4.1.1.6 The applicant's printed name, title, and signature, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation.

2.4.1.1.7 The application shall include any additional information the Department determines to be necessary for evaluation of the application for registration.

2.4.1.2 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3.

2.4.1.3 ~~Upon review of the above information, the Department shall issue a facility registration approval.~~ Registration approval shall not be granted until all required information has been deemed adequate by the Department.

2.4.1.4 A facility shall not install or cause to be installed any x-ray producing equipment until ~~the Department has issued a facility registration~~ approval has been granted.

2.4.2 ~~Fixed Installation-Mobile Facility~~Out-of-State Facilities. ~~Any facility planning to install an x-ray producing machine in a fixed location of a mobile facility shall meet the provisions of this Subpart.~~Any person proposing to bring x-ray producing equipment into the state, for any temporary use, shall apply for Facility Registration Approval (FRA).

2.4.2.1 ~~Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit to the Department the following information:~~ Prior to possessing or utilizing x-ray equipment in the state, the Out-of-State Facility shall submit to the Department a completed application on a form prescribed and provided by the Department prior to installation of an x-ray producing machine. The FRA application shall include, at a minimum:

2.4.2.1.1 Facility ~~N~~name and ~~M~~mailing ~~A~~address where correspondence may be sent;

2.4.2.1.2 The name and signature of the ~~radiation safety officer~~Radiation Safety Officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.2.1.3 Type and make of x-ray equipment to be ~~installed~~utilized;

2.4.2.1.4 An operating schedule, indicating when and where the equipment will be used shall be submitted to the Department five (5) calendar days prior to equipment use in the state as required by RHB 2.9;

2.4.2.1.5 A radiation area survey as required by RHB 4.4 or ~~8.12.2~~8.13.2;

2.4.2.1.6 The name, address, registration number, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale or installation, then the above information shall be provided for all companies involved~~.~~; and

2.4.2.1.7 The applicant's printed name, title, and signature, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation.

2.4.2.1.8 The application shall include any additional information the Department determines to be necessary for evaluation of the application for registration.

2.4.2.2 Prior to ~~installation of any x-ray producing equipment~~entering the state, the Out-of-State ~~f~~Facility ~~where~~that will utilize the equipment ~~will be installed~~ shall submit any application and shielding review fees as required by RHB 2.3.

2.4.2.3 ~~Upon review of the above information, the Department shall issue a facility registration approval.~~ Approval shall not be granted until the required application has been deemed adequate.

2.4.2.4 An Out-of-State ~~f~~Facility shall not ~~install or cause to be installed any x-ray producing equipment~~possess or utilize x-ray equipment in the state until ~~the Department has issued a facility registration~~ approval has been granted.

~~2.4.3 Mobile or Portable Equipment. Any facility acquiring or using mobile or portable x-ray producing equipment shall meet the provisions of this Subpart.~~

~~2.4.3.1 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit to the Department the following information:~~

~~2.4.3.1.1 Facility Name, Location Address and Mailing Address;~~

~~2.4.3.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;~~

~~2.4.3.1.3 Type and make of x-ray equipment to be used;~~

~~2.4.3.1.4 The name, address, and contact person of the company selling the equipment. If more than one company is involved in the sale, then the above information shall be provided for all companies involved.~~

~~2.4.3.2 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit any application and shielding review fees as required by RHB 2.3.~~

~~2.4.3.3 Upon review of the above information, the Department shall issue a facility registration approval.~~

~~2.4.3.4 A facility shall not use any x-ray producing equipment until the Department has issued a facility registration approval.~~

~~2.4.4 Out of State Facility. Any person proposing to bring an x-ray producing machine into the State, for any temporary use, shall meet the provisions of this Subpart.~~

~~2.4.4.1 Prior to entering the state, the Out of State Facility shall submit to the Department the following information:~~

~~2.4.4.1.1 Facility Name and Mailing Address where correspondence may be sent;~~

~~2.4.4.1.2 The name of the radiation safety officer responsible for radiation protection, and the individual's qualifications to serve in such a capacity;~~

~~2.4.4.1.3 Type and make of x-ray equipment to be utilized; and~~

~~2.4.4.1.4 A radiation area survey, as required by RHB 4.4 or 8.12.2.~~

~~2.4.4.2 An operating schedule, indicating when and where the equipment will be used, shall be submitted to the Department 5 days prior to equipment use in the State.~~

~~2.4.5~~2.4.3 It shall be unlawful for any person to install x-ray producing equipment until the facility acquiring that equipment has ~~received~~been granted a ~~f~~Facility ~~r~~Registration ~~a~~Approval ~~from the Department~~.

RHB 2.5. Equipment Registration Requirements, Users of X-ray Machines.

2.5.1 Initial Equipment Registration. Every person who possesses an x-ray machine shall register the machine's control and tubes with the Department, within thirty (30) calendar days of the date of installation. Registration shall be made on the form ~~furnished~~provided by the Department.

2.5.1.1 Upon registration of a control, the Department shall issue the facility a registration sticker to be placed on each control. The registration sticker shall be placed on the control panel in a clearly visible location.

2.5.1.2 When a control is removed from a facility, the facility shall remove the registration sticker.

2.5.1.3 A registration sticker on a control, displaying the facility's proper name, shall be considered indicative of a facility's and a control's registration status, as required to be confirmed by RHB ~~2.7.2~~2.8.2.

~~2.5.2 Renewal of Equipment Registration. The Department shall provide an annual re-registration statement to all registrants. The re-registration statements shall be reviewed, corrected, signed, and returned to the Department within 30 days.~~

~~2.5.3 Report of Change. The registrant shall report to the Department, within thirty days, any changes of status affecting any x-ray machine or facility. Report of a change of status shall be made in writing , and forwarded to the Department.~~

~~2.5.4~~2.5.2 Verification of Service Representative. Each registrant shall require any person furnishing x-ray machine servicing or services as described in this Part to provide evidence that he or she has been registered with the Department as a vendor or facility in accordance with ~~these~~this regulation~~s~~.

~~2.5.5~~2.5.3 Leasing of Equipment. When a facility leases x-ray equipment, it shall be the facility's responsibility to register the equipment and to ensure that the equipment is maintained to meet ~~these~~this regulation~~s~~.

RHB 2.6. Report of Change.

The registrant shall report to the Department, within thirty (30) calendar days, any changes of status affecting any x-ray machine or facility. Report of a change of status shall be made on forms provided by and submitted to the Department. The Report of Change form shall include, at a minimum:

2.6.1 The facility name as currently registered with the Department and the registration number;

2.6.2 The printed name and signature of the Radiation Safety Officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.6.3 The registrant's printed name, title, and signature, assuring that the contents of the form are accurate and true;

2.6.4 Any additional information the Department determines to be necessary.

RHB ~~2.6~~2.7. Registration Requirements-Servicing and Services (VENDOR).

~~2.6.1~~2.7.1 Each person who is engaged in the business of selling, leasing, assembling, or installing or offering to sell, lease, assemble, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish ~~any equipment services~~x-ray equipment servicing or services in this ~~S~~state shall ~~apply for registration~~be registered as a vendor with the Department ~~within thirty days following the effective dates of these regulations or thereafter~~ prior to furnishing or offering to furnish any such services.

~~2.6.1.1~~2.7.1.1 The owner of an x-ray system and ~~I~~in-house personnel employed by a facility or corporation shall be exempt from the vendor registration requirement, provided such personnel:

~~2.6.1.1.1~~2.7.1.1.1 Shall meet the education, training, and experience requirements for the appropriate vendor Class; and

~~2.6.1.1.2~~2.7.1.1.2 Shall exclusively service one (1) facility or corporation.

~~2.6.1.2~~2.7.1.2 Documentation of education, training, and experience for in-house service personnel shall be maintained by the facility or corporation and available for Departmental review.

~~2.6.2~~2.7.2 Application for vendor registration shall be completed on the current version of the forms ~~furnished~~provided by the Department, be submitted with vendor application fees required by RHB 2.3, and ~~shall~~ contain all information required by the Department as indicated on the forms~~,~~ and accompanying instructions. This information shall include at a minimum:

~~2.6.2.1~~2.7.2.1 The name, physical address, mailing address, email address, business website, and telephone number of the individual or company to be registered~~, along with the owner(s) of the company~~;

2.7.2.2 The full printed name of the owner and any partner, co-owner, or corporate owner, if applicable;

2.7.2.3 The printed name, title, mailing address, email address, and telephone number of the contact person for the company;

~~2.6.2.2~~2.7.2.4 The description of the services and the x-ray machine types for which x-ray machine services are to be provided;

~~2.6.2.3~~2.7.2.5 The printed name, title, signature, documented training, education, and experience of each person ~~who~~to provide~~s~~ x-ray machine servicing or services;

~~2.6.2.4~~2.7.2.6 The date of the application ~~and the signature of the individual responsible for the company~~;

~~2.6.2.5~~2.7.2.7 A sample of equipment performance test procedures and forms, if registering as a Class II-C or Class IX vendor;

~~2.6.2.6~~2.7.2.8 A sample of a shielding plan, if registering as a Class III, Class IV, Class VII, Class VIII, or Class IX vendor;

~~2.6.2.7~~2.7.2.9 A sample area survey if registering as a Class III, Class IV, Class VII, Class VIII, or Class IX vendor;

2.7.2.10 The applicant's or registrant's printed name, title, and signature, assuring that the contents of the application are accurate and true, and that the applicant or registrant will comply with this regulation; and

~~2.6.2.7~~2.7.2.11 Any additional information the Department determines to be necessary for evaluation of the application for registration~~;~~.

~~2.6.3~~2.7.3 Each person applying for registration under this Part shall specify that he or she has read and understands the applicable requirements of ~~these~~this regulation~~s~~.

2.7.4 A vendor registration application will not be reviewed or otherwise processed until payment of the application fee.

2.7.5 Notice of Vendor Registration.

2.7.5.1 Upon a determination that an applicant meets the requirements of the regulation, the Department will issue a Notice of Vendor Registration.

2.7.5.2 No individual shall perform x-ray machine services except as specified on the Notice of Vendor Registration issued by the Department.

2.7.5.3 The Department may incorporate in the Notice of Vendor Registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of x-ray machines as it deems appropriate or necessary.

2.7.5.4 A vendor shall not furnish or offer to furnish x-ray machine services until the Department has issued a Notice of Vendor Registration.

~~2.6.4~~2.7.6 For the purpose of this section, ~~equipment~~x-ray machine services are:

~~2.6. 4.1~~2.7.6.1 Class I - Direct sale and transfer of radiation machines and machine components to end users;

~~2.6.4.2~~2.7.6.2 Class II – Installation, assembly, ~~or~~ servicing, or testing of radiation machines and associated radiation machine components including the making of machine diagnostic radiation output measurements to verify performance associated with the installation, assembly, or service;

~~2.6.4.2.1~~2.7.6.2.1 Class II-A – Installation and assembly of radiation machines and associated radiation machine components;

~~2.6.4.2.2~~2.7.6.2.2 Class II-B - Servicing of radiation machines and associated radiation machine components;

~~2.6.4.2.3~~2.7.6.2.3 Class II-C - Perform "Equipment Performance Tests" as outlined in RHB 4.2.16. Refer to Appendix F;

~~2.6.4.3~~2.7.6.3 Class III - ~~Diagnostic radiographic~~Non-therapeutic healing arts facility ~~and~~ shielding design and area radiation survey (e.g., shielding evaluation);

~~2.6.4.4~~2.7.6.4 Class IV - Non-~~Diagnostic fluoroscopic~~healing arts facility and shielding design and area radiation survey (e.g., shielding evaluation);

~~2.6.4.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation;~~

~~2.6.4.6~~2.7.6.5 Class VI - Radiation instrument calibration;

~~2.6.4.7~~2.7.6.6 Class VII - Therapeutic facility and shielding design, area radiation surveys, ~~or~~and calibration;

~~2.6.4.8~~2.7.6.7 Class VIII - General health physics consulting, non-healing arts~~,~~ (e.g., independent ~~diagnostic~~ radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, and acting as the ~~radiation safety officer~~Radiation Safety Officer);

~~2.6.4.9~~2.7.6.8 Class IX - General health physics consulting, healing arts~~,~~ (e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, equipment performance tests, and acting as the ~~radiation safety officer~~Radiation Safety Officer); and

~~2.6.4.10~~2.7.6.9 Such other ~~equipment~~x-ray machine services which can affect compliance with ~~these~~this ~~R~~regulation~~s~~ by a registrant, as determined by the Department.

~~2.6.5~~2.7.7 Report of Change. The vendor shall notify the Department in writing, within thirty (30) calendar days, of any changes that would render the information contained on the ~~company and/or employee~~ vendor registration forms no longer accurate. Changes shall be made on forms provided by the Department and include, but not be limited to, changes in name, ownership, equipment type services, employee's status, ~~new employees, and in vendor Class or services~~physical address, mailing address, and contact person's name, address, email address, and telephone number.

~~2.6.6~~2.7.8 Training and Educational Requirements for ~~Equipment~~X-ray Machine Services. Each person providing x-ray machine services ~~registered~~ pursuant to RHB ~~2.6~~2.7 shall be qualified by reason of education, training, and experience to provide the service for which registration is requested. The following are minimum qualifications for specific types of services:

~~2.6.6.1~~2.7.8.1 Class I - ~~Sales~~ Direct sale and transfer of radiation machines and machine components to end users: The applicant ~~must~~shall certify knowledge of familiarity with the rules and regulations which govern the possession, installation and use of radiation machines in South Carolina.

~~2.6.6.2~~2.7.8.2 Class II - A, B, or C - Installation, assembly, ~~and~~ service, and testing of radiation machines and machine components ~~including the making of diagnostic radiation output measurements to verify performance associated with the installation or service~~:

~~2.6.6.2.1~~2.7.8.2.1 ~~Documented manufacturer's equipment school of service, testing, or equivalent training~~ Experience or education providing familiarity with the type of equipment to be serviced;

~~2.6.6.2.2~~2.7.8.2.2 ~~Maintenance and installation for the type of machine use (e.g., dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training~~Knowledge of radiation safety to include principles of radiation protection;

~~2.6.6.2.3~~2.7.8.2.3 ~~Training in principles of radiation protection; and a minimum of three months of experience in installation, service, and/or testing of radiation machines and machine components.~~Six (6) months of supervised installation, assembly, service, and/or testing of the type of equipment to be serviced;

2.7.8.2.4 And one (1) of the following:

2.7.8.2.4.1 One (1) year of documented formal training from the manufacturer's school, military technical training school, or other courses in radiation machine installation, assembly or repair, or an equivalent combination of training and experience;

2.7.8.2.4.2 An associate's degree in biomedical equipment technology; or

2.7.8.2.4.3 A bachelor's degree in electrical engineering with specialized training in radiation producing devices.

~~2.6.6.3~~2.7.8.3 Class III - ~~Diagnostic radiographic~~Non-therapeutic healing arts facility ~~and~~ shielding design and area radiation survey (e.g., shielding evaluation):

~~2.6.6.3.1~~2.7.8.3.1 Documented training in principles of radiation protection;

~~2.6.6.3.2~~2.7.8.3.2 Documented training in shielding design and shielding evaluation; ~~and~~

~~2.6.6.3.3~~2.7.8.3.3 One (1) year of experience in ~~diagnostic radiographic~~healing arts facility and shielding design for the specific type of machine application~~.~~; and

2.7.8.3.4 One (1) year of experience performing area radiation surveys.

~~2.6.6.4~~2.7.8.4 Class IV – Non-~~Diagnostic fluoroscopic~~healing arts facility and shielding design and area radiation survey (e.g., shielding evaluation):

~~2.6.6.4.1~~2.7.8.4.1 Documented training in principles of radiation protection;

~~2.6.6.4.2~~2.7.8.4.2 Documented training in shielding design and shielding evaluation; and

~~2.6.6.4.3~~2.7.8.4.3 One year of experience in non-~~diagnostic fluoroscopic~~healing arts facility and shielding design for the specific type of machine application~~.~~; and

2.7.8.4.4 One (1) year of experience performing area radiation surveys.

~~2.6.6.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation:~~

~~2.6.6.5.1 Documented training in principles of radiation protection;~~

~~2.6.6.5.2 Documented training in shielding evaluation; and~~

~~2.6.6.5.3 One year of experience performing area radiation surveys.~~

~~2.6.6.6~~2.7.8.5 Class VI - Radiation instrument calibration:

~~2.6.6.6.1~~2.7.8.5.1 ~~The applicant must p~~Possess a current radioactive materials license if instrument calibration is done utilizing radioactive materials or registration authorizing radiation instrument calibration;

~~2.6.6.6.2~~2.7.8.5.2 Training in principles of radiation protection;

~~2.6.6.6.3~~2.7.8.5.3 Training in operation and calibration of radiation detection and measurement instrumentation;

~~2.6.6.6.4~~2.7.8.5.4 One (1) year experience in an instrument calibration laboratory; and

~~2.6.6.6.5~~2.7.8.5.5 Shall submit a description of the procedures that will be utilized in performing instrument calibrations.

~~2.6.6.7~~2.7.8.6 Class VII - Therapeutic facility and shielding design, area radiation survey, ~~or~~and calibration:

~~2.6.6.7.1~~2.7.8.6.1 Certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x-ray and gamma ray physics, or certification by the American Board of Medical Physics in therapeutic radiological physics; or

~~2.6.6.7.2~~2.7.8.6.2 Having the following minimum training and experience:

~~2.6.6.7.2.1~~2.7.8.6.2.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one (1) year full-time training in therapeutic radiological physics; and

~~2.6.6.7.2.2~~2.7.8.6.2.2 One (1) year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one (1) machine~~;~~.

~~2.6.6.7.3~~2.7.8.6.3 Shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed.

~~2.6.6.7.4~~2.7.8.6.4 Shall submit a copy of all forms, reports, and documents that will be supplied to registrants; and shall submit one (1) sample of each specific type~~,~~ (e.g., therapy, accelerator).

~~2.6.6.8~~2.7.8.7 Class VIII - General health physics consulting, non-healing arts, (e.g., independent ~~diagnostic~~ radiation output measurements, dose analysis, design of safety programs~~,~~ and radiation safety training programs, facility and shielding design, area radiation surveys, and acting as the ~~radiation safety officer~~Radiation Safety Officer)~~;~~:

~~2.6.6.8.1 One year experience in non-healing arts facility design and area radiation surveys.~~2.7.8.7.1 Master’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university and have forty (40) hours practical training and/or supervised experience in x-ray physics; or

~~2.6.6.8.2 Baccalaureate degree in physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; or~~2.7.8.7.2 Certification by the American Board of Health Physics, American Board of Radiology, or American Board of Medical Physics in the appropriate fields or specialties in which services are provided.

~~2.6.6.8.3 Baccalaureate degree in physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years graduate training in medical or health physics; or~~2.7.8.7.3 All training and experience requirements of RHB 2.7.8.4, as applicable.

~~2.6.6.8.4 Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.~~2.7.8.7.4 Any person registered as a vendor of this Class prior to the effective date of this regulation and holding a baccalaureate degree in a physical science (e.g., physics, chemistry, or radiologic science), engineering or related field, and having two (2) years of progressive experience in medical or health physics or two (2) years of graduate training in medical or health physics is exempt from the requirements in RHB 2.7.8.7.1 and 2.7.8.7.2, provided he/she is in good standing with the Department.

~~2.6.6.9~~2.7.8.8 Class IX - General health physics consulting, healing arts, (e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs~~,~~ and radiation safety training programs, facility and shielding design, area radiation surveys, equipment performance tests, and acting as the ~~radiation safety officer~~Radiation Safety Officer):

~~2.6.6.9.1Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; or~~2.7.8.8.1 Master's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university and have forty (40) hours practical training and/or supervised experience in x-ray physics; or

~~2.6.6.9.2Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years graduate training in medical or health physics; or~~ 2.7.8.8.2 Certification by the American Board of Health Physics, American Board of Radiology, or American Board of Medical Physics in the appropriate fields or specialties in which services are provided.

~~2.6.6.9.3 Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.~~2.7.8.8.3 Medical physicists for mammography shall meet the requirements specified by RHB 5.9.3.

~~2.6.6.9.4~~2.7.8.8.4 All training and experience requirements of RHB ~~2.6.6.2, 2.6.6.3, 2.6.6.4, 2.6.6.5, 2.6.6.7~~2.7.8.3, as applicable. ~~Any person registered prior to the effective date of this regulation as a vendor of this Class shall meet the education, training, and experience requirements no later than 24 months after the effective date of these regulations.~~

2.7.8.8.5 Any person registered as a vendor of this Class prior to the effective date of this regulation and holding a baccalaureate degree in a physical science (e.g., physics, chemistry, or radiologic science), engineering or related field, and having two (2) years of progressive experience in medical or health physics or two (2) years of graduate training in medical or health physics is exempt from the requirements in RHB 2.7.8.8.1 and 2.7.8.8.2, provided he/she is in good standing with the Department.

~~2.6.6.10~~2.7.8.9 For the purpose of RHB ~~2.6~~2.7, the required work experience may be gained while working for a manufacturer or while working under the direct supervision of a vendor registered in the particular class.

~~2.6.7~~2.7.9 Any branch office of a vendor shall be considered a separate entity and shall be registered separately pursuant to RHB ~~2.6~~2.7.

RHB ~~2.7~~2.8. Vendor Obligation.

~~2.7.1~~2.8.1 Any person who sells, leases, transfers, lends, moves, assembles, or installs x-ray machines in this ~~S~~state shall notify the Department within thirty (30) calendar days of:

~~2.7.1.1~~2.8.1.1 The name and address of persons who have received these machines;

~~2.7.1.2~~2.8.1.2 The manufacturer, the control and tube(s) model number, the control and tube(s) serial number of each radiation machine transferred; and

~~2.7.1.3~~2.8.1.3 The date of transfer of each x-ray machine.

~~2.7.1.4~~2.8.1.4 Notification to the Department shall be made on forms ~~furnished~~provided by the Department and shall be submitted to the Department each month by Class I and Class II-A vendors ~~regardless of whether x-ray equipment was sold that month~~.

~~2.7.2~~2.8.2 No person shall furnish any x-ray machine services or make, sell, lease, transfer, lend, maintain, calibrate, test, repair, assemble, reassemble, reinstall, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and ~~used~~use, meet the requirements of ~~these~~this regulation~~s~~. Each vendor shall ensure that the facility it is providing with services or supplies is registered with the Department prior to providing services or supplies.

~~2.7.2.1~~2.8.2.1 Any vendor acting as a Radiation Safety Officer on behalf of a registered facility shall be registered as a Class VIII or IX vendor and shall meet all applicable ~~p~~Parts of this regulation.

~~2.7.3~~2.8.3 Each vendor shall maintain records for review by the Department. These records shall include, at a minimum:

~~2.7.3.1~~2.8.3.1 All information required by RHB 2.7 and RHB ~~2.7.~~2.8;

~~2.7.3.2~~2.8.3.2 A copy of ~~the~~ any shielding plan~~s, if one was required, and if provided by that vendor~~ and/or area surveys. Records of shielding plans and area surveys shall include the date that the service was performed and the legible signature of the person performing the service;

~~2.7.3.3~~2.8.3.3 Tests performed at the time of installation to ensure that the equipment complies with ~~these~~this regulation~~s~~. A copy of these results shall be provided to the registrant at the time of installation;

~~2.7.3.4~~2.8.3.4 Records of any routine maintenance, repair, alterations, or reassembly of x-ray equipment. Records of maintenance, repair, alterations, or reassemblies shall include the date that the service was performed and the legible signature of the person performing the service. A copy of these records shall be provided to the registrant at the time the service is provided;

~~2.7.3.5~~2.8.3.5 Names of all employees and their dates of employment with the vendor. Records shall also be maintained of training provided to the employees during their term of employment~~.~~; and

~~2.7.3.6~~2.8.3.6 ~~Records~~A copy of equipment performance ~~testing~~ tests, including data collected during the testing.

~~2.7.3.6.1~~2.8.3.6.1 A copy of the equipment performance test ~~must~~shall be provided to the facility either at the time of testing or within thirty (30) calendar days of the testing date.

~~2.7.3.6.2~~2.8.3.6.2 The report of equipment performance testing shall include the testing of all items listed in Part IV, Appendix F, except as noted in the Appendix.

~~2.7.3.6.3~~2.8.3.6.3 The equipment performance test record provided to the facility must clearly indicate all equipment parameters tested and each item must include a designation, such as "Pass/Fail" or "Compliant/Non-compliant,"~~,~~ that is easily understandable by the facility. Use of any designation other than "Pass/Fail" or "Compliant/Non-compliant" shall be approved by the Department prior to use on equipment performance reports of testing.

~~2.7.3.6.4~~2.8.3.6.4 The equipment performance test record shall include a summary of findings and recommendations for necessary improvements and/or corrective actions.

~~2.7.3.6.5~~2.8.3.6.5 The record of equipment performance shall be legible and include the date that the testing was performed; the facility name, facility location address, and facility registration number issued by the Department; the legible signature of the person performing the service; manufacturer, model number, serial number, and the calibration date of the instrument used to perform the test; and the manufacturer, serial number, model number, and location of the equipment.

~~2.7.4~~2.8.4 All records required by this Part shall be maintained by the vendor until their disposal is authorized by the Department. All records shall be legible, accurate, and factual.

~~2.7.5~~2.8.5 Each vendor shall maintain sufficient calibrated and operable instruments to perform the testing appropriate to the class in which the vendor is registered. Instruments ~~must~~shall be calibrated with sources consistent with the conditions under which they are used. Legible ~~R~~records shall be maintained of the calibrations performed on instrumentation used for testing. All provisions of RHB 1.4.4 apply.

RHB ~~2.8~~2.9. Out-of-State Facilities.

2.9.1 Any person proposing to bring x-ray producing equipment into the state, for any temporary use, shall apply for Facility Registration Approval (FRA), as required by RHB 2.4.2 and shall submit any application and shielding review fees as required by RHB 2.3.

~~2.8.1~~2.9.2 No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five (5) working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five (5) working day-period would impose an undue hardship on the person, he or she may, upon application to the agency, obtain permission to proceed sooner. This notice shall be made on a form provided by the Department.

~~2.8.2~~2.9.3 Such facilities shall meet all applicable ~~p~~Parts of this regulation.

RHB ~~2.9~~2.10. Modification, Revocation, Termination of Registrants.

~~2.9.1~~2.10.1 The terms and conditions of all registrations are subject to amendment, revision, or modification and all registrations are subject to suspension or revocation by reason of:

~~2.9.1.1~~2.10.1.1 Amendments to the Act;

~~2.9.1.2~~2.10.1.2 Rules and regulations adopted pursuant to provisions of the Act; or

~~2.9.1.3~~2.10.1.3 Orders issued by the Department.

~~2.9.2~~2.10.2 Any registration may be revoked, suspended, or modified in whole or part:

~~2.9.2.1~~2.10.2.1 For any material false statement in the application or in any statement of fact required by provisions of this ~~p~~Part;

~~2.9.2.2~~2.10.2.2 Because of any statement of fact, any report, record, inspection, or other means which would warrant the Department to refuse to grant a registration on original application; or

~~2.9.2.3~~2.10.2.3 For violations of, or failure to observe any of the terms and conditions of the Act, the registration, ~~these~~this regulation~~s~~, or any order of the Department.

~~2.9.3~~2.10.3 Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the Department shall:

~~2.9.3.1~~2.10.3.1 Call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

~~2.9.3.2~~2.10.3.2 Provide an opportunity for the registrant to demonstrate or achieve compliance with all regulations.

~~2.9.4~~2.10.4 The Department may terminate a registration upon written request submitted by the registrant to the Department.

~~2.9.5~~2.10.5 The provisions of this ~~p~~Part shall apply to both registration of x-ray equipment and registration of x-ray services (vendors).

RHB ~~2.10~~2.11. Annual Fees.

~~2.10.1~~2.11.1 ~~Any person issued or granted a registration for the possession and use of x-ray machine(s)~~ Each registrant shall pay an annual registration fee per ~~machine~~ x-ray equipment tube possessed, except for Combination Rad/Fluoro. Vendors and Out-of-State Facilities shall pay an annual flat fee. Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.

2.11.1.1 The annual registration fee shall be due ~~on January 15 of each year~~ no later than thirty (30) calendar days after the date of the “Statement of Fees Due.”

~~2.10.2~~ 2.11.1.2 ~~Persons~~Registrants failing to pay the fees required by RHB ~~2.10.1~~2.11.1 ~~by March 15 of that year~~within thirty (30) calendar days after payment is due shall also pay a penalty of ~~F~~fifty ~~D~~dollars ($50.00).

2.11.1.3 If the required fees are not paid ~~by April 15 of that year~~ within sixty (60) calendar days after payment is due, the registrant shall be notified by certified mail to be sent to his or her last known address that his or her registration is revoked, and that any activities permitted under the authority of the registration must cease immediately.

~~2.10.3~~ 2.11.1.4 A registrant ~~suspended~~revoked for failure to pay the required fees under RHB ~~2.10.2~~ 2.11.1 may be reinstated by the Department upon payment of the required fees, the penalty of ~~F~~fifty ~~D~~dollars ($50.00), and an additional penalty of ~~O~~one ~~H~~hundred ~~D~~dollars ($100.00), if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his or her failure to pay the required fees.

~~2.10.4 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.~~

~~2.10.5~~2.11.2 Fees required by RHB ~~2.10.1~~2.11.1 for ~~an~~ x-ray ~~machine~~equipment, out-of-state facility, or vendor registration which is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the registration.

~~2.10.6~~2.11.3 Schedule of Fees. Chapter 7, Nuclear Energy, Article 1, Atomic Energy and Radiation Control Act, Section 13-7-45~~,~~ (A)(1) requires the Department to establish a schedule for the collection of annual fees for the licensing, registration, and certification of users of sources of ionizing radiation.

Type of Equipment	Fee
Radiographic	$131
Fluoroscopic	$131
Combination Rad/Fluoro	$231
Dental	$93.50
Therapy (medical)	$156
Diffraction	$99.75
X-ray Fluorescence	$99.75
Accelerator (industrial)	$156
Electron Microscope	$68.50
Spectrograph	$99.75
Cephalometer	$131
Panoramic	$81
Cabinet X-ray	$124.75
CT Scanner, and/or PET/CT, SPECT, Dental CT	$131

C-Arm Fluoroscopic	$131
Mammography	(See RHB ~~5.6~~5.8)
Stereotactic Mammography	$131
Baggage Checker	$99.75
Bone Densitometer	$131
Lithotripter	$131
Simulator	$131
Other	$131
X-ray Gauge	$99.75
Personnel Security Screening System	$131
Out-of-State Facilities	$187.25
Vendors and Installers	$187.25

PART III
STANDARDS FOR PROTECTION AGAINST RADIATION

RHB 3.1. ~~Purpose and~~ Scope.

3.1.1 This Part establishes standards for protection against ionizing radiation ~~resulting from activities conducted pursuant to registrations issued by the Department pursuant to these regulations~~.

3.1.2 The requirements of this Part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Part. However, nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.

3.1.3 Except as specifically provided in other Parts of ~~these~~this regulation~~s~~, this Part applies to persons registered by the Department to receive, possess, use, install, service, transfer, or dispose of sources of radiation. The limits in this Part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

RHB 3.2. Implementation.

3.2.1 Any existing registration condition that is more restrictive than this Part remains in force until there is an amendment of the registration.

3.2.2 If a registration condition exempts a registrant from a provision of a previous Part III in effect on or before the effective date of ~~these~~this regulation~~s~~, it also exempts the registrant from the corresponding provision of this Part III.

3.2.3 If a registration condition cites provisions of a previous Part III in effect prior to the effective date of ~~these~~this regulation~~s~~, which do not correspond to any provisions of this Part, the registration condition

remains in force until there is an amendment or renewal of the registration that modifies or removes this condition.

3.2.4 For determining the doses specified in this Part, a dose from x-rays up to three megaelectron volts (3 MeV) may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

RHB 3.3. Authority and Responsibility for the Radiation Protection Programs.

3.3.1 Each registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this ~~Part~~regulation. See RHB 3.18 for record keeping requirements relating to these programs.

3.3.2 The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

3.3.3 ~~The registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.~~Where applicable, as determined by the Department and indicated on the Facility Registration Approval, the registrant shall appoint a committee to review the radiation protection program content and implementation. This committee shall include, at a minimum, the Radiation Safety Officer and representatives from all areas in which x-ray equipment is utilized and meet at intervals not to exceed twelve (12) months.

3.3.4 Radiation Safety Officer. The registrant shall designate, in writing, an individual who will be responsible for radiation protection at the facility. Such individual shall:

3.3.4.1. Be qualified by training and experience concerning all hazards and precautions involved in operating the equipment for which he or she is responsible;

3.3.4.2 Develop and implement a program of radiation safety for effective compliance with the applicable requirements of this regulation;

3.3.4.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the equipment; and

3.3.4.4 Ensure that surveys are made, procedures are carried out, and radiation safety instructions are given as required by this regulation.

~~3.3.4~~ 3.3.5 The registrant shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative~~,~~ to:

~~3.3.4.1~~ 3.3.5.1 Identify radiation safety problems;

~~3.3.4.2~~ 3.3.5.2 Initiate, recommend, or provide corrective actions;

~~3.3.4.3~~ 3.3.5.3 Stop unsafe operations; and~~,~~

~~3.3.4.4~~ 3.3.5.4 Verify implementation of corrective actions.

~~3.3.5~~ 3.3.6 The registrant shall establish either monthly or quarterly investigative limits to ensure individuals will not exceed annual occupational exposure limits.

RHB 3.4. Occupational Dose Limits for Adults.

3.4.1 The registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to RHB 3.6, to the following dose limits:

3.4.1.1 An annual limit, which is the more limiting of:

3.4.1.1.1 The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

3.4.1.1.2 The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

3.4.1.2 The annual limits to the lens of the eye, to the skin, and to the extremities which are:

3.4.1.2.1 An eye dose equivalent of 15 rem (0.15 Sv), and

3.4.1.2.2 A shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

3.4.1.3 Any individual exceeding his~~/~~ or her annual occupational exposure limit shall not be exposed to additional occupational radiation for the remainder of the calendar year.

3.4.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are provided in RHB 3.6.

3.4.3 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. The deep dose equivalent, eye dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

3.4.4 If an occupationally exposed adult is likely to receive in one (1) year, from sources external to the body, a dose in excess of fifty percent (50%) of the limits in RHB 3.4.1, the registrant shall monitor all of the individual’s occupationally received doses, and shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

RHB 3.5. Compliance with Requirements for the Summation of External and Internal Doses.

If a registrant is also a radioactive material licensee of the Department, all regulations of Title A pertaining to dose limits are applicable. Nothing in this Part relieves a registrant from complying with Title A.

RHB 3.6. Planned Special Exposures.

A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the dose received under the limits specified in RHB 3.4 provided that each of the following conditions ~~is~~are satisfied:

3.6.1 The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

3.6.2 The registrant, and employer if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

3.6.3 Before a planned special exposure, the registrant ensures that each individual involved is:

3.6.3.1 Informed of the purpose of the planned operation; ~~and~~

3.6.3.2 Informed of the estimated doses, ~~and~~ associated potential risks, and specific radiation levels or other conditions that might be involved in performing the task; and

3.6.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

3.6.4 Prior to permitting an individual to participate in a planned special exposure, the registrant ascertains prior doses as required by RHB 3.20 during the lifetime of the individual for each individual involved.

3.6.5 Subject to RHB 3.4.2, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

3.6.5.1 The numerical values of any of the dose limits in RHB 3.4.1 in any year; and

3.6.5.2 Five (5) times the annual dose limits in RHB 3.4.1 during the individual's lifetime.

3.6.6 The registrant maintains records of the conduct of a planned special exposure in accordance with RHB 3.21 and submits a written report in accordance with RHB ~~3.27.~~3.26.

3.6.7 The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within thirty (30) calendar days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to RHB 3.4.2.

RHB 3.7. Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are ten ~~(10)~~ percent (10%) of the annual occupational dose limits specified for adult workers in RHB 3.4.

RHB 3.8. Dose to an Embryo/Fetus.

3.8.1 The registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See RHB 3.22 for record keeping requirements.

3.8.2 The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in RHB 3.8.1.

3.8.3 The dose to an embryo/fetus shall be taken as the sum of:

3.8.3.1 The deep dose equivalent to the declared pregnant woman; and

3.8.3.2 The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

3.8.4 ~~If by the time the woman declares pregnancy to the registrant, the dose to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the registrant shall be deemed to be in compliance with RHB 3.8.1 if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.~~ If the dose equivalent to the embryo/fetus is found to have exceeded five millisieverts (0.5 rem), or is within 0.5 millisieverts (0.05 rem) of this dose, by the time the woman declares the pregnancy to the registrant, the registrant shall be deemed to be in compliance with RHB 3.8.1 if the additional dose to the embryo/fetus does not exceed 0.5 millisievert (0.05 rem) during the remainder of the pregnancy.

RHB 3.9. Dose Limits for Individual Members of the Public.

3.9.1 Each registrant shall conduct operations so that:

3.9.1.1 The total effective dose equivalent to individual members of the public from the registered operation does not exceed 0.1 rem (1 mSv) in a year, and

3.9.1.2 The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one (1) hour.

3.9.2 If the registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

3.9.3 A registrant, or an applicant for a registration, may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

3.9.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in RHB 3.9.1; and

3.9.3.2 The registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

3.9.3.3 The procedures to be followed to maintain the dose ALARA.

~~3.9.4 Retrofit shall not be required for locations within facilities where only radiation machines existed prior to the effective date of these Regulations, and met the previous requirements of 0.5 rem (5 mSv) in a year.~~

RHB 3.10. Compliance with Dose Limits for Individual Members of the Public.

3.10.1 The registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RHB 3.9.

3.10.2 A registrant shall show compliance with the annual dose limit in RHB 3.9 by:

3.10.2.1 Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit; or

3.10.2.2 Demonstrating that if an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

RHB 3.11. Surveys.

3.11.1 Each registrant shall make, or cause to be made, surveys that:

3.11.1.1 Are necessary for the registrant to comply with this Part; and

3.11.1.2 Are necessary under the circumstances to evaluate:

3.11.1.2.1 Radiation levels; and

3.11.1.2.2 The potential radiological hazards that could be present.

3.11.2 The registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed ~~12~~ twenty-four (24) months for the radiation measured.

RHB 3.12. Personnel Monitoring.

3.12.1 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with RHB 3.4, with other applicable provisions of ~~these~~this regulation~~s~~, or with conditions specified in a registration shall be processed and evaluated by a dosimetry processor:

3.12.1.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

3.12.1.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

3.12.2 Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

3.12.3 Personnel Monitoring Devices.

3.12.3.1 Personnel Monitoring (or other dosimeters approved by the Department) shall meet the following requirements:

3.12.3.1.1 The monitoring device shall be assigned to and worn only by one individual; ~~and~~

3.12.3.1.2 When a ~~lead~~protective apron is worn, the monitoring device shall be worn at the collar, outside the apron; ~~and~~

3.12.3.1.3 If a personnel monitoring device is lost or damaged, the ~~worker shall cease work immediately until a replacement badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the badge. In the event a replacement badge is not available, the Radiation Safety Officer shall be contacted immediately to evaluate the probable radiation exposure to the worker until a replacement device is received~~Radiation Safety Officer shall be contacted to calculate the exposure for the time period from issuance to loss or damage of the device, provide a replacement device, and evaluate the probable radiation exposure to the worker until a replacement device is issued; ~~and~~

3.12.3.1.4 The Registrant shall ensure that personnel monitoring devices are returned within forty-five (45) calendar days of the end of the monitoring period. ~~Direct read~~All dosimeters must be read ~~according to the manufacturer specifications~~ at least quarterly, ~~and~~ the results from the readings recorded and evaluated for compliance with RHB 3.3.2 and 3.4, and be available for ~~d~~Departmental review; ~~and~~

3.12.3.1.5 Documentation providing explanation of any late, absent, or unused personnel monitoring devices must be recorded and available for Departmental review; ~~and~~

3.12.3.1.6 Personnel monitoring devices must be worn in accordance with manufacturer guidelines~~.~~; and

3.12.3.1.7 Fetal dose dosimeters shall be read in accordance with RHB 3.12.6.

3.12.3.2 Control badges are used to measure background radiation. They shall be stored away from the radiation area. Control badges are not to be worn as a personnel monitoring device. Ensure the control badge is returned with the lot of badges with which it was issued.

3.12.3.3 Upon ~~d~~Departmental approval, area monitors may be used in place of personnel monitoring devices.

3.12.4 Each registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this ~~p~~Part. As a minimum:

3.12.4.1 Each registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

3.12.4.1.1 Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of ~~10~~ten percent (10%) of the limits in RHB 3.4; ~~and~~

3.12.4.1.2 Minors and declared pregnant women likely to receive, in one (1) year from sources external to the body, a dose in excess of ~~10~~ten percent (10%) of any of the applicable limits in RHB 3.7 or 3.8; and

3.12.4.1.3 Individuals entering a high or very high radiation area.

~~3.12.4.1.3.1~~3.12.4.1.4 ~~Personnel monitoring devices shall be worn appropriately by~~ ~~p~~Personnel working with medical fluoroscopic equipment.

~~3.12.4.1.4~~3.12.4.1.5 Such other individuals as the Department deems necessary.

3.12.5 Determination of Dose

3.12.5.1 ~~When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual.~~ When only one (1) individual device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation.

3.12.5.2 ~~The Radiation Safety Officer may give consideration that an Effective Dose Equivalent be used as the permanent record provided that all provisions of RHB 3.3 apply. The Radiation Safety Officer must ensure individuals utilizing the Effective Dose Equivalent shall meet the following requirements:~~ The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure.

3.12.5.2.1 ~~Protective equipment must be used. The use of protective equipment shall be routinely documented in each room and this documentation shall periodically be reviewed by the Radiation Safety Officer, or other responsible persons to determine if it is being completed correctly.~~ The Radiation Safety Officer may give consideration that an effective dose equivalent be used as the permanent record provided that all provisions of RHB 3.3 are met. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified RHB 3.12, the effective dose equivalent for external radiation shall be determined as follows:

3.12.5.2.1.1 When only one (1) individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds twenty-five percent (25%) of the limit specified in RHB 3.4, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose for external radiation; or

3.12.5.2.1.2 When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

3.12.5.2.2 ~~Periodic~~ Quarterly visits shall be made by the ~~radiation safety officer~~Radiation Safety Officer or his or her designee for personal observation adherence to proper radiation safety practices. Documentation of these reviews must be available for Departmental review.

3.12.5.2.3 The Department may immediately revoke the use of the ~~E~~effective ~~D~~dose ~~E~~equivalent upon determination that a violation of RHB 3.12.5 has occurred.

3.12.5.3 Adjustments to the dose of permanent record shall be determined by the Radiation Safety Officer prior to any changes to the record. Records of these actions shall be maintained for Departmental review.

3.12.6 When an individual who has been given responsibility that involves occupational exposure to x-rays declares that she is pregnant, the employer must, at her request, provide her with an additional personnel monitoring device to be worn on the trunk underneath the leaded apron, when such apron is worn. The fetal badge shall be processed and evaluated on a monthly basis, at a minimum.

RHB 3.13. Control of Access to High Radiation Areas.

3.13.1 The registrant shall ensure that each entrance or access point to a high radiation area has one (1) or more of the following features:

3.13.1.1 A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in one (1) hour at ~~30~~thirty centimeters (30 cm) from the source of radiation from any surface that the radiation penetrates; ~~or~~

3.13.1.2 A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

3.13.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

3.13.2 In place of the controls required by RHB 3.13.1 for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

3.13.3 The registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

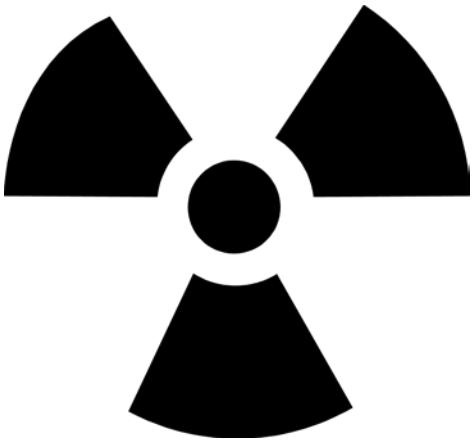
3.13.4 The registrant shall establish the controls required by RHB 3.13.1 and 3.13.3 in a way that does not prevent individuals from leaving a high radiation area.

RHB 3.14. Control of Access to Very High Radiation Areas.

In addition to the requirements in RHB 3.13, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in one (1) hour at ~~1~~one meter (1 m) from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation.

RHB 3.15. Caution Signs.

3.15.1 The radiation symbols prescribed by this regulation shall be the conventional three-bladed design as shown. The ~~cross-hatched area~~symbol shall be magenta, purple, or black, and the background shall be yellow.



3.15.2 Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in this Part, the registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

RHB 3.16. Posting Requirements.

3.16.1 Posting of Radiation Areas. The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

3.16.2 Posting of High Radiation Areas. The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

3.16.3 Posting of Very High Radiation Areas. The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

3.16.4 Exceptions to Posting Requirements. A registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight (8) hours, if each of the following conditions is met:

3.16.4.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and

3.16.4.2 The area or room is subject to the registrant's control.

RHB 3.17. General Provisions for Records.

3.17.1 Each registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part.

3.17.2 The registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

3.17.3 Form of Records. Each record required by this Part shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

RHB 3.18. Records of Radiation Protection Programs.

3.18.1 Each registrant shall maintain records of the radiation protection program, including:

3.18.1.1 The provisions of the program; and

3.18.1.2 Audits and other reviews of program content and implementation.

3.18.2 The registrant shall retain the records required by RHB 3.18.1.1 until the Department terminates each pertinent registration requiring the record. The registrant shall retain the records required by RHB 3.18.1.2 for ~~3~~ five (5) years after the record is made.

RHB 3.19. Records of Surveys.

3.19.1 Each registrant shall maintain records showing the results of surveys and instrument calibrations required by RHB 3.11. The registrant shall retain these records for five (5) years after the record is made.

3.19.2 The registrant shall retain records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents for five (5) years after the termination of the registration.

RHB 3.20. Determination and Records of Prior Occupational Dose.

3.20.1 For each individual who may enter the registrant's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to RHB 3.12, the registrant shall determine the occupational radiation dose received during the current year.

3.20.2 Prior to permitting an individual to participate in a planned special exposure, the registrant shall determine:

3.20.2.1 The internal and external doses from all previous planned special exposures; ~~and~~

3.20.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

3.20.2.3 All lifetime cumulative occupational radiation dose.

3.20.3 In complying with the requirements of RHB 3.20.1, a registrant may:

3.20.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work

involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

3.20.3.2 Attempt to ~~O~~obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, ~~telegram,~~ facsimile, letter, or other electronic means. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

3.20.4 The registrant shall record the exposure history, as required by RHB 3.20.1, on a clear and legible record, of all the information required. The record shall show each period in which the individual received occupational exposure to radiation. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing the record. For any period in which the registrant does not obtain a report, the registrant shall place a notation on the record indicating the periods of time for which data are not available.

3.20.5 If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:

3.20.5.1 In establishing administrative controls pursuant to RHB 3.4.4 for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

3.20.5.2 That the individual is not available for planned special exposures.

3.20.6 The registrant shall retain the records and/or attempts to obtain records of prior occupational dose and exposure history until the Department terminates each pertinent registration requiring this record. The registrant shall retain records for five (5) years after the termination of the registration.

RHB 3.21. Records of Planned Special Exposures.

3.21.1 For each use of the provisions of RHB 3.6 for planned special exposures, the registrant shall maintain records that describe:

3.21.1.1 The exceptional circumstances requiring the use of a planned special exposure; ~~and~~

3.21.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; ~~and~~

3.21.1.3 What actions were necessary; ~~and~~

3.21.1.4 Why the actions were necessary; ~~and~~

3.21.1.5 What precautions were taken to assure that doses were maintained ALARA; ~~and~~

3.21.1.6 What individual and collective doses were expected to result; and

3.21.1.7 The doses actually received in the planned special exposure.

3.21.2 The registrant shall retain the records until the Department terminates each pertinent registration requiring these records.

RHB 3.22. Records of Individual Monitoring Results.

3.22.1 Record-keeping Requirement. Each registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RHB 3.12, and records of doses received during planned special exposures, accidents, and emergency conditions. ~~Assessments of dose equivalent and records made using units in effect before the effective date of this Part need not be changed.~~ These records shall include the deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.

3.22.2 Record-keeping Frequency. The registrant shall make entries of the records specified in RHB 3.22.1 at intervals not to exceed one (1) year.

3.22.3 Record-keeping Format. The registrant shall maintain the records specified in RHB 3.22.1.

3.22.4 The registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

3.22.5 The registrant shall retain each required form or record until the Department terminates each pertinent registration requiring the record.

RHB 3.23. Records of Dose to Individual Members of the Public.

3.23.1 Each registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public in RHB 3.10.

3.23.2 The registrant shall retain the records required by RHB 3.23.1 until the Department terminates each pertinent registration requiring the record.

RHB 3.24. Notification of Incidents.

3.24.1 Immediate Notification. Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a source of radiation possessed by the registrant that may have caused or threatens to cause an individual to receive:

3.24.1.1 A total effective dose equivalent of 25 rem (0.25 Sv) or more; ~~or~~

3.24.1.2 An eye dose equivalent of 75 rem (0.75 Sv) or more; or

3.24.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 Gy) or more~~; or~~.

3.24.2 Twenty-Four Hour Notification. Each registrant shall, within twenty-four (24) hours of discovery of the event, report to the Department each event that may have caused, or threatens to cause, an individual to receive, in a period of twenty-four (24) hours:

3.24.2.1 A total effective dose equivalent exceeding 5 rem (0.05 Sv); ~~or~~

3.24.2.2 An eye dose equivalent exceeding 15 rem (0.15 Sv); or

3.24.2.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 Sv)~~; or~~.

3.24.3 The registrant shall prepare each report filed with the Department pursuant to this Part so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

3.24.4 Registrants shall make the reports required by this Part to the Department by telephone, ~~telegram, mailgram,~~ mail, electronic mail, or facsimile to the Department.

3.24.5 The provisions of this Part do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to RHB 3.27.

RHB 3.25. Reports of Exposures and Radiation Levels Exceeding the Limits.

3.25.1 In addition to the notification required by RHB ~~3.25~~3.24, each registrant shall submit a written report within thirty (30) calendar days after learning of any of the following occurrences:

3.25.1.1 Any incident for which notification is required by RHB ~~3.25~~3.24;

3.25.1.2 Doses in excess of any of the following:

3.25.1.2.1 The occupational dose limits for adults in RHB 3.4;

3.25.1.2.2 The occupational dose limits for a minor in RHB 3.7;

3.25.1.2.3 The limits for an embryo/fetus of a declared pregnant woman in RHB 3.8; or

3.25.1.2.4 The limits for an individual member of the public in RHB 3.9.

3.25.2 The written report shall include the following:

3.25.2.1 A description of the extent of exposure of individuals to radiation, including, as appropriate:

3.25.2.1.1 Estimates of each individual's dose; ~~and~~

3.25.2.1.2 The levels of radiation involved; ~~and~~

3.25.2.1.3 The cause of the elevated exposures or dose rates; and

3.25.2.1.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits.

3.25.2.2 For each individual exposed: the name and date of birth. With respect to the limit for the embryo/fetus in RHB 3.8, the identifying information shall be that of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

3.25.3 Reports made by registrants in response to the requirements of this Part shall be addressed to the ~~d~~Department ~~as specified in RHB 1.12~~.

RHB 3.26. Reports of Planned Special Exposures.

The registrant shall submit a written report to the Department within thirty (30) calendar days following any planned special exposure conducted in accordance with RHB 3.6, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RHB 3.21.

RHB 3.27. Reports of Individual Monitoring.

The Department may require by registration condition, or order pursuant to RHB 1.6.1, annual reports of the results of individual monitoring carried out by the registrant for each individual for whom monitoring was required by RHB 3.12.

RHB 3.28. Notifications and Reports to Individuals.

3.28.1 Requirements for notification and reports to individuals of exposure to radiation are specified in RHB ~~10.4~~11.4.

3.28.2 When a registrant is required pursuant to RHB 3.26 to report to the Department any exposure of an individual to radiation, the registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of RHB ~~10.4~~11.4.

RHB 3.29. Storage and Control of Radiation Sources.

3.29.1 ~~Security of Stored Sources of Radiation. The registrant shall secure from unauthorized removal or access sources of radiation that are stored in controlled or unrestricted areas.~~ The registrant shall secure all radiation equipment, including equipment in storage, from unauthorized removal.

3.29.2 ~~Control of Sources of Radiation not in Storage. The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.~~ The registrant shall maintain control of all radiation equipment, including equipment in storage, to prevent unauthorized use.

RHB 3.30. Reports of Stolen, Lost, Abandoned, or Missing Radiation Sources.

3.30.1 Telephone Reports. Each registrant shall report to the Department by telephone, immediately after its occurrence becomes known to the registrant, a stolen, lost, abandoned, or missing radiation machine.

3.30.2 Written Reports. Each registrant required to make a report pursuant to RHB ~~3.31.1~~ 3.30.1 shall, within thirty (30) calendar days after making the telephone report, make a written report to the Department setting forth the following information:

3.30.2.1 A description of the registered source of radiation involved, including the manufacturer, model and serial number, type and maximum energy of radiation emitted;

3.30.2.2 A description of the circumstances under which the loss or theft occurred; ~~and~~

3.30.2.3 A statement of disposition, or probable disposition, of the registered source of radiation involved; ~~and~~

3.30.2.4 Actions that have been taken, or will be taken, to recover the source of radiation; and

3.30.2.5 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.

3.30.3 Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within thirty (30) calendar days after the registrant learns of such information.

PART IV
USE OF X-RAYS IN THE HEALTH PROFESSIONS

RHB 4.1. Scope.

This ~~p~~Part establishes requirements for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with ~~S~~state statutes to engage in the healing arts or veterinary medicine.

RHB 4.2. General Safety Provisions.

4.2.1 An x-ray system which does not meet the provisions of ~~these~~this regulation~~s~~ shall not be operated for diagnostic or therapeutic purposes if so directed by the Department.

4.2.2 The registrant shall assure that all ~~X-ray~~x-ray machines under his or her control are operated only by a radiologic technologist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association, or a licensed practitioner. For the purpose of this Part, a radiologic technologist is defined as a person who is a limited practice radiographer, radiographer, podiatric limited practice radiographer, or limited chest radiographer certified by the American Registry of Radiologic Technologists, or who is certified by the South Carolina Radiation Quality Standards Association or who has obtained a certificate acceptable to the South Carolina Radiation Quality Standards Association. A person who applies ionizing radiation to humans or performs x-ray exam setups, including, but not limited to, patient positioning and technique selection shall be considered a radiologic technologist.

4.2.2.1 No person other than a licensed practitioner or a radiologic technologist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes.

4.2.2.2 No person shall employ or designate as a radiologic technologist a person who does not hold a current, valid certificate issued by the South Carolina Radiation Quality Standards Association.

4.2.2.3 No person holding a certificate issued by the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

4.2.2.4 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer,"~~;~~ "podiatric limited practice radiographer,"~~;~~ "limited chest radiographer,"~~;~~ or "radiographer" or any other title, sign, display, or

declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for diagnostic purposes.

4.2.2.5 A student enrolled in and attending a school or college of medicine, osteopathy, chiropractic, podiatry, radiologic technology, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine, osteopathy, chiropractic, or podiatry may apply ionizing radiation to humans without a certificate from the South Carolina Radiation Quality Standards Association, as long as the student or resident is under the direct supervision of a licensed practitioner or direct supervision of a certified radiologic technologist appropriately trained to supervise the specific procedure.

4.2.2.6 The registrant shall display each operator's current South Carolina Radiation Quality Standards Association certificate or the registrant may post a notice to the public that these certificates are available for review upon request. The certificate or posting shall be displayed in public view, not obstructed by any barrier, equipment, or other object.

4.2.2.7 The registrant shall ensure that each operator has received facility specific training to include the equipment and operating conditions. Documentation of this training for each operator shall be made available for Departmental review.

4.2.2.8 Dentists and their auxiliaries who meet the requirements of the South Carolina Dental Practice Act are exempt from the requirements of RHB 4.2.2.1 through 4.2.2.6.

4.2.3 The operator shall be able to demonstrate familiarity and competence with the facility's operating conditions.

4.2.4 X-ray producing machines and associated equipment shall be maintained in such a condition to ensure that the patient and staff are not exposed to radiation unnecessarily.

4.2.5 If an x-ray system is identified as not being in compliance with the provisions of ~~these~~this regulation~~s~~ and cannot meet the regulation~~s~~, or if the registrant is unwilling to make corrections, and if that system is accessible for use, it shall be rendered inoperable (i.e.~~,~~ dismantle the x-ray source from the source support assembly) if so ordered by the Department.

4.2.6 For general radiographic systems not equipped with an operational anatomic programming option, ~~protocols~~techniques shall be documented and readily available to the operator. At a minimum, ~~these protocols~~this shall include:

4.2.6.1 Patient's body part and anatomical size, or body part thickness or age (for pediatrics), versus technique factors to be used;

4.2.6.2 Source to image receptor distance (SID) to be used (except for dental intra-oral radiography) ~~and~~;

4.2.6.3 If an automatic exposure control (AEC) system is operated in a manual mode, the technique chart shall specify the requirements of RHB 4.2.6.1 and ~~RHB~~ 4.2.6.2~~.~~; and

4.2.6.4 The technique chart shall accurately reflect techniques currently in use at the facility.

4.2.7 A sign shall be posted so as to be easily seen by the patient to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician shall be notified.

4.2.8 The effectiveness of protective equipment and apparel shall not be impaired. ~~Lead~~Protective aprons and gloves shall be checked at least annually for cracks and holes that could compromise the radiation protection it provides. ~~This testing~~ These checks shall be documented~~. R~~ and records ~~of this testing~~ shall be kept for two (2) years, or until the next Department inspection, whichever is later.

4.2.9 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure other than the patient being examined.

4.2.9.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.

4.2.9.2 The x-ray operator, other staff, and ancillary persons shall be protected from the direct scattered radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material. Temporary placement of the physician's and/or assistant's hands in the primary beam during procedures that require sterility and increased dexterity are exempt from RHB 4.2.9.2.

4.2.9.3 Persons who cannot be removed from the room shall be protected from the direct scattered radiation by whole body protective barriers of 0.25 mm lead equivalent and when feasible shall be so positioned that the nearest portion of the body is at least ~~2~~two meters (2 m) from both the tube head and the nearest edge of the image receptor.

4.2.9.4 When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one quarter of the maximum permissible dose as defined in RHB 3.4 of ~~these~~this regulation~~s~~, additional protective devices may be required by the Department.

4.2.10 ~~Shielding of not less than 0.5 mm lead equivalent material shall be used for patients during x-ray procedures except in cases where the shielding would interfere with the diagnostic image desired.~~The useful x-ray beam shall be limited to the area of clinical interest.

4.2.11 Individuals shall not be exposed to the useful beam of electronically produced ionizing radiation except for healing arts purposes, and unless such exposure has been authorized by a licensed practitioner ~~of the healing arts~~. This provision specifically prohibits deliberate exposure for the following purposes:

4.2.11.1 Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided. Demonstrations or training on new x-ray equipment must be performed with proper protection of the observers and operator(s). Phantoms, not humans, must be used for demonstrations and training.

4.2.11.2 Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of this ~~p~~Part. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within fifteen (15) calendar days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

4.2.12 When a patient or film must be provided with auxiliary support during a radiation exposure:

4.2.12.1 Mechanical holding devices shall be used when the technique permits.

4.2.12.2 The facility shall indicate the requirements for selecting a holder, and the procedure the holder shall follow.

4.2.12.3 The human holder shall be instructed in personal radiation safety and shall be protected as required by 4.2.9.

4.2.12.4 No person shall be used routinely to hold patients or film. ~~All requirements of RHB 4.2.14 and 4.2.15 apply.~~

4.2.12.5 In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material.

4.2.12.6 When practical, a pregnant female shall not be used to hold film or patients.

4.2.12.7 Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved in x-ray operations who are not otherwise shielded.

4.2.13 Procedures and auxiliary equipment designed to minimize patient and personnel exposure shall be used.

4.2.13.1 The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging. The film cassettes shall provide good contact between the intensifying screens and the film.

4.2.13.2 The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality. Exposures shall not exceed limits as listed in Appendix D ~~provides patient exposures that are typical of good practices. These shall be used by the registrant in evaluating patient exposure~~.

4.2.13.3 Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation. Portable or mobile dental equipment~~, not to include handheld,~~ shall be exempt from this regulation.

4.2.13.4 Radiologic technologists performing fluoroscopy as a localizing procedure shall be monitored by the supervising radiologist who is personally and immediately available.

4.2.14 Personnel Monitoring.

4.2.14.1 All persons who are associated with the operation of an ~~X-ray~~x-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses which are stated in RHB 3.4. In addition, the following requirements are made:

4.2.14.1.1 When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one (1) such device shall be utilized as follows:

4.2.14.1.2 When an apron is worn, and one (1) monitoring device is worn, the monitoring device shall be worn at the collar outside of the apron. If more than one (1) monitoring device is worn, the devices shall be worn in accordance with RHB 3.12.5.

4.2.14.1.3 The dose to the whole body based on the maximum dose attributed to any one (1) critical organ shall be recorded in the reports required by RHB 3.22. If more than one (1) device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

4.2.14.2 Exposure of a personnel monitoring device to falsely indicate a dose delivered to an individual is prohibited.

4.2.14.3 When an individual who has been given responsibility that involves occupational exposure to x-rays declares that she is pregnant, the employer must, at her request, provide her with an additional personnel monitoring device to be worn on the trunk underneath the leaded apron, when such apron is worn.

4.2.15 X-ray Log.

4.2.15.1 Each facility (excluding dental and veterinary facilities) shall keep an x-ray log containing the patient's name; the type of examination, given by title as denoted on the technique chart; identification of the operator performing the examination; and the dates the examinations were performed.

4.2.15.2 When the examination is performed using any type of fluoroscopy, the log shall include a record of the amount of time that fluoroscopy was performed or the number of times that the cumulative timer was reset. The fluoroscopy time is not required to be recorded for radiation therapy simulation units or instrument guided radiation therapy units.

4.2.15.3 X-ray log records shall be maintained for two (2) years or until the next Department inspection, whichever is later.

~~4.2.15.4 Logs are not required for dental or veterinary x-ray equipment~~.

4.2.16 Quality Assurance.

4.2.16.1 Each registrant covered under RHB 4.5 through 4.12 must have "Equipment Performance Tests" performed on each x-ray unit. The registrant is required to meet the minimum performance criteria and test frequency. Facilities utilizing x-ray equipment for teaching or demonstration purposes only are exempt from this Part. Appendix F provides the required minimum performance criteria that must be tested. Equipment performance tests results must include numerical data. Items found to be non-compliant during such testing shall be corrected within sixty (60) calendar days of receipt of the report. Records showing the test results and the correction of any non-compliant items found must be retained for five (5) years or until the next Department inspection, whichever is later. Equipment performance tests are to be performed:

4.2.16.1.1 At the time installation at all facilities, including veterinary facilities~~,~~; or

4.2.16.1.2 Within thirty (30) calendar days of installation, provided that the manufacturer's specified testing is performed at the time of installation and before patient use~~.~~; and

4.2.16.1.3 At the following specified intervals thereafter:

4.2.16.1.3.1 Dental intraoral and dental extraoral units shall be tested every two (2) years. Dental computed tomography and dental handheld units shall be tested annually.

4.2.16.1.3.2 All medical x-ray equipment, including fluoroscopic, computed tomography, and radiation therapy simulators, shall be tested annually. ~~Self-calibrating~~Self-calibrating bone densitometry systems are exempt from this requirement. Mammography units shall meet the requirements of Part V.

4.2.16.1.3.3 Veterinary facilities are required to have equipment performance tests performed at the time of installation, every five (5) years, and at any time the Department deems necessary.

4.2.16.1.4 On any unit expected to remain at a facility for more than thirty (30) calendar days. If a unit is expected to remain at a facility for less than thirty (30) calendar days, the manufacturer's specified testing must be performed, at a minimum, prior to patient use. Mammography units shall meet the requirements of Part V.

4.2.16.2 The darkroom shall be light tight to the dark-adapted eye and use proper safelighting such that a film exposed to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

4.2.16.3 If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:

4.2.16.3.1 Be positioned properly~~,~~ (i.e., tube side facing the right direction, and grid centered to the central ray~~,~~).

4.2.16.3.2 If of the focused type, be of the proper focal distance for the source-to-image receptor distance (SID's) being used.

4.2.16.4 Repeat Analysis.

4.2.16.4.1 Each registrant shall establish a repeat analysis program. An analysis of repeats shall include, at a minimum, the overall repeat rate and the causes for the repeats.

4.2.16.4.2 The repeat analysis shall be done at least quarterly. Records shall be maintained for two (2) years or until the next Department inspection, whichever is later.

4.2.16.4.3 Facilities with a single operator may document reasons for repeats on the patient log in lieu of a repeat analysis rate.

4.2.16.4.4 Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.17 X-ray Film Processing. Each installation using a radiographic x-ray system and using analog imaging systems (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

4.2.17.1 Manual Film Processing Systems.

4.2.17.1.1 Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

4.2.17.1.2 A dedicated darkroom thermometer shall be used. The thermometer shall be used to adjust the film processing time according to solution temperature.

4.2.17.1.3 A dedicated darkroom timer with an adjustable preset function shall be used. The timer shall be used to adjust film processing time according to solution temperature.

4.2.17.1.4 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval as recommended by the chemical manufacturer shall be used.

4.2.17.1.5 Safelight. If a safelight is used, it shall be adequate for the film speed(s) ~~and the darkroom operating procedures~~ used to prevent fogging of unprocessed film.

4.2.17.1.6 The temperature of solutions in the tanks shall be maintained within the range of 60°-F to 80°-F (16°-C to 27°-C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

TIME TEMPERATURE CHART

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½
20.6	69	4 ½
20.0	68	5
19.4	67	5
18.9	66	5 ½
18.3	65	6
17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

4.2.17.1.7 Radiographs shall not be "sight developed."

4.2.17.2 Automated Processors and Other Closed Processing Systems.

4.2.17.2.1 The temperature of film processing chemicals shall be appropriate for the type of film(s) being processed at the film transport speed selected.

4.2.17.2.2 The film processing chemicals used and their replenishing rate (if applicable) shall be appropriate for the film transport speed selected.

4.2.17.2.3 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval recommended by the chemical manufacturer shall be used.

4.2.17.2.4 Safelight. If a safelight is used, it shall be adequate for the film speed(s) ~~and the darkroom operating procedures~~ used to prevent fogging of unprocessed film.

4.2.17.2.5 Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time *
°C	°F	Seconds
35	95	20
34	94	21
34	93	22
33	92	23
33	91	24
32	90	25

*Immersion time only, no crossover time included.

4.2.17.2.6 The specified developer temperature shall be available.

4.2.17.2.7 The sensitometric performance of an automatic processor shall be equivalent to other operating processor models set up to meet the above developer temperature and immersion time specifications. This is determined by processing identically exposed film through each model and comparing the results.

4.2.17.2.8 Densitometric and sensitometric performance testing.

4.2.17.2.8.1 Densitometric and sensitometric performance testing of the processor is required of facilities that process more than two hundred fifty (250) films per week.

4.2.17.2.8.2 Control limits shall be established for each parameter monitored. Provisions for correctable action shall be undertaken whenever the pre-established control limits are exceeded.

4.2.17.2.8.3 Documentation of testing must be maintained for at least two (2) years or until the next Department inspection, whichever is later.

4.2.17.2.8.4 Facilities processing more than two hundred fifty (250) films per day are required to perform this testing on each day that examinations are performed before any clinical films are processed that day.

4.2.17.2.8.5 Facilities that operate twenty-four (24) hours per day must perform the required testing once each day.

4.2.17.2.8.6 Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.17.2.9 Records of processor maintenance shall be kept for at least two (2) years or until the next Department inspection, whichever is later.

4.2.17.3 Other Requirements.

4.2.17.3.1 Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

4.2.17.3.2 Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

4.2.17.3.3 Film cassettes and intensifying screens ~~shall be inspected in accordance with the facility's approved procedures and~~ shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of this periodic inspection and cleaning must be maintained for at least two (2) years or until the next Department inspection, whichever is later.

4.2.17.4 Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.

4.2.17.5 Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

RHB 4.3. General Requirements for all Diagnostic X-ray Systems.

All diagnostic x-ray systems shall meet the following requirements.

4.3.1 Warning Label. The control panel containing the main power switch shall bear the warning statement: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

4.3.1.1 The warning label shall be legible and its view unobstructed.

4.3.2 Battery Charge Indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate that the battery is adequately charged.

4.3.3 Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of ~~1~~one meter (1 m) in any direction from the source shall not exceed ~~100~~one hundred milliRoentgen (100 mR) in one (1) hour when the ~~X ray~~x-ray tube is operated at its maximum technique factors.

4.3.4 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the ~~X ray~~x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of ~~2~~two milliRoentgen (2 mR) per hour at five ~~(5)~~ centimeters (5 cm) from any accessible surface of the diagnostic source assembly, with the beam limiting device fully open.

4.3.5 Beam Quality. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an ~~X-ray~~x-ray tube potential that is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (kVp)	Measured Potential (kVp)	Specified Dental Systems (mm Al)	All other Diagnostic (mm Al)
30 to 50	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

4.3.5.1 Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

4.3.5.2 For capacitor energy storage equipment, compliance with RHB 4.3.5 shall be determined with the maximum quantity of charge per exposure.

4.3.5.3 The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

4.3.5.4 All intraoral dental units manufactured after December 1, 1980, shall have at least ~~1.5~~one and one-half millimeters (1.5 mm) aluminum equivalent filtration permanently installed in the useful beam.

4.3.6 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RHB 4.3.5 is in the useful beam for the given kVp which has been selected.

4.3.7 Multiple Tubes. Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure.

4.3.7.1 This indication shall be on both the ~~X-ray~~x-ray control and at or near the tube housing assembly.

4.3.8 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the ~~X-ray~~x-ray system.

4.3.9 Technique Indicators.

4.3.9.1 The technique factors, whether manual or automatic exposure control, shall be indicated before the exposure begins. This requirement may be met by permanent markings on equipment having fixed technique factors.

4.3.9.2 Technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

4.3.9.3 The x-ray control shall provide visual indication of the production of x-rays.

4.3.9.4 X-ray systems utilizing arbitrary number or letter designators for kVp, time and milliAmperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.

4.3.10 Focal Spot Indication. The focal spot shall be denoted in such a manner and area as to be easily seen on the tube housing.

4.3.11 Mechanical Timers. Use of mechanical timers is prohibited.

4.3.12 Imaging Systems other than Screen/Film. The provisions of this ~~p~~Part are in addition to, and not in substitution for, applicable provisions of ~~these~~this regulation~~s~~.

4.3.12.1 Users of digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital imaging acquisition system. Records documenting adherence to this protocol shall be kept for at least two (2) years or until the next Department inspection, whichever is later.

4.3.12.2 The manufacturer's current operating manual shall be available for Departmental review.

RHB 4.4. Shielding.

4.4.1 Shielding Plan Required.

4.4.1.1 Each registrant and/or applicant shall ensure that ~~P~~prior to construction of a new facility, modification, or renovation of an existing x-ray facility, or replacement of an x-ray machine, the floor plans and equipment arrangement ~~shall be~~are reviewed by a Class III, Class IV, Class VII, Class VIII, or Class IX vendor and submitted to the Department for review and acceptance. Notification shall be made on the current version of the form provided by the Department and shall include shielding review fees as required by RHB 2.3.2.

4.4.1.2 A shielding plan shall be required for any space utilized as a radiation area for a period of greater than ~~five (5)~~four (4) consecutive days.

4.4.1.3 A shielding plan shall be required when the parameters, as required by Appendix B of this Part, of the original shielding plan change to an extent so as to render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class VII, Class VIII, or Class IX vendor.

4.4.2 Equipment Replacement.

4.4.2.1 A shielding plan is not required upon the replacement of an existing x-ray ~~machine,~~ control~~,~~ or generator with like equipment and when there are no other changes which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, ~~Class V,~~ Class VII, Class VIII, or Class IX vendor. The appropriate vendor shall notify the Department ~~regarding~~within thirty (30) calendar days of such replacement. ~~A~~ Notification shall be made on the current version of the form ~~shall be~~ provided by the Department ~~for this notification~~ and shall be exempt from RHB 2.3.2.

4.4.2.2 A shielding plan shall be required when a facility replaces an existing x-ray ~~machineor~~ system. A shielding plan shall also be required when an x-ray control or generator is replaced with ~~a unit~~ components with increased capabilities which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, ~~Class V,~~ Class VII, Class VIII, or Class IX vendor, or when the original shielding plan is not available.

~~4.4.2.3 A shielding plan shall be required when the parameters of the original shielding plan change to an extent so as to render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor.~~

4.4.3 X-ray equipment shall not be installed or operated before a shielding plan for the unit has been reviewed and accepted by the Department. In addition, x-ray equipment shall be installed according to the accepted shielding plan. Deviations shall be documented in accordance with RHB 4.4.6.3 and 4.4.7.2.

4.4.4 Shielding Plan Requirements.

4.4.4.1 The registrant shall submit plans and a report, including any recommendations and all basic assumptions used, from the vendor to the Department. Applicable fees shall be submitted in accordance with RHB 2.3.2. In order for the Department to accept the submitted shielding plan, the information listed in Appendix B shall be submitted. The design considerations listed in Appendix C shall be followed.

4.4.4.2 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to ~~assure~~ensure compliance with RHB 3.3, RHB 3.4, and RHB 3.5. The requirement shall be deemed to be met if the thickness of such barriers is equivalent to the thickness as computed in accordance with the current version of the appropriate National Council of Radiation Protection and Measurements~~,~~ Reports as deemed by the Department~~Number 147, "Structural Shielding Design for Medical X-ray Imaging Facilities;" the National Council of Radiation Protection and Measurements, Report Number 145, "Radiation Protection in Dentistry;" the National Council of Radiation Protection and Measurements, Report Number 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," or an equivalent reference~~.

4.4.4.3 All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 2.13 meters above the floor.

4.4.4.4 Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

4.4.4.5 The operator's station at the control shall be behind a protective barrier either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation that has been scattered only once. The operator's station shall meet all applicable requirements of Appendix C of this Part.

4.4.4.6 Mobile and portable x-ray systems used in conjunction with a permanently installed cassette holder shall be considered a stationary radiographic system and shall meet the requirements for such an installation.

4.4.5 The acceptance of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of ~~these~~this regulation~~s~~.

4.4.6 Area Surveys. The registrant shall have a radiation area survey performed by a Class ~~V~~III, Class IV, Class VII, Class VIII, or Class IX vendor, registered with the Department.

4.4.6.1 The survey shall be submitted to the Department for review and shall include a scale drawing of the room indicating the composition of the walls, floor, ceiling, windows, and doors, and the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided. If a film bin is used, ~~T~~the location and composition of the film bin shall also be included, if applicable. The survey shall include an evaluation of the adequacy of each protective barrier to include the ceiling and the floor, the operator's location, and if film is used, the film storage area~~, if appropriate~~. The survey shall include the date performed, the legible signature of the person performing the survey, and a certification that the shielding is adequate.

4.4.6.2 A copy of the radiation area survey shall be submitted to the Department within thirty (30) calendar days after installation of the x-ray equipment. The survey shall be submitted along with the completed, current version of forms provided by the Department.

4.4.6.3 Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy.

4.4.6.4 The Department may determine that a survey is not required for some installations.

4.4.7 ~~"~~As-built~~"~~ Drawings.

4.4.7.1 ~~Within 30 days a~~After construction and installation are complete, the facility shall ensure that ~~"~~as-built~~"~~ drawings are submitted to the Department. The drawings ~~must~~shall indicate the composition of the walls, floor, ceiling, windows, and doors. The drawings ~~must also~~shall indicate the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided, as well as the location and composition of the film bin, if present.

4.4.7.2 A copy of the as-built drawing shall be submitted to the Department within thirty (30) calendar days after the date of installation of the x-ray equipment. The as-built drawing shall include the legible signature of the person submitting the drawing and the date it is submitted. The as-built drawings shall be submitted along with the completed, current version of forms provided by the Department.

~~4.4.7.2~~4.4.7.3 Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy by a Class III, Class IV, Class VII, Class VIII, or Class IX vendor.

4.4.8 Bone Density, ~~And~~ Mammography, and Transportable Installations.

4.4.8.1 Bone Density and Mammography Installations.

4.4.8.1.1 Prior to installation of new or replacement equipment:

4.4.8.1.1.1 A shielding plan shall be submitted to the Department for review and acceptance or;

4.4.8.1.21.2 A written request shall be made by a Class VIII, Class VII, or Class IX vendor registered with the Department to perform a post-install survey in lieu of a shielding plan. All provisions of RHB 4.4.6 apply.

4.4.8.1.31.3 Notification shall be made on the current version of forms provided by the Department. Applicable fees shall be submitted in accordance with RHB 2.3.2.

4.4.8.2 Transportable X-ray Installations.

4.4.8.2.1 When transportable x-ray equipment is installed in the same location for thirty (30) calendar days, an area survey shall be performed in accordance with RHB 4.4.6.

4.4.8.2.2 Notification shall be made on the current version of forms provided by the Department. Applicable fees shall be submitted in accordance with RHB 2.3.2.

4.4.9 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

4.4.9.1 A copy of the shielding plan, as required by RHB 4.4,

4.4.9.2 A copy of the Department's acceptance letter, and

4.4.9.3 A copy of the area survey or "as-built" drawing, as required by RHB 4.4.6 or 4.4.7.

RHB 4.5. Intraoral Dental Radiographic Installations Systems.

In addition to the applicable provisions of RHB 4.3this regulation, the requirements of RHB 4.5 apply to x-ray equipment and associated facilities used for dental radiography this Part apply to all stationary, transportable, mobile, portable, and hand-held dental systems.

4.5.1 Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance, to not less than eighteen (18) centimeters (18 cm).

4.5.2 Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that:

4.5.2.1 The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7seven centimeters (7 cm).

4.5.2.2 An open-ended Position Indication Device (PID) shall be used, and shall provide the same degree of protection as the housing. Pointed PIDs shall not be used.

4.5.2.3 The operator shall position the end of the PID as close as practicable to the skin of the patient.

4.5.3 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

4.5.3.1 It shall not be possible to make an exposure when the timer is set to a "zero (0)" or "off" position if either position is provided.

4.5.3.2 Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "~~Z~~zero (0).".~~.~~

4.5.3.3 Timer reproducibility. The average exposure period ($\overline{T}$) shall be greater than or equal to five (5) times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four (4) timer tests are performed: $\overline{T} \geq 5$ (Tmax - Tmin).

4.5.4 X-ray Control.

4.5.4.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half ~~(1/2)~~ second (0.5 s) or less.

4.5.4.2 Each x-ray control shall be located in such a way as to meet the following requirements:

4.5.4.2.1 Stationary and transportable x-ray systems installed after July 1, 1993, shall have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

4.5.4.2.2 For stationary and transportable x-ray systems without a protected area and installed before July 1, 1993, the exposure switch shall be such that the operator shall stand at least six feet (6 ft) away from the tube housing and out of the direct beam.

4.5.4.2.3 For mobile and portable x-ray systems, the exposure switch shall meet the requirements of 4.5.4.2.2.

4.5.4.2.4 Visual and/or audible indication, observable at or from the operator's protected position, shall be provided whenever x-rays are initiated and terminated.

4.5.5 Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5$ (Emax - Emin).

4.5.6 Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the maximum rating, the average ratios of exposure to the indicated milliAmpere-seconds product obtained at any two (2) tube current settings shall not differ by more than 0.10 times their sum: $[X1 - X2] < 0.10 (X1 + X2)$ where X1 and X2 are the average mR/mAs values obtained at each of the two (2) tube current settings.

4.5.7 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by the manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%) of the indicated value.

4.5.8 kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than fifty kilovoltage peak (50 kVp) shall not be used to make diagnostic dental radiographs of humans.

4.5.9 Multiple Tubes. Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the ~~X-ray~~x-ray control and at or near the tube housing which has been selected.

4.5.10 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the ~~X-ray~~x-ray system.

4.5.11 Structural Shielding.

4.5.11.1 Dental rooms containing x-ray machines shall be provided with primary and secondary barriers for all areas struck by the useful beam, as required by RHB 4.4.4.2.

4.5.11.2 When dental x-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas.

4.5.11.3 Pass throughs between adjacent areas shall be securely interlocked in a functional, permanent manner.

4.5.11.4 Shielding plans are not required for intraoral dental radiographic installations.

4.5.12 Operating Procedures.

4.5.12.1 Neither the dentist nor his or her assistant shall hold patients or films during exposure, nor shall any individual be regularly used for this service.

4.5.12.2 The tube housing and the PID shall not be hand-held during an exposure.

4.5.12.3 Dental fluoroscopy without image intensification shall not be used.

4.5.12.4 ~~Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25 millimeter lead equivalent to cover the gonadal area unless the patient refuses~~Thyroid shielding shall be utilized for patients when it will not interfere with examination.

4.5.12.5 Only persons required for the radiographic procedure shall be in the radiographic room during exposures.

4.5.13 Hand-Held X-ray System - Intraoral Equipment

4.5.13.1 Any hand-held x-ray systems for intraoral use shall be equipped with a non-removable backscatter shield of not less than 0.25 millimeter lead equivalent and 15.2 centimeters (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indicating device.

4.5.13.2 The facility shall maintain documentation that each operator has completed training as specified by the manufacturer.

4.5.13.3 The facility shall adopt and follow protocols provided by the manufacturer and approved by the Department regarding the safe operation of the device.

4.5.13.4 When operating a hand-held x-ray system for intraoral use, operators shall wear a 0.25 millimeter lead equivalent apron.

4.5.13.5 If the operator has difficulty in holding the hand-held x-ray system stationary during the exposure, the operator shall use a stand to immobilize.

4.5.13.6 The registrant shall secure the hand-held x-ray system from unauthorized removal or use.

RHB 4.6. Extraoral Dental Radiographic ~~Installations~~Systems.

In addition to the applicable provisions of this regulation, the requirements of this Part apply to all cephalometric, panoramic and dental computed tomography (CT) systems.

4.6.1 Cephalometric Installations

4.6.1.1 Where applicable, ~~A~~all provisions of RHB 4.4 and 4.7 apply.

4.6.1.2 The radiographic field shall be restricted to the area of the image receptor.

4.6.2 Panoramic Installations

4.6.2.1 Where applicable, ~~A~~all provisions of RHB 4.5 apply, except 4.5.1 and 4.5.2.1.

4.6.2.2 Shielding plans are not required for Panoramic Installations.

4.6.3 Dental CT

~~4.6.3.1~~ Where applicable, all provisions of RHB 4.4 and 4.11.5 apply~~, except RHB 4.11.2.3~~.

~~4.6.4 Hand-Held Intraoral Equipment~~

~~4.6.4.1 The hand-held x-ray system shall be equipped with a non-removable backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.~~

~~4.6.4.2 The facility shall maintain documentation that each operator has completed training as specified by the manufacturer, and approved by the Department.~~

~~4.6.4.3 The facility shall adopt and follow protocols provided by the manufacturer and approved by the Department regarding the safe operation of the device.~~

~~4.6.4.4 When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 mm lead equivalent apron and thyroid collar.~~

~~4.6.4.5 If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.~~

~~4.6.4.6 The registrant shall secure the hand-held device from unauthorized removal or use.~~

RHB 4.7. Medical Radiographic Systems.

In addition to the applicable provisions of this regulation, ~~T~~the requirements of this Part apply to x-ray equipment and associated facilities used for radiography with stationary and transportable radiographic systems other than intraoral dental, fluoroscopic, computed tomography (CT), mammography, or veterinary medical systems.

4.7.1 Stationary and Tranportable General Purpose Units. In addition to the other provisions of this ~~p~~Part, all stationary and transportable general purpose units must also meet the following requirements:

4.7.1.1 Means shall be provided for independent stepless adjustment of at least two (2) dimensions of the x-ray field.

4.7.1.2 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.1.3 Means shall be provided for visually defining the perimeter of the ~~X-ray~~x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the ~~X-ray~~x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the ~~X-ray~~x-ray beam.

4.7.1.4 The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.7.1.5 Indication of field size dimensions and SID~~'~~s used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in ~~X-ray~~x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.7.1.6 The beam limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.7.1.7 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within ~~2~~two percent (2%) of the SID.

4.7.2 X-ray Systems Designed ~~for One Image Receptor Size~~with a fixed collimator. Radiographic equipment designed ~~for only one image receptor size~~with a fixed collimator at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.7.3 Special Purpose X-ray Systems. In addition to the other provisions of this Part, all special purpose x-ray systems shall also meet the following requirements:

4.7.3.1 Means shall be provided to limit the x-ray field in the plane of the image receptor such that the x-ray field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.3.2 Means shall be provided to align the center of the ~~X-ray~~x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

4.7.3.3 The above RHB 4.7.3.1 and 4.7.3.2 may be met with a system that meets the requirements for a general purpose ~~X-ray~~x-ray system as specified in ~~Part~~ RHB 4.7.3~~, above~~ or, when alignment means are also provided, may be met with either:

4.7.3.3.1 An assortment of removable, fixed aperture, beam limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

4.7.3.3.2 A beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

4.7.4 Radiation Exposure Control Devices.

4.7.4.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero (0)" or "off" position if either position is provided.

4.7.4.2 X-ray Control.

4.7.4.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time (~~"deadman"~~dead man's switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.7.4.2.2 Stationary and transportable x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure to include the requirements of Appendix C.

4.7.4.2.3 The ~~X-ray~~x-ray control shall provide visual indication observable at or from the operator protected position whenever ~~X-ray~~x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.7.4.2.4 The ~~X-ray~~x-ray control shall be so placed that the operator can view the patient during any exposure and still stand in a protected area.

4.7.4.2.5 Automatic Exposure Controls. When an automatic exposure control is provided:

4.7.4.2.5.1 Indication shall be made on the control panel when this mode of operation is selected;

4.7.4.2.5.2 If the x-ray tube potential is equal to or greater than fifty kilovoltage peak (50 kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;

4.7.4.2.5.3 The minimum exposure time for all equipment other than that specified in RHB 4.7.4.2.5.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five milliAmpere-seconds (5 mAs), whichever is greater;

4.7.4.2.5.4 Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than sixty kilowatt-seconds (60 kWs) per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than six hundred milliAmpere-seconds (600 mAs) per exposure except that, when the x-ray tube potential is less than fifty kilovoltage peak (50 kVp), the product of x-ray tube current and exposure time shall be limited to not more than two thousand milliAmpere-seconds (2000 mAs) per exposure; and

4.7.4.2.5.5 A visible signal shall indicate when an exposure has been terminated at the limits required by RHB 4.7.4.2.5.4, and manual resetting shall be required before further automatically timed exposures can be made.

4.7.4.2.6 Timer Reproducibility. With a timer setting of ~~0.5~~one-half second (0.5 s) or less, the average exposure period ($\overline{T}$) shall be greater than or equal to five (5) times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four (4) timer tests are performed: $\overline{T} \geq 5$ (Tmax - Tmin).

4.7.5 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5$ (Emax - Emin).

4.7.6 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%) of the indicated value.

4.7.7 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of ~~40~~forty percent to ~~100~~one hundred percent (40% to 100%) of the maximum rated.

4.7.7.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two (2) tube current settings.

4.7.7.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two (2) mAs selector settings shall not differ by more than 0.10 times their sum. This is : $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.7.7.3 Measuring Compliance. Determination of compliance shall be based on four (4) exposures, at each of the two (2) settings. The two (2) settings may include any two (2) focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two (2) settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.7.8 Light Localization.

4.7.8.1 When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than ~~15~~fifteen footcandles (15 fc) at ~~100~~one hundred centimeters (100 cm) or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. ~~Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.~~

4.7.8.2 Exemptions to RHB 4.7.8.1 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet ~~these~~this regulation~~s~~, and the Department determines that patient safety or image quality is not compromised.

4.7.9 Certified Systems. In addition to the requirements of these rules, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified pursuant to U.S. Food and Drug Administration Regulation 21 CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" in any manner that could cause the installations or the components to fail to meet the requirements of the applicable ~~p~~Parts of the standards specified in 21 CFR 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, Food and Drug Administration.

4.7.10 Maintenance Schedule. On all equipment containing components certified pursuant to U.S. Food and Drug Administration Regulation 21 CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products," the registrant shall perform, or cause to be performed, the schedule of maintenance provided by the manufacturer pursuant to 21 CFR 1020.30(h)(l)(ii). A log book of such maintenance shall be maintained for inspection by the Department.

4.7.11 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within ~~2~~two percent (2%).

4.7.12 Positive Beam Limitation. For units having an operable positive beam limitation (PBL) system, the following requirements must be met:

4.7.12.1 Neither the length nor width of the x-ray field shall differ from the corresponding image receptor dimensions by more than ~~3~~three percent (3%) of the SID; and

4.7.12.2 The sum of the length and width differences, without regard to sign, shall not exceed ~~4~~four percent (4%) of the SID.

4.7.12.3 The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of ~~100~~one hundred centimeters (100 cm) shall be equal to or less than ~~5~~five centimeters by ~~5~~five centimeters (5 cm x 5 cm).

4.7.12.4 The positive beam limitation system shall be designed such that if a change in image receptor does not cause automatic return to positive beam limitation function and any change of image receptor size or SID must cause the automatic return.

4.7.12.5 PBL compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

4.7.13 The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device has been properly used or if evidence of collimation has been shown on at least three (3) sides or three (3) corners of the film, (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

4.7.14 Minimum Field Size. The minimum field size at an SID of one hundred centimeters (100 cm) shall be equal to or less than 5five centimeters by 5five centimeters (5 cm x 5 cm).

RHB 4.8. Mobile and Portable Radiographic EquipmentSystems.

In addition to the applicable provisions of this regulation, the requirements of this Part apply to all mobile and portable radiographic systems.

4.8.1 All provisions of RHB 4.7.4 through 4.7.14 apply, except 4.7.12 and 4.7.4.2.2.

4.8.2 Means shall be provided for independent stepless adjustment of at least two (2) dimensions of the x-ray field.

4.8.3 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.8.4 Means shall be provided for visually defining the perimeter of the X-rayx-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-rayx-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-rayx-ray beam.

4.8.5 If provided, the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.8.6 If collimator indications are provided, the indications shall be such that aperture adjustments result in X-rayx-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.8.7 Means shall be provided to measure SIDs, and shall be accurate to within two percent (2%).

4.8.8 Mobile and portable x-ray systems which are used in a single location for a period of greater than fivefour (4) consecutive days shall be considered a stationary radiographic system and shall meet the requirements of RHB 4.4.

4.8.9 Mobile and portable x-ray systems which are used at multiple locations shall be provided with an adequate protective barrier or protective apron for the operator and with a method of control which will

permit the operator to be at least ~~6~~six feet (6 ft) from the tube head and the nearest edge of the useful beam during exposures.

~~4.8.10 Personnel monitoring shall be required for all operators of mobile and portable x-ray systems.~~

~~4.8.11~~4.8.10 Tube stands. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

~~4.8.12~~4.8.11 All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than ~~30~~thirty centimeters (30 cm).

RHB 4.9. Fluoroscopic X-ray Systems.

In addition to the applicable provisions of this regulation, ~~T~~the requirements of this ~~p~~Part apply to all stationary, transportable, mobile, portable, and C-Arm type fluoroscopes. All fluoroscopic x-ray systems shall be image intensified or direct digital receptor, and meet the following requirements.

4.9.1 Source-to-Skin Distance (SSD). The SSD shall not be less than:

4.9.1.1 ~~t~~Thirty-eight ~~(38)~~ centimeters (38 cm) on stationary and transportable fluoroscopic systems manufactured on or after August 1, 1974~~.~~;

4.9.1.2 ~~t~~Thirty-five and one half ~~(35.5)~~ centimeters (35.5 cm) on stationary and transportable fluoroscopic systems manufactured prior to August 1, 1974~~.~~;

4.9.1.3 ~~t~~Thirty ~~(30)~~ centimeters (30 cm) on all mobile and portable fluoroscopes~~,~~; and

4.9.1.4 ~~t~~Twenty ~~(20)~~ centimeters (20 cm) for mobile fluoroscopes used for specific surgical procedures. If removable, the appropriate spacer shall be replaced after the specific surgical procedure application is complete.

4.9.1.4.1 For stationary, transportable, mobile, or portable fluoroscopes manufactured on or after June 10, 2006, having a maximum source-to-image receptor distance of less than forty-five centimeters (45~~)~~ cm), means shall be provided to limit the source-to-skin distance (SSD) to not less than nineteen centimeters (19~~)~~ cm). Such systems shall be labeled for extremity use only.

4.9.1.4.2 For those systems intended for specific surgical applications that would be prohibited at the source-skin distance specified above, provisions may be made for operation at shorter source-skin distances but in no case less than ten centimeters (10~~)~~ cm).

4.9.2 Limitation of Useful Beam.

4.9.2.1 Primary Barrier

4.9.2.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.9.2.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.9.2.2 X-ray field. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than ~~3~~three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than ~~4~~four percent (4%) of the SID. In addition:

4.9.2.2.1 Means shall be provided to permit further limitation of the x-ray field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than ~~300~~three hundred square centimeters (300 cm^2) shall be provided with means for stepless adjustment of the x-ray field;

4.9.2.2.2 All equipment with a fixed SID and a visible area of ~~300~~three hundred square centimeters (300 cm^2) or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to ~~125~~one hundred twenty-five square centimeters (125 cm^2) or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of ~~5~~five centimeters by ~~5~~five centimeters (5 cm x 5 cm) or less.

4.9.2.2.3 For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.9.2.2.4 Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

4.9.2.2.5 For uncertified image-intensified fluoroscopic equipment with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than ~~20~~twenty centimeters (20 cm) table top to the film plane distance.

4.9.2.3 Spot film devices which are certified components shall meet the following additional requirements.

4.9.2.3.1 Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

4.9.2.3.2 Spot film field size. Neither the length nor the width of the x-ray field in the spot film plane shall exceed the image receptor by more than ~~3~~three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than ~~4~~four percent (4%) of the SID.

4.9.2.3.3 It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, ~~5~~five centimeters by ~~5~~five centimeters (5 cm x 5 cm).

4.9.2.3.4 The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within ~~2~~two percent (2%) of the SID.

4.9.2.3.5 On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4.9.3 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.4 Exposure Rate Limits. Entrance Exposure Rate Allowable Limits.

4.9.4.1 For equipment manufactured prior to May 19, 1995:

4.9.4.1.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~10~~ten Roentgens (10 R)(2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.1.1 During recording of fluoroscopic images, or

4.9.4.1.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~5~~five Roentgens (5 R)(1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special~~s~~ means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.1.2 Equipment without automatic exposure rate control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~5~~five Roentgens (5 R)(1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.2.1 During recording of fluoroscopic images, or

4.9.4.1.2.2 When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2 For equipment manufactured after May 19, 1995:

4.9.4.2.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~10~~ten Roentgens (10 R)(2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.1.1 During recording of fluoroscopic images, or

4.9.4.2.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~20~~twenty Roentgens (20 R)(5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2.2 Equipment without automatic exposure control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~5~~five Roentgens (5 R)(1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.2.1 During recording of fluoroscopic images, or

4.9.4.2.2.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~20~~twenty Roentgens (20 R)(5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.3 Compliance with RHB 4.9.4.1 and 4.9.4.2 shall be determined as follows:

4.9.4.3.1 If the source is below the x-ray table, the exposure rate shall be measured ~~1~~one centimeter (1 cm) above the tabletop or cradle.

4.9.4.3.2 If the source is above the x-ray table, the exposure rate shall be measured at ~~30~~thirty centimeters (30 cm) above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

4.9.4.3.3 In a C-arm type of fluoroscope, the exposure rate shall be measured ~~30~~thirty centimeters (30 cm) from the input surface of the fluoroscopic imaging assembly.

4.9.4.3.4 For a variable SID C-arm type of fluoroscope the exposure rate shall be measured ~~30~~thirty centimeters (30 cm) from the input surface of the fluoroscopic imaging assembly, with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.

4.9.4.3.5 In a C-arm type of fluoroscope having an SID less than ~~45~~forty-five centimeters (45 cm), the exposure rate shall be measured at the minimum SSD.

4.9.4.3.6 In a lateral type fluoroscope, the exposure rate shall be measured at a point ~~15~~fifteen centimeters (15 cm) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than ~~15~~fifteen centimeters (15 cm) to the centerline of the x-ray table.

~~4.9.4.3.7 Periodic measurement of entrance exposure rate shall be performed for both maximum and typical values in each mode used clinically annually, and after any maintenance of the system which~~

~~might affect the exposure rate. Results of the most recent measurements in each mode used clinically shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and be included in the records required in RHB 4.2.16.1. The measurement results shall be stated in Roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.~~

~~4.9.4.3.8~~4.9.4.3.7 Conditions of measurement of maximum entrance exposure rate are as follows:

~~4.9.4.3.8.1~~4.9.4.3.7.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

~~4.9.4.3.8.2~~4.9.4.3.7.2 The kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate.

~~4.9.4.3.8.3~~4.9.4.3.7.3 The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system.

~~4.9.4.3.8.4~~4.9.4.3.7.4 Testing shall be performed in each mode used clinically.

~~4.9.4.3.9~~4.9.4.3.8 Conditions of measurement of typical entrance exposure rate are as follows:

~~4.9.4.3.9.1~~4.9.4.3.8.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

~~4.9.4.3.9.2~~4.9.4.3.8.2 The kVp and mA shall be typical of clinical use of the x-ray system.

~~4.9.4.3.9.3~~4.9.4.3.8.3 The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliAmpere and/or kiloVoltage typical of the use of the x-ray system.

~~4.9.4.3.9.4~~4.9.4.3.8.4 Testing shall be performed in each mode used clinically.

4.9.5 Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, shall not exceed ~~2~~two milliRoentgen (2 mR)(0.516 uC/kg) per hour at ~~10~~ten centimeters (10 cm) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.9.5.1 Measuring Compliance of Barrier Transmission.

4.9.5.1.1 The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of ~~100~~one hundred square centimeters (100 cm^2) with no linear dimension greater than ~~20~~twenty centimeters (20 cm).

4.9.5.1.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned ~~30~~thirty centimeters (30 cm) above the tabletop.

4.9.5.1.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than ~~30~~thirty centimeters (30 cm).

4.9.5.1.4 Compression devices shall be removed from the useful beam during the measurement.

4.9.6 Indication of Potential and Current. During fluoroscopy and cinefluoroscopy the kV and mA shall be continuously indicated.

4.9.7 Fluoroscopic Timer.

4.9.7.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.

4.9.7.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.8 Control of Scattered Radiation.

4.9.8.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.9.8.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.9.8.2.1 Is at least ~~120~~one hundred twenty centimeters (120 cm) from the center of the useful beam, or

4.9.8.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, ~~B~~bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RHB 4.2.9.2.

4.9.8.3 The Department may grant exemptions to RHB 4.9.8.2.2 where a sterile field will not permit the use of the normal protective barriers. Automatic exemptions will be granted for fluoroscopic procedures listed in Appendix E.

4.9.9 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.9.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero (0)" or "off" position if either position is provided.

4.9.9.2 Timer Reproducibility. With a timer setting of one-half (0.5) second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to five (5) times the maximum exposure period (Tmax)

minus the minimum exposure period (Tmin) when four (4) timer tests are performed: $\overline{T} \geq 5$ (Tmax - Tmin).

4.9.9.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5$ (Emax - Emin).

4.9.10 Mobile and Portable fluoroscopic x-ray systems which are used in a single location for a period of greater than ~~five~~ four (4) consecutive days shall be considered a stationary fluoroscopic system, and shall meet all the requirements of RHB 4.4.

4.9.11 Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of RHB 4.9.2, 4.9.4, 4.9.5, and 4.9.7 provided that:

4.9.11.1 Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays, unless the procedure requires the presence of other individuals.

4.9.11.2 Systems which do not meet the requirements of RHB 4.9.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

4.9.12 Fluoroscopic Quality Assurance. In addition to the requirements of RHB 4.2.16, the fluoroscopic image resolution shall be tested as part of the quality assurance program. This shall be performed at least annually.

4.9.13 Vertical Fluoroscopic Imaging Systems.

4.9.13.1 SSD. The SSD shall not be less than ~~38~~thirty-eight centimeters (38 cm).

4.9.13.2 Limitation of Useful Beam. All provisions of RHB 4.9.2 apply.

4.9.13.3 Entrance Exposure Rates. All provisions of RHB 4.9.4 apply.

4.9.13.4 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.13.5 Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and mA shall be continuously indicated.

4.9.13.6 Fluoroscopic Timer.

4.9.13.6.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.

4.9.13.6.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.13.7 Operators shall remain in a protected area during exposures, or shall be protected by aprons of not less than 0.25 millimeter lead equivalent material.

4.9.13.8 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.13.8.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero (0)" or "off" position if either position is provided.

4.9.13.8.2 Timer Reproducibility. With a timer setting of one-half (0.5) second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to five (5) times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four (4) timer tests are performed: $\overline{T} \geq 5(\text{Tmax} - \text{Tmin})$.

4.9.13.8.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5(\text{Emax} - \text{Emin})$.

RHB 4.10. Bone Densitometry Systems.

In addition to the applicable provisions of this regulation, ~~T~~the requirements of this ~~p~~Part apply to all stationary, transportable, mobile, and portable x-ray bone densitometry systems.

4.10.1 Registration. All provisions of RHB 2.3 and 2.4 apply.

4.10.2 Shielding.

4.10.2.1 Stationary units. The registrant shall submit a shielding plan, as required by RHB 4.4, to the Department for review and acceptance.

4.10.2.2 Peripheral units are exempt from RHB 4.10.2.1.

4.10.3 Location. The bone densitometry system shall be placed in a controlled area. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter (1 m) from the patient and bone densitometry system during examination.

4.10.4 Administrative Requirements.

4.10.4.1 Personnel Monitoring. All provisions of RHB 3.12 and 3.22 apply.

4.10.4.2 Posting Requirements. All provisions of RHB 3.16.1, 4.2.7, 11.2.1, and ~~10.2.1~~11.2.3 apply.

4.10.4.3 Operators. All provisions of RHB 4.2.2 apply.

RHB 4.11. Computed Tomography (CT) X-ray Systems.

In addition to the applicable provisions of this regulation, the requirements of this Part apply to all stationary, transportable, and mobile CT X-ray systems.

4.11.1 Equipment Requirements.

4.11.1.1 Tomographic Plane Indication and Alignment.

4.11.1.1.1 For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

4.11.1.1.2 For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

4.11.1.1.3 If a device using a light source is used to satisfy the requirements of RHB 4.11.1.1.1 or 4.11.1.1.2, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions.

4.11.1.2 Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence ~~are~~shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

4.11.1.3 ~~Initiation of Operation.~~Beam-On and Shutter Status Indicators and Control Switches

4.11.1.3.1 The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

4.11.1.3.2 ~~Means shall be provided to require operator initiation of each individual scan or series of scans.~~ All emergency buttons or switches shall be clearly labeled as to their functions.

~~4.11.1.3.3 All emergency buttons/switches shall be clearly labeled as to their functions.~~

4.11.1.4 Termination of Exposure.

4.11.1.4.1 Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than ~~110~~one hundred ten percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

4.11.1.4.2 A visible signal shall indicate when the x-ray exposure has been terminated through the means required by RHB 4.11.1.4.1.

4.11.1.4.3 The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than one-half (0.5) second duration. ~~Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.~~

~~4.11.1.5 Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by RHB 4.3.3.~~

~~4.11.1.6~~4.11.1.5 Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985.

~~4.11.1.6.1~~4.11.1.5.1 The total error in the indicated location of the tomographic plane or reference plane shall not exceed ~~5~~five millimeters (5 mm).

~~4.11.1.6.2~~4.11.1.5.2 If the x-ray production period is less than one-half (0.5) second, the indication of x-ray production shall be actuated for at least one-half (0.5) second. Indicators at or near the gantry shall be ~~discernable~~discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

~~4.11.1.6.3~~4.11.1.5.3 The deviation of indicated scan increment versus actual increment shall not exceed to within ~~1~~one millimeter (1 mm) with any mass from ~~0~~zero to ~~100~~one hundred kilograms (0 to 100 kg) resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or ~~30~~thirty centimeters (30 cm), whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

4.11.1.5.4 Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

4.11.2 Facility Design Requirements.

4.11.2.1 The control panel and x-ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

4.11.2.2 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

4.11.2.3 Facilities designed with an open area in the control room that leads to the gantry shall mark this open area conspicuously ~~indicating~~and indicate not to stand or sit in this area during x-ray exposures.

4.11.2.4 Viewing Systems.

4.11.2.4.1 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

4.11.2.4.2 When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

4.11.3 ~~Dose Measurements and Spot Checks.~~Equipment Performance Tests and Routine Quality Control

4.11.3.1 ~~Dose Measurement.~~Equipment Performance Tests

4.11.3.1.1 ~~Dose measurements of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a Class IX Vendor.~~Equipment performance tests shall be performed by a Class IX vendor.

4.11.3.1.2 ~~Dose measurements of a CT x-ray system shall be performed at intervals specified by a Class IX Vendor and after any change or replacement of components which, in the opinion of the vendor could cause a significant change in the radiation output.~~Evaluation standards and tolerances shall be established by the Class IX vendor and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT x-ray system and shall include the required minimum criteria for performance tests provided by Appendix F.

4.11.3.1.3 The ~~M~~measurements of the radiation output of the CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated ~~or intercompared with a calibrated chamber~~ within the preceding two (2) years. ~~The calibration of such system shall be traceable to a national standard.~~

4.11.3.1.4 Records of equipment performance tests performed shall be maintained for inspection by the Department.

4.11.3.2 S~~pot Checks.~~Routine Quality Control (QC)

4.11.3.2.1 ~~Spot check procedures shall be developed by a Class IX vendor who specializes in diagnostic radiological physics.~~A routine QC program shall be developed by or have written approval by a Class IX vendor and include:

4.11.3.2.1.1 Instructions on performing routine QC;

4.11.3.2.1.2 Frequency and conditions of QC testing;

4.11.3.2.1.3 Acceptable tolerances for items evaluated; and

4.11.3.2.1.4 Daily use of a water equivalent phantom to evaluate CT number, noise, and artifacts.

4.11.3.2.2 ~~All spot checks shall be included in the calibration required by RHB 4.11.3.1, and otherwise at time intervals and system conditions specified by a Class IX Vendor.~~The CT operator shall have access to the QC program and the results of the most recent routine QC completed on the system.

4.11.3.2.3 ~~Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by RHB 4.11.3.1. The images shall be retained, until a new dose measurement is performed, in one of two forms as follows:~~Routine QC records shall be documented and maintained for inspection by the Department. Records shall be maintained for two (2) years or the next Department inspection, whichever is later.

~~4.11.3.2.3.1 Photographic copies of the images obtained from the image display view; and~~

~~4.11.3.2.3.2 Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.~~

4.11.4 Ancillary personnel who are not necessary for the safety of the patient shall not be present in the area of the CT unit while exposures are being made.

4.11.5 ~~CT units used in radiation therapy treatment planning are exempt from the requirements of RHB 4.11.3.1. All other provisions of RHB 4.11 apply.~~Cone Beam Computed Tomography (CBCT) Systems

4.11.5.1 The registrant shall follow QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer-provided QC recommendations, the registrant shall implement and document QC guidelines established by a Class IX vendor in accordance to nationally recognized guidelines or those recognized by the Department.

4.11.5.2 As applicable, all provisions of RHB 4.4 and 4.11 apply, except 4.11.2.4 and 4.11.3.2.1 through 4.11.3.2.2.

4.11.5.3 The minimum source-skin distance shall not be less than thirty centimeters (30 cm), except veterinary equipment.

4.11.5.4 Beam alignment. The x-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within two percent (2%) of the SID.

4.11.5.5 The registrant shall implement and document a policy addressing deviations from established protocols.

4.11.5.6 The following information shall be readily available to the CBCT operator:

4.11.5.6.1 Instructions on performing routine QC, including the use of the CBCT phantom(s);

4.11.5.6.2 A schedule of routine QC appropriate for the system;

4.11.5.6.3 Allowable variations set by the Class IX vendor, if required, for the indicated parameters; and

4.11.5.6.4 The results of at least the most recent routine QC completed on the system.

RHB 4.12. Veterinary ~~Radiographic~~ Systems.

In addition to the applicable provisions of this regulation, the requirements of this Part apply to all stationary, transportable, mobile, portable, and hand-held X-ray systems for veterinary use.

4.12.1 Administrative Requirements. All provisions of RHB 4.2 apply, except 4.2.2, 4.2.7, ~~4.2.10,~~ and 4.2.11. No person other than a licensed ~~practitioner~~veterinarian or an adequately trained individual, as required by RHB 4.12.22, shall use equipment emitting ionizing radiation for diagnostic purposes.

4.12.2 Radiation Protection. All provisions of RHB 4.2.9 apply, except 4.2.9.3.

4.12.3 Holding of Patients and Films. All provisions of RHB 4.2.12 apply. In addition:

4.12.3.1 Each human holder in a veterinary facility shall utilize protective apparel.

4.12.3.2 Each veterinary facility that holds patients shall provide personnel monitoring devices. If the human holder's hands are in or near the primary beam and lead gloves are not utilized, then ring badges shall also be provided and worn.

4.12.4 General Requirements. All provisions of RHB 4.3 and 4.4 apply.

4.12.5 Means shall be provided for independent stepless adjustment of at least two (2) dimensions of the x-ray field.

4.12.6 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.12.7 Means shall be provided for visually defining the perimeter of the ~~X-ray~~x-ray field. The total misalignment of the edges of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

4.12.8 The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.12.9 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in ~~X-ray~~x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.12.10 The beam-limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.12.10.1 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID.

4.12.10.2 Diaphragms or cones when provided for collimating the useful beam to the area of clinical interest shall meet the requirements of RHB 4.7.2.

4.12.10.3 Minimum Field Size. The minimum field size at an SID of one hundred centimeters (100 cm) shall be equal to or less than five centimeters by five centimeters (5 cm ~~X~~x 5 cm).

4.12.11 Radiation Exposure Control Devices.

4.12.11.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer has been set to a "zero (0)" or "off" position if either position is provided.

4.12.11.2 X-ray Control.

4.12.11.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time (~~"deadman"~~dead man's switch) except for exposures of one-half

(~~1/2~~0.5) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.12.11.2.2 The ~~X-ray~~x-ray control shall provide visual indication observable at or from the operator protected position whenever ~~X-ray~~x-ray are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.12.11.2.3 Timer Reproducibility. With a timer setting of one-half (0.5) second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to five (5) times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four (4) timer test are performed: $\overline{T} \geq 5$ (Tmax - Tmin).

4.12.12 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): $\bar{E} \geq 5$ (Emax - Emin).

4.12.13 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the ~~X-ray~~x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of ~~2~~two milliRoentgen (2 mR) per hour at five ~~(5)~~ centimeters (5 cm) from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

4.12.14 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%) of the indicated value.

4.12.15 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of ~~40~~forty percent to ~~100~~one hundred percent (40% to 100%) of the maximum rated.

4.12.15.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: [X1-X2] < 0.10 (X1+X2); where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two (2) tube current settings.

4.12.15.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two (2) mAs selector settings shall not differ by more than 0.10 times their sum. This is: [X1-X2] < 0.10 (X1+X2); where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.12.15.3 Measuring compliance. Determination of compliance shall be based on four (4) exposures, at each of the two (2) settings. These two (2) settings may include any two (2) focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two (2) settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.12.16 Light Localization.

4.12.16.1 When a light field is used to define the x-ray field, it shall provide an average illumination of not less than ~~15~~fifteen footcandles (15 fc) at ~~100~~one hundred centimeters (100 cm) or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

4.12.16.2 Exemptions to RHB 4.12.16.1 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet ~~these~~this regulation~~s~~.

4.12.17 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within ~~2~~two percent (2%).

4.12.18 Fluoroscopic X-ray Systems. Veterinary fluoroscopic x-ray systems shall meet the following requirements:

4.12.18.1 Limitation of Useful Beam.

4.12.18.1.1 Primary Barrier.

4.12.18.1.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.12.18.1.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.12.18.1.2 X-ray Field. The x-ray field produced by non-image intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

4.12.18.1.2.1 Means shall be provided for stepless adjustment of the field size;

4.12.18.1.2.2 The minimum field size at the greatest SID shall be equal to or less than ~~5~~five centimeters by ~~5~~five centimeters (5 cm x 5 cm).

4.12.18.1.2.3 For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than ~~3~~three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than ~~4~~four percent (4%) of the SID. In addition, means shall be provided to permit further limitation of the field.

4.12.18.2 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means shall be provided to permit completion of any single exposure of the series in process.

4.12.18.3 Barrier Transmitted Radiation Rate Limits.

4.12.18.3.1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall

not exceed ~~2~~two milliRoentgen (2 mR)(0.516 uC/kg) per hour at ~~10~~ten centimeters (10 cm) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.12.18.3.2 Measuring Compliance of Barrier Transmission.

4.12.18.3.2.1 The exposure rate due to transmission through the protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall be determined by measurements averaged over an area of ~~100~~one hundred square centimeters (100 cm^2) with no linear dimension greater than ~~20~~twenty centimeters (20 cm).

4.12.18.3.2.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned ~~30~~thirty centimeters (30 cm) above the tabletop.

4.12.18.3.2.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than ~~30~~thirty centimeters (30 cm).

4.12.18.4 Indication of Potential and Current. During fluoroscopy the kV and mA shall be continuously indicated.

4.12.18.5 Mobile Fluoroscopes. In addition to the other requirements of this Part, mobile fluoroscopes shall provide intensified imaging.

4.12.18.6 Control of Scattered Radiation.

4.12.18.6.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.12.18.6.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.12.18.6.2.1 Is at least ~~120~~one hundred twenty centimeters (120 cm) from the center of the useful beam, or

4.12.18.6.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apparel referred to in RHB 4.12.3.1.

4.12.19 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one (1) image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.12.20 Veterinary Computed Tomography X-ray Systems - Where applicable, all provisions of RHB 4.11 apply.

4.12.21 Veterinary Dental Systems - Where applicable, all provisions of RHB 4.5 and 4.6 apply.

4.12.22 ~~Operator Requirements.~~ Training Plan Requirements. ~~The registrant shall assure that all x-ray machines under his control are operated only by individuals adequately instructed in safe operating procedures and competent in the safe use of the equipment.~~ The registrant shall maintain a written training plan, available for Departmental review, to include all parts of RHB 4.12.22.1.

4.12.22.1 The registrant shall require persons operating registered equipment and associate equipment and/or holding patients to receive, at a minimum, instruction in the following areas:

4.12.22.1.1 Radiation Protection. Training in radiation protection standards shall include, but ~~is~~are not limited to, protective clothing; patient holding; time, distance, and shielding; ~~radiation protection standards;~~ dose limits specified in Part III of this regulation; use of personnel monitoring devices; and the biological effects of radiation.

4.12.22.1.2 Darkroom Techniques/Digital Imaging Acquisition Systems. Training in darkroom techniques shall include, but is not limited to, developing chemicals; film protection; cassettes; and screens. Training in digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital imaging acquisition system.

4.12.22.1.3 Machine ~~Safety~~Specific Training. Training ~~in machine safety~~ shall include, at a minimum, machine functions; machine safety procedures; ~~and~~ recognizing machine problems; patient positioning for x-ray exams; and radiographic techniques.

~~4.12.22.1.4 General Operating Procedures. Training in general operating procedures shall include patient positioning for x-ray exams; radiographic techniques; use of personnel monitoring devices; and quality assurance procedures.~~

4.12.22.2 Instruction required by RHB 4.12.22.1 shall ~~begin within 30 days after employment~~be completed prior to the operator working independently. ~~Training shall be provided for each type of exam that the operator will be required to perform at that facility.~~ Such training shall be certified in writing by the Radiation Safety Officer and ~~The registrant shall maintain a record of all training for each operator. Such~~ records shall be made available for Departmental ~~inspection~~review.

RHB 4.13. Medical Specimen ~~Unit~~Systems.

In addition to the applicable provisions of this regulation, the requirements of this Part apply to all stationary, transportable, mobile, and portable medical specimen systems.

4.13.1 Administrative Requirements. All provisions of RHB 4.2.2.7 apply.

4.13.2 Radiation Protection. Upon installation, the medical specimen unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. A radiation survey of the unit and areas adjacent to the unit shall also be performed at least annually, and after any repair, modification, or maintenance on the system. Documentation of the surveys shall be maintained for inspection by the Department.

4.13.3 Tests of all safety devices such as interlocks shall be conducted annually for medical specimen units. Documentation of such tests shall be maintained for inspection by the Department.

4.13.4 Radiation emitted from the medical specimen unit shall not exceed 0.5 milliRoentgens per hour at any point five centimeters from the external surface.

4.13.5 When not in operation, the medical specimen unit shall be secured.

~~APPENDIX~~Appendix A. Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening.

Persons requesting that the Department approve a healing arts screening program shall submit the following information for review and approval:

1. Name and address of the applicant, and where applicable, the names and addresses of agents within the ~~S~~state.

2. Diseases or conditions for which the ~~X-ray~~x-ray examinations are to be used.

3. Description in detail of the ~~X-ray~~x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program~~,~~ (i.e., age, sex, physical condition, and other appropriate information).

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the ~~X-ray~~x-ray examinations.

6. An evaluation by a qualified expert of the ~~X-ray~~x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of ~~these~~this regulation~~s~~.

7. A description of the ~~diagnostic film~~image quality control program.

8. A copy of the technique chart for the ~~X-ray~~x-ray examinations procedures to be used.

9. The qualifications of each individual who will be operating the ~~X-ray~~x-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the ~~X-ray~~x-ray system(s).

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the ~~X-ray~~x-ray examinations.

~~APPENDIX~~Appendix B. Information on Radiation Shielding Required for Plan Review.

The following information must be provided to the Department for review and acceptance of a shielding plan:

1. Plans shall show, at a minimum, the following:

a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth/station; the location of the x-ray control panel, and the location of the wall bucky or chest board, if applicable.

b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

c) An accurate drawing of the room(s) concerned.

d) The type of occupancy of all adjacent areas subject to primary and secondary scatter inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

e) The type of x-ray equipment and the maximum technique factors.

f) Location of the darkroom and the area where the film will be stored. Any shielding which will be used to protect the film must be noted. The use of filmless systems shall be indicated in writing.

2. Information on the anticipated workload of the x-ray system(s). Give the number of individual exposures per week. This is the total number of exposures (not patients) taken each week. This figure should include allowances for future growth so that the shielding will continue to remain adequate.

3. Individual barrier radiation shielding specifications and descriptions of all assumptions that were used in the shielding calculations.

4. The date the plan was prepared and the printed name and signature of the person preparing the plan.

~~APPENDIX~~Appendix C. Design Requirements for an Operator's Booth/Station.

1. Space Requirements:

a) The operator shall be allotted not less than ~~7.5~~seven and one-half square feet (7.5 ft^2)(0.697 $m~~2~~^2$) of unobstructed floor space in the booth/station.

b) The operator's booth/station may be any geometric configuration with no dimension less than ~~2~~two feet (2 ft)(0.61 m).

c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

d) The booth/station shall be located or constructed such that unattenuated direct scattered radiation originating on the examination table or at the wall cassette cannot reach the operator's station in the booth/station.

2. Structural Requirements:

a) The booth walls shall be permanently fixed barriers of at least ~~7~~seven feet (7 ft)(2.13 m) high.

b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

c) Shielding shall be provided to meet the requirements of RHB 4.4.

3. X-ray Control Placement:

The x-ray control for the system shall be fixed within the booth/station and:

a) Shall be at least ~~40~~forty inches (40 in)(1.02 m) from any open edge of the booth wall which is nearest to the source of radiation, excluding mammography ~~equipment~~ and ~~intraoral~~ dental systems. If the exposure switch is separate from the control panel, the exposure switch shall be at least ~~40~~forty inches (40 in)(1.02 m) from any open edge of the booth wall which is nearest to the source of radiation, excluding computed tomography exposure switches designed to provide a delay before initiating x-rays.

b) Shall allow the operator to use the majority of the available viewing windows and allow the operator to control all access to the radiation area.

4. Viewing System Requirements:

a) Each booth/station shall have at least one (1) viewing device which will:

i) Be so placed that the operator can view the patient during any exposure, and

ii) ~~The device shall b~~Be so placed that the operator can have full view of any occupant of the room and shall be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth/station, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

b) When the viewing system is a window, the following requirements also apply:

i) It shall have a viewing area of at least ~~1~~one square foot (1 ft^2)(0.0929 $m~~2~~^2$)

ii) The design of the ~~booth~~station shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least ~~18~~eighteen inches (18 in)(~~0.457mm~~45.72 cm) from the edge of the ~~booth~~station.

iii) The material constituting the window shall have the same lead equivalence as that required in the booth wall in which it is mounted.

c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B.

d) When the viewing system is by electronic means:

i) The camera shall be so located as to accomplish the general requirements of this Part, and

ii) There shall be an alternate viewing system as a backup for the primary system.

5. Alternative Design Criteria. The design considerations listed in Appendix C shall be followed. If design criteria in Appendix C cannot be followed, the registrant may offer alternative design criteria to the Department for acceptance as long as the same degree of safety is being met.

~~APPENDIX~~Appendix D. ~~Average~~ Patient Exposure Guide.

Medical ESE~~'~~s

Compliance with RHB 4.2.13.2 ~~may~~ shall be ~~determined~~ considered adequate if the patient's exposure at skin entrance (ESE) does not ~~vary from the national averages~~ exceed the limits listed below ~~by more than 50%~~. ~~Facilities should strive for an ESE that does not vary from the national average by more than 20%.~~ Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a 200 speed system.

ESE Limits

~~Projection~~ Exam Type	Thickness	200 Speed/Digital (mR)	400 Speed (mR)
PA Chest – Grid - Non Grid	23 cm	~~12 –~~ 38 ~~7 –~~ 23	~~7 –~~ 23 ~~2 –~~ 8
AP Abdomen	23 cm	~~245 –~~ 735	~~150 –~~ 450
AP Lumbar Spine	23 cm	~~225 –~~ 675	~~175 –~~ 525
Full Spine (AP)	23 cm	~~130 –~~ 390	~~72 –~~ 218
AP Cervical Spine	13 cm	~~67 –~~ 203	~~47 –~~ 142
Lateral Skull	15 cm	~~72 –~~ 218	~~35 –~~ 105
Ret Pyelogram (AP)	23 cm	~~297~~ 893	~~297~~ 893
Thoracic Spine (AP)	23 cm	~~204~~ 612	~~204~~ 612
DP Foot	8 cm	~~37 –~~ 111	~~37 –~~ 111
Cephalometric	15 cm	~~15 –~~ 45	~~15 –~~ 45

Notes:

a) Patient thicknesses are expressed in centimeters (cm).
b) All measurements are made in air (no phantom).
c) If the film/screen speed cannot be determined, it will be assumed to be 200 speed.

Mammography ESE's: Refer to RHB 5.11.5.10

Dental Intraoral ESE's:

~~This chart represents the range of exposures that will produce acceptable quality radiographs.~~ Compliance with RHB 4.2.13.2 shall be considered ~~met~~ adequate if the patient's exposure at skin entrance (ESE) ~~is within shown~~ does not exceed the limits listed below. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a “D” speed film system.

kVp	"D" Speed Film and Digital	"E" and “F” Speed Film
	ESE Limits (mR)	ESE Limits (mR)
50	~~340~~ 690	~~176~~ 384
55	~~280~~ 600	~~152~~ 324
60	~~248~~ 528	~~132~~ 276
65	~~216~~ 480	~~112~~ 240
70	~~192~~ 420	~~96~~ 204
75	~~136~~ 312	~~80~~ 168
80	~~120~~ 276	~~72~~ 144
85	~~104~~ 240	~~64~~ 126
90	~~96~~ 216	~~56~~ 108
95	~~88~~ 192	~~48~~ 64
100	~~80~~ 168	~~40~~ 56

~~APPENDIX~~Appendix E. Automatic e~~E~~xemptions ~~to RHB 4.9.8.2.2~~for Sterile Fields.
Automatic exemptions to RHB 4.9.8.2.2 will be granted for the following procedures:

1. Myelograms
2. Arthrograms
3. Angiograms
4. Percutaneous nephrostomies
5. Biliary drainage procedures
6. Percutaneous cholangiograms
7. T-tube cholangiograms
8. Sinograms or fistulograms
9. Fluoroscopic biopsy procedures

~~APPENDIX~~Appendix F. Minimum Criteria for Performance Tests.

The following items must be tested. Each item tested must include an indication of Pass/Fail, Compliant/ Non-compliant, as required by RHB ~~2.7.3.6~~2.8.3.6. ~~Items marked with an asterisk (*) indicate that this item is not necessarily required to be tested by the vendor, but must be tested in order for the facility to meet the requirements of RHB 4.2.16.1.~~ Each record of equipment performance testing shall be legible and include company name, service person name, and the date of the test, and all applicable requirements of RHB ~~2.7.3.6.6~~2.8.3.6.5.

MEDICAL RADIOGRAPHIC (Including veterinary facilities)

1. Half-value layer (HVL) (4.3.5)

2. X-ray field/light field alignment (4.7.1.3, 4.8.4)
3. Exposure reproducibility (4.7.5)
4. mA/mAs linearity (4.7.7)
5. kVp accuracy (4.7.6)
6. Timer reproducibility and accuracy (4.7.4.2.6, 4.7.6)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Collimator light illuminance (4.7.8)
9. Actual vs. indicated collimator field sizes (4.7.1.5, 4.8.6)
10. Positive beam limitation function, if operable (4.7.12)
11. Visual and audible indication of exposure (4.7.4.2.~~4~~3)
12. Minimum field size (4.7.14)
13. Patient exposure at skin entrance, for most common exams performed at the facility to include the source-to-image receptor distance (SID) used (Techniques clinically used by the facility must be evaluated) (except veterinary facilities) (4.2.13.2)
14. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
15. Grid uniformity and alignment (4.2.16.3)
~~16. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*~~
~~17~~16. Actual vs. Indicated ~~Source to Image Distance (~~SID~~)~~, for all clinically used SIDs (4.7.11)
~~18~~17. Beam size(s) for fixed collimation, if applicable (4.7.3)
~~19~~18. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:
~~1. Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)~~
~~2.~~1. Minimum source-to-skin distance on mobile radiographic units (~~4.8.12~~4.8.11)
~~3.~~2. Proper indication of multiple tubes on units so equipped (~~4.7.4.2.3~~4.3.7)

FLUOROSCOPIC

1. X-ray beam/Viewed image size comparison (4.9.2.2)
2. Exposure rate output measurement, using average techniques, using maximum techniques, and in high level exposure mode, if so equipped, in each mode routinely used (4.9.4)
3. Image intensifier interlock with unit in park position (4.9.2.1.2)
4. Cumulative timer function (4.9.7.1)
5. Control of scattered radiation (4.9.8)
6. High contrast resolution and low contrast performance (4.9.12)
7. Minimum source-to-skin distance, upon initial installation (4.9.1)
8. Spot film beam size (4.9.2.3.2)
9 Spot film beam centering (4.9.2.3.4)
10. Spot film exposure reproducibility (4.9.9.3)
11. Spot film mA/mAs linearity (4.7.7)
12. Spot film timer reproducibility and accuracy (4.9.9.2, 4.7.6)
13. Proper function of spot film automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
14. Half-value layer (HVL) (4.3.5)
15. Cinefluorographic exposure rates (4.9.4)
~~16. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*~~
~~17~~16. Integrity of bucky slot cover shielding and lead drapes ~~(4.2.8)*~~ (4.9.8)
~~18~~17. Continuous indication of kV and mA during fluoroscopy (4.9.6)

~~19~~18. X-ray control placement (Appendix C, 3a)

~~These items~~Primary Barrier Transmission (4.9.5) must be checked upon initial installation and after any maintenance or repair that could affect its status~~:~~.
~~1. Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)~~
~~2. Primary Barrier Transmission (4.9.5)~~

RADIATION THERAPY SIMULATION SYSTEMS

1. Half-value layer (HVL) (4.3.5)
2. X-ray field/light field alignment (4.7.1.3)
3. Exposure reproducibility (4.7.5)
4. mA/mAs linearity (4.7.7)
5. kVp accuracy (4.7.6)
6. Timer reproducibility and accuracy (4.7.4.2.6, 4.7.6)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Actual vs. indicated collimator field sizes (4.7.1.5)
9. Positive beam limitation function, if operable (4.7.12)
10. Visual and audible indication of exposure (~~4.5.4.2.4~~4.7.4.2.3)
11. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
12. Grid uniformity and alignment (4.2.16.3)
~~13. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*~~
~~14~~13. Actual vs. Indicated Source-to-Image Receptor Distance (SID), for all clinically used SIDs (4.7.11)
~~15~~14. Exposure rate output measurement, using average techniques, using maximum techniques, and in high level exposure mode, if so equipped, in each mode routinely used (4.9.4)
~~16~~15. Cumulative timer function (4.9.7.1)
~~17~~16. Measurement of scattered radiation (4.9.8)
~~18~~17. High contrast resolution and low contrast performance
~~19~~18. Minimum source-to-skin distance, upon initial installation (4.9.1)
~~20~~19. X-ray control placement (Appendix C, 3a)

~~These items must be checked upon initial installation and after any maintenance or repair that could affect its status: Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)~~

COMPUTED TOMOGRAPHY (CT) (Including CT treatment planning systems used in radiation therapy, PET CT and SPECT CT if used for diagnostic CT imaging, and Cone Beam CT and ~~d~~Dental CT, where applicable)

1. ~~Actual vs. indicated scan increment (4.11.1.6.3)~~ Geometric factors and alignment including alignment light accuracy and table increment accuracy
2.~~Measurement of radiation output (patient dose) (CT treatment planning systems are exempt) (4.11.3.1)~~ Image localization from scanned projection radiograph (localization image)
3.~~CT number calibration and constancy (4.11.3)~~ Radiation beam width
4.~~High and low contrast resolution~~Image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation
5.~~Precision (noise)~~CT number accuracy
6.~~Contrast scale~~Image quality for acquisition workstation display devices

7.~~Spot checks as specified by a Class IX Vendor (4.11.3.2)~~A review of the results of the routine QC required under RHB 4.11.3.2 (CT) or 4.11.5.1 (CBCT)
8. ~~An area survey, upon initial installation~~Dosimetry
9. ~~X-ray control placement (Appendix C, 3a)~~Visible and audible signals
~~10. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*~~X-ray control placement (Appendix C, 3a)
11. Radiation output (patient dose) for the following clinical protocols if performed: pediatric head; pediatric abdomen; adult head; adult abdomen; and brain perfusion (CT systems solely used for treatment planning in radiation therapy are exempt from this item)

~~These items must be checked upon initial installation and after any maintenance or repair that could affect its status: Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)~~

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1. Half-value layer (HVL) (4.3.5)
2. Exposure reproducibility (4.5.5)
3. mA/mAs linearity (4.5.6)
4. kVp accuracy (4.5.7)
5. Timer reproducibility and accuracy (4.5.3.3, 4.5.7)
6. Visual and audible indication of exposure (4.5.4.2.4)
7. Patient exposure at skin entrance, bitewing, and/or periapicals (Techniques clinically used by the facility must be evaluated) (except veterinary facilities) (4.2.13.2)
8. Mechanical support of tubehead (4.5.10)
9. Integrity of pass through interlocks (4.5.11.3)
~~10. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*~~
~~11~~10. X-ray control placement (4.5.4.2)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:
~~1. Adherence to the accepted shielding plan, if applicable (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)~~
~~2.~~1. Minimum source-to-skin distance (4.5.1)
~~3.~~2. X-ray beam size (4.5.2)
~~4.~~3. Proper indication of multiple tubes on units so equipped (4.5.9)
NOTE: Cephalometric units are considered medical units by the Department, and are subject to the requirements for medical radiographic units.

PART V
QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR FACILITIES PERFORMING MAMMOGRAPHY

RHB 5.1. Scope.

This Part establishes quality standards and certification requirements for facilities performing mammography to ensure that all mammography facilities are adequately and consistently evaluated for compliance with the standards provided.

5.1.1 Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of Part IV. ~~If any information submitted to the Department becomes~~

~~invalid or outdated, the Department shall be notified within 15 days.~~ Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

5.1.2 Exemptions.

5.1.2.1 Mammography units used only during invasive interventions for localization or biopsy procedures are exempt from the requirements of this Part, except that such systems shall satisfy the criteria specified in RHB 5.25, and all ~~p~~Parts to which RHB 5.25 refers.

5.1.2.2 Each mobile mammography facility based outside of South Carolina that operates in South Carolina and which has not been certified by the Department is exempt from the requirements of RHB ~~5.3~~5.4 and ~~RHB 5.6~~5.8, provided that:

5.1.2.2.1 The mobile mammography facility is certified to perform mammography by the U.S. Food and Drug Administration (FDA) or other FDA-approved certifying agency at all times while conducting operations in South Carolina; ~~and~~

5.1.2.2.2 The mobile mammography facility meets the requirements of RHB 5.28~~.~~;

5.1.2.2.3 The mobile mammography facility ~~shall comply~~complies with all other requirements in Part V~~.~~; and

5.1.2.2.4 The mobile mammography facility meets the requirements of RHB 2.3 and 2.4.

RHB 5.2. Requirements for Certification.

A certificate issued by the Department is required for lawful operation of all mammography facilities subject to the provisions of this Part. Certificate-holding facilities shall meet the requirements of RHB ~~5.6~~5.8 and be accredited by an FDA-approved accreditation body.

RHB 5.3. Revocation of Accreditation.

If a facility's accreditation is revoked by an accreditation body, the Department may conduct an investigation into the reasons for the revocation. Following such investigation, the Department may suspend or revoke the facility's certificate and take whatever action or combination of actions to protect public health, including requiring the establishment and implementation of a corrective plan of action that shall permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.

RHB ~~5.3~~5.4. Certificates.

~~5. 3.1~~5.4.1 In order to qualify for a certificate, a facility ~~must~~shall apply to an FDA-approved accreditation body.

~~5. 3.2~~5.4.2 Following the Department's receipt of the accreditation body's decision to accredit a facility, the Department may issue a certificate to the facility, or renew an existing certificate, if the Department determines that the facility has satisfied the requirements for certification or recertification.

~~5. 3.3~~5.4.3 Provisional Certificates.

~~5. 3.3.1~~5.4.3.1 A new facility is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process.

~~5. 3.3.2~~5.4.3.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to six (6) months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a ninety (90)-day extension of the provisional certificate.

~~5. 3.4~~5.4.4 Extension of Provisional Certificate.

~~5. 3.4.1~~5.4.4.1 To apply for a ninety (90)-day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

~~5. 3.4.2~~5.4.4.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a ninety (90)-day extension of the provisional certificate to the facility upon determination that the facility has satisfied the requirements for the ninety (90)-day extension.

~~5. 3.4.3~~5.4.4.3 There can be no renewal of a provisional certificate beyond the ninety (90)-day extension.

~~5. 3.5~~5.4.5 Interim Notices. The Department may issue an interim notice of mammography certification by facsimile to a facility if a delay is anticipated in providing a certificate to the facility under one (1) or more of the following circumstances:

~~5. 3.5.1~~5.4.5.1 The Department has been notified by an accreditation body that the facility meets the requirements for a provisional or provisional reinstatement certificate and delivery of the certificate may be delayed;

~~5. 3.5.2~~5.4.5.2 The Department has been notified by an accreditation body that the facility has completed accreditation or reaccreditation and delivery of the certificate to the facility may be delayed; or

~~5. 3.5.3~~5.4.5.3 The Department has been notified by an accreditation body that the facility has timely submitted an application for accreditation or reaccreditation but the completion of the accreditation process may extend beyond the expiration date of a facility's existing certificate through no fault of the facility.

~~5. 3.5.4~~5.4.5.4 An interim notice shall authorize the facility to perform mammography until the facility receives its certificate but in no case for more than forty-five (45) calendar days. No more than one (1) interim notice may be issued to a facility per application for certification.

RHB 5.5. Suspension or Revocation of Certificates.

5.5.1 Except as provided in RHB 5.5.2, the Department may suspend or revoke a certificate if the Department finds that the owner, operator, or any employee of the facility:

5.5.1.1 Has been guilty of misrepresentation in obtaining the certificate;

5.5.1.2 Has failed to comply with the standards of RHB 5.2 through 5.24;

5.5.1.3 Has failed to comply with reasonable requests of the Department or the accreditation body for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of RHB 5.2 through 5.24;

5.5.1.4 Has refused a reasonable request of a duly designated FDA inspector, Department inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

5.5.1.5 Has violated or aided and abetted in the violation of any provision of this regulation;

5.5.1.6 Has failed to comply with prior sanctions imposed by the Department; or

5.5.1.7 Has failed to pay any required fees.

5.5.2 The Department may summarily suspend the certificate of a facility if the Department makes a finding described in RHB 5.5.1 and also determines that:

5.5.2.1 The failure to comply with required standards presents a serious risk to human health;

5.5.2.2 The refusal to permit inspection makes immediate suspension necessary;

5.5.2.3 There is a reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud; or

5.5.2.4 Makes other finding that public health, safety, or welfare imperatively requires emergency action.

5.5.3 If the Department summarily suspends a certificate in accordance with RHB 5.5.2:

5.5.3.1 Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23;

5.5.3.2 The suspension shall remain in effect until the Department determines that:

5.5.3.2.1 Allegations of violations or misconduct were not substantiated;

5.5.3.2.2 Violations of required standards have been corrected to the Department's satisfaction; or

5.5.3.2.3 The facility's certificate is revoked in accordance with RHB 5.5.4.

5.5.4 The Department may revoke the facility's certificate if the Department determines that the facility:

5.5.4.1 Is unwilling or unable to correct violations that were the basis for suspension; or

5.5.4.2 Has engaged in fraudulent activity to obtain or continue certification.

RHB ~~5.4~~5.6. Reinstatement Policy.

A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by the FDA or the Department, or that has had its certificate suspended or revoked by the FDA or the Department, may apply for reinstatement. If reinstated, the facility will be eligible for a provisional certificate.

~~5.4.1~~5.6.1 Unless prohibited from reinstatement under ~~5.4.4~~ RHB 5.6.4, a facility applying for reinstatement shall:

~~5.4.1.1~~5.6.1.1 Contact an FDA-approved accreditation body to determine the requirements for reapplication or accreditation;

~~5.4.1.2~~5.6.1.2 Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

~~5.4.1.2.1~~5.6.1.2.1 Name and address of the facility under which it was previously provisionally certified or certified;

~~5.4.1.2.2~~5.6.1.2.2 Name of previous owner/lessor;

~~5.4.1.2.3~~5.6.1.2.3 FDA facility identification number assigned to the facility under its previous certification; and

~~5.4.1.2.4~~5.6.1.2.4 Expiration date of the most recent FDA provisional certificate or certificate.

~~5.4.1.3~~5.6.1.3 Justify application for reinstatement of accreditation by submitting to the accreditation body~~,~~ a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

~~5.4.2~~5.6.2 The Department may issue a provisional certificate to the facility if:

~~5.4.2.1~~5.6.2.1 Following the Department's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

~~5.4.2.2~~5.6.2.2 The Department determines that the facility has taken sufficient corrective action since the lapse ~~of~~, denial, or revocation of its previous certificate.

~~5.4.3~~5.6.3 After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

~~5.4.4~~5.6.4 If a facility's certificate was revoked on the basis of an act described in ~~5.24~~RHB 5.5, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within two (2) years of the date of revocation.

RHB ~~5.5~~5.7. ~~Appeals of a~~Adverse accreditation or reaccreditation decisions.

The appeals procedures described in this Part are available only for adverse accreditation or reaccreditation decisions that preclude certification by the Department. Department decisions to suspend or revoke certificates that are already in effect shall be conducted in accordance with RHB ~~5.24~~5.5.

~~5.5.1~~5.7.1 Upon learning that a facility has failed to become accredited or reaccredited, the Department will notify the facility that the Department is unable to certify that facility without proof of accreditation.

~~5.5.2~~5.7.2 A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the FDA. ~~A facility shall avail itself of the accreditation body's appeal process before requesting a review from the Department.~~

~~5.5.3 In the event that a facility, after availing itself of the accreditation body's appeal process, receives an adverse accreditation or reaccreditation decision, the facility may within 30 days after such adverse decision submit a request for review of the adverse accreditation decision to the Department.~~

~~5.5.4 Within 30 days following receipt of such written request, the Director of Health Regulation shall review the facility's appeal.~~

~~5.5.5~~5.7.3 A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

RHB ~~5.6~~5.8. Fees.

~~5.6.1~~5.8.1 The Department shall assess each certified mammography facility an annual certification fee of one thousand thirty-one dollars ($1031.00) in accordance with RHB ~~2.10~~2.11. This certification fee includes one (1) mammographic tube. The Department shall assess each certified mammography facility an additional fee of two hundred thirty-one dollars ($231.00) per mammographic tube for each additional tube.

~~5.6.2~~5.8.2 The annual fee described in ~~5.6.1~~ RHB 5.8.1 applies to both fully and provisionally certified mammography facilities.

~~5.6.3~~5.8.3 A new mammography facility issued an initial provisional certificate during the calendar year shall be issued a prorated fee for the remainder of the year, in accordance with RHB ~~2.10~~2.11.

~~5.6.4~~5.8.4 All fees shall be due and payable in accordance with RHB ~~2.10~~2.11.

~~5.6.5~~5.8.5 Follow-up Inspection Fees

~~5.6.5.1~~5.8.5.1 In the event that the Department deems a follow-up inspection necessary, an inspection fee of five hundred dollars ($500.00) shall be assessed upon the completion of the follow-up inspection.

~~5.6.5.2~~5.8.5.2 The follow-up inspection invoice shall be issued in conjunction with the follow-up inspection report.

~~5.6.5.3~~5.8.5.3 Payment of the follow-up inspection fee shall be due within thirty (30) calendar days of the date of the follow-up inspection fee invoice.

RHB ~~5.7~~5.9. Personnel Requirements.

The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

~~5.7.1~~5.9.1 Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

~~5.7.1.1~~5.9.1.1 Initial qualifications. Unless the exemption in ~~5.7.1.3.1~~ RHB 5.9.1.3 applies, before beginning to interpret mammograms independently, the interpreting physician shall:

~~5.7.1.1.1~~5.9.1.1.1 Be a licensed physician to practice medicine in this ~~S~~state;

~~5.7.1.1.2~~5.9.1.1.2 Be certified in diagnostic radiology by either the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada, or have had at least three (3) months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of ~~5.7.1~~ RHB 5.9.1 of this Part.

~~5.7.1.1.3~~5.9.1.1.3 Have a minimum of sixty (60) hours of documented medical education in mammography, which shall include instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All sixty (60) of these hours shall be Category I and have at least fifteen (15) hours of the Category I hours shall have been acquired within three (3) years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

~~5.7.1.1.4~~5.9.1.1.4 Unless the exemption in RHB ~~5.7.1.3.2~~5.9.1.3.2 applies, have interpreted or multi-read at least two hundred forty (240) mammograms examinations within the six (6)-month period immediately prior to the date that the physician qualifies as an interpreting physician. The interpretation or multi-reading shall be under direct supervision of a qualified interpreting physician.

~~5.7.1.2~~5.9.1.2 Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

~~5.7.1.2.1~~5.9.1.2.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of ~~5.7.1.1~~ RHB 5.9.1.1 of this Part~~,~~ were completed, the interpreting physician shall have interpreted or multi-read at least nine hundred sixty (960) mammographic examinations during the twenty-four (24) months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the twenty-four (24)-month period.

~~5.7.1.2.2~~5.9.1.2.2 Following the third anniversary of the end of the calendar quarter in which the requirements of ~~5.7.1.1~~ RHB 5.9.1.1 of this Part were completed, the interpreting physician shall have taught or completed at least fifteen (15) Category I continuing medical education units in mammography during the thirty-six (36) months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the thirty-six (36)-month period. This training shall include at least six (6) Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

~~5.7.1.2.3~~5.9.1.2.3 Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least eight (8) hours of training in the new mammographic modality.

~~5.7.1.2.4~~5.9.1.2.4 Units earned through teaching a specific course can be counted only once towards the fifteen (15) units required by RHB ~~5.7.1.2.2~~5.9.1.2.2, even if the course is taught multiple times during the previous thirty-six (36) months.

~~5.7.1.3~~5.9.1.3 Exemptions

~~5.7.1.3.1~~5.9.1.3.1 Those physicians who qualified as interpreting physicians under FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of ~~5.7.1.1~~ RHB 5.9.1.1 of this Part. These physicians may continue to interpret mammograms provided they continue to meet the requirement of ~~5.7.1~~ RHB 5.9.1 and the continuing experience and education requirements of ~~5.7.1.2~~ RHB 5.9.1.2. Any physician added to a facility after April 28, 1999, must provide documentation of initial qualifications. This documentation must be maintained by the facility for Departmental review

~~5.7.1.3.1.1 Any physician added to a facility after April 28, 1999, must provide documentation of initial qualifications. This documentation must be maintained by the facility for Department review.~~

~~5.7.1.3.2~~5.9.1.3.2 Physicians who have interpreted or multi-read at least two hundred forty (240) mammographic examinations under the direct supervision of an interpreting physician in any six (6)-month period during the last two (2) years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are exempt from ~~5.7.1.1.4~~RHB 5.9.1.1.4.

~~5.7.1.4~~5.9.1.4 Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements~~,~~ shall reestablish their qualifications before resuming the independent interpretation of mammograms as follows:

~~5.7.1.4.1~~5.9.1.4.1 Interpreting physicians who fail to meet the continuing experience requirements of ~~5.7.1.2.1~~ RHB 5.9.1.2.1 shall interpret or multi-read at least two hundred forty (240) mammographic examinations within six (6) months or less under the direct supervision of an interpreting physician; or interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to nine hundred sixty (960) examinations from the prior twenty-four (24) months, whichever is less. The interpretations required shall be done within the six (6) months immediately prior to resuming independent interpretation.

~~5.7.1.4.2~~5.9.1.4.2 Interpreting physicians who fail to meet the continuing education requirements of ~~5.7.1.2.2~~ RHB 5.9.1.2.2 shall obtain a sufficient number of additional Category I continuing medical education credits in mammography to bring their total up to the required fifteen (15) credits in the previous thirty-six (36) months before resuming independent interpretation.

~~5.7.2~~5.9.2 Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education requirements:

~~5.7.2.1~~5.9.2.1 ~~General Requirements~~Initial Qualifications

~~5.7.2.1.1~~5.9.2.1.1 Be registered in active status with the American Registry of Radiologic Technologists in the field of radiography; and

~~5.7.2.1.2~~5.9.2.1.2 All provisions of RHB 4.2.2 apply to the operators of mammography equipment.

~~5.7.2.2~~5.9.2.2 Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under FDA's interim regulations or completed at least forty (40) contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

~~5.7.2.2.1~~5.9.2.2.1 Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

~~5.7.2.2.2~~5.9.2.2.2 The performance of a minimum of twenty-–five (25) examinations under the direct supervision of an individual qualified under ~~5.7.2~~ RHB 5.9.2; and

~~5.7.2.2.3~~5.9.2.2.3 At least eight (8) hours of training in each mammography modality to be used by the technologist in performing mammography exams.

~~5.7.2.3~~5.9.2.3 Continuing education requirements

~~5.7.2.3.1~~5.9.2.3.1 Following the third anniversary date of the end of the calendar quarter in which the requirements of ~~5.7.2.1~~ RHB 5.9.2.1 and ~~5.7.2.2~~ RHB 5.9.2.2 were completed, the radiologic technologist who performs mammography shall have taught or completed at least fifteen (15) continuing education units in mammography during the thirty-six (36) months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any day in between the two. The facility will choose one of these dates to determine the thirty-six (36)-month period.

~~5.7.2.3.2~~5.9.2.3.2 Units earned through teaching a specific course can be counted only once towards the fifteen (15) hours of continuing education requirements required in ~~5.7.2.3.1~~ RHB 5.9.2.3.1, even if the course is taught multiple times during the previous thirty-six (36) months.

~~5.7.2.3.3~~5.9.2.3.3 At least six (6) of the continuing education units required in ~~5.7.2.3.1~~ RHB 5.9.2.3.1 shall be related to each mammographic modality used by the technologist.

~~5.7.2.3.4~~5.9.2.3.4 Requalification. Radiologic technologists who fail to meet the continuing education requirements of ~~5.7.2.3.1~~ RHB 5.9.2.3.1, shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least fifteen (15) in the previous three (3) years, at least six (6) of which shall be related to each modality used by the technologist in mammography. The technologist shall not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

~~5.7.2.3.5~~5.9.2.3.5 Before a radiologic technologist may begin independently performing mammography examinations using a mammographic modality other than one of those for which the technologist received training under ~~5.7.2.3.3~~ RHB 5.9.2.3.3, the technologist shall have at least eight (8) hours of continuing education units in the new modality.

~~5.7.2.3.6~~5.9.2.3.6 Programs, courses, or other activities intended to meet the requirement for initial, or requalification, mammography training or continuing education in mammography shall be approved by the Department.

~~5.7.2.3.7~~5.9.2.3.7 Completion of initial or requalification mammography training and continuing education in mammography shall be verified to the Department.

~~5.7.2.4~~5.9.2.4 Continuing experience requirements.

~~5.7.2.4.1~~5.9.2.4.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of ~~5.7.2.1~~ RHB 5.9.2.1 and ~~5.7.2.2~~5.9.2.2 were completed or as of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of two hundred (200) mammography examinations during the twenty-four (24) months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the twenty-four (24)-month period.

~~5.7.2.4.2~~5.9.2.4.2 Requalification. Radiologic technologists who fail to meet the continuing experience requirements of ~~5.7.2.4.1~~RHB 5.9.2.4.1 shall perform a minimum of twenty-five mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography.

~~5.7.3~~5.9.3 Medical Physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall meet the following:

~~5.7.3.1~~5.9.3.1 Initial Qualifications. The medical physicist must be approved by the Department as a Class IX vendor, prior to providing or offering to provide services, as required in ~~2.6.1~~RHB 2.7.1. Unless the alternative initial qualifications in RHB ~~5.7.3.2~~5.9.3.2 apply, the medical physicist must:

~~5.7.3.1.1~~5.9.3.1.1 Have a master's degree or higher in a physical science from an accredited institution, with no less than twenty (20) semester hours or equivalent (e.g., thirty (30) quarter hours) of college undergraduate or graduate level physics;

~~5.7.3.1.2~~5.9.3.1.2 Have twenty (20) contact hours of documented specialized training in conducting surveys of mammography facilities; and

~~5.7.3.1.3~~5.9.3.1.3 Have the experience of conducting surveys of at least one (1) mammography facility and a total of at least ten (10) mammography units. No more than one (1) survey of a specific unit within a period of sixty (60) days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets all the requirements of ~~5.7.3.1~~RHB 5.9.3.1 and ~~5.7.3.3~~5.9.3.3.

~~5.7.3.2~~5.9.3.2 Alternative initial qualifications.

~~5.7.3.2.1~~5.9.3.2.1 Have qualified as a medical physicist under the FDA's interim-regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required;

~~5.7.3.2.2~~5.9.3.2.2 Prior to April 28, 1999, obtained a bachelor's degree or higher in a physical science from an accredited institution with no less than ten (10) semester hours or equivalent of college undergraduate or graduate level physics;

~~5.7.3.2.3~~5.9.3.2.3 Prior to April 28, 1999, have forty (40) contact hours of documented specialized training in conducting surveys of mammography facilities; and

~~5.7.3.2.4~~5.9.3.2.4 Prior to April 28, 1999, have the experience of conducting surveys of at least one (1) mammography facility and a total of at least twenty (20) mammography units. No more than one (1) survey of a specific unit within a period of sixty (60) days can be counted towards the total

mammography survey requirement. The training and experience requirements shall be met after fulfilling the degree requirement.

~~5.7.3.3~~5.9.3.3 Continuing education and experience.

~~5.7.3.3.1~~5.9.3.3.1 Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of ~~5.7.3.1~~RHB 5.9.3.1 and ~~5.7.3.2~~5.9.3.2 were completed, the medical physicist shall have taught, or completed, at least fifteen (15) continuing education units in mammography during the thirty-six (36)-months immediately preceding the date of the facility annual inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the thirty-six (36)-month period. This continuing education shall include hours of training appropriate to each mammography modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required fifteen (15) continuing education units in a thirty-six (36)-month period, even if the course is taught multiple times during the thirty-six (36) months.

~~5.7.3.3.2~~5.9.3.3.2 Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of RHB ~~5.7.3.1~~5.9.3.1 and ~~5.7.3.2~~5.9.3.2 were completed or as of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two (2) mammography facilities and a total of at least six (6) mammography units during the twenty-four (24) months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the twenty-four (24)-month period. No more than one (1) survey of a specific facility within a ten (10)-month period or a specific unit within a period of sixty (60) days can be counted towards the total mammography unit survey requirement.

~~5.7.3.3.3~~5.9.3.3.3 Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under ~~5.7.3.1~~RHB 5.9.3.1 and ~~5.7.3.2~~5.9.3.2, the physicist shall receive at least eight (8) hours of training in surveying units of the new mammographic modality.

~~5.7.3.4~~5.9.3.4 Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of ~~5.7.3.3~~RHB 5.9.3.3 may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists shall reestablish their qualifications, as follows:

~~5.7.3.4.1~~5.9.3.4.1 Medical physicists who fail to meet the continuing educational requirements of 5.~~7~~9.3.3.1 shall obtain a sufficient number of continuing education units to bring their total units up to the required fifteen (15) in the previous three (3) years.

~~5.7.3.4.2~~5.9.3.4.2 Medical physicists who fail to meet the continuing experience requirement of ~~5.7.3.3.2~~RHB 5.9.3.3.2 shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualification of ~~5.7.3.1~~RHB 5.9.3.1 and ~~5.7.3.3~~5.9.3.3 to bring their total surveys up to the required two (2) facilities and six (6) units in the previous twenty-four (24) months. No more than one (1) survey of a specific unit within a period of sixty (60) days can be counted towards the total mammography unit survey requirement.

~~5.7.4~~5.9.4 Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic

technologists, or medical physicists. These records must be available for review by the Department. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the MQSA/State personnel requirements of this Part.

RHB ~~5.8~~5.10. Equipment Requirements.

The equipment requirements of this Part are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

~~5.8.1~~5.10.1 Prohibited equipment. Xeromammography equipment shall not be used for mammography procedures. Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in 21 CFR, Section 1020.31(f)(3).

~~5.8.2~~5.10.2 General. Only special purpose equipment designed for mammography shall be specifically used for mammography and shall be certified pursuant to 21 CFR, Section 1010.2 as meeting the applicable requirements of 21 CFR, Section 1020.30, effective as of April 1, 1997.

~~5.8.3~~5.10.3 Motion of tube-image receptor assembly.

~~5.8.3.1~~5.10.3.1 The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

~~5.8.3.2~~5.10.3.2 The mechanism ensuring compliance with RHB ~~5.8.3.1~~5.10.3.1 shall not fail in the event of power interruption.

~~5.8.4~~5.10.4 Image receptor sizes.

~~5.8.4.1~~5.10.4.1 Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of eighteen by twenty-four centimeters (18 x 24 ~~centimeters (~~cm) and twenty-four by thirty centimeters (24 x 30 cm).

~~5.8.4.2~~5.10.4.2 Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

~~5.8.4.3~~5.10.4.3 Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

~~5.8.5~~5.10.5 Beam limitation and light fields.

~~5.8.5.1~~5.10.5.1 All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

~~5.8.5.2~~5.10.5.2 For any mammography system with a light beam that passes through the x-ray beam limiting device, the light shall provide an average illumination of not less than ~~160~~one hundred sixty lux (160 lx)(15 footcandles) at one hundred centimeters (100 cm) or the maximum source-image receptor distance (SID), whichever is less.

~~5.8.6~~5.10.6 Magnification

~~5.8.6.1~~5.10.6.1 Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

~~5.8.6.2~~5.10.6.2 Systems used for magnification procedures shall provide, at a minimum, at least one (1) magnification value within the range of 1.4 to 2.0.

~~5.8.7~~5.10.7 Focal Spot Selection

~~5.8.7.1~~5.10.7.1 When more than one (1) focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

~~5.8.7.2~~5.10.7.2 When more than one (1) target material is provided, the system shall indicate, prior to exposure, the preselected target material.

~~5.8.7.3~~5.10.7.3 When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and /or focal spot actually used during the exposure.

~~5.8.8~~5.10.8 Compression. All mammography systems shall incorporate a compression device that shall be used for all routine projections and for all projections except when necessity requires imaging without compression.

~~5.8.8.1~~5.10.8.1 Application of compression. Effective October 28, 2002, each system shall provide:

~~5.8.8.1.1~~5.10.8.1.1 An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

~~5.8.8.1.2~~5.10.8.1.2 Fine adjustment compression controls operable from both sides of the patient.

~~5.8.8.2~~5.10.8.2 Compression paddle:

~~5.8.8.2.1~~5.10.8.2.1 Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of subsections ~~5.8.8.2.4~~RHB 5.10.8.2.4 and ~~5.8.8.2.5~~5.10.8.2.5 of this Section.

~~5.8.8.2.2~~5.10.8.2.2 Except as provided in subsection ~~5.8.8.2.3~~RHB 5.10.8.2.3 of this Part, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than one centimeter (1~~.0~~ cm) at any point on the surface of the compression paddle when compression is applied.

~~5.8.8.2.3~~5.10.8.2.3 Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

~~5.8.8.2.4~~5.10.8.2.4 The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

~~5.8.8.2.5~~5.10.8.2.5 The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

~~5.8.9~~5.10.9 Technique factor selection and display.

~~5.8.9.1~~5.10.9.1 Manual selection of milliAmpere seconds (mAs) or at least one (1) of its component parts (milliAmpere (mA) and~~-~~/or time) shall be available.

~~5.8.9.2~~5.10.9.2 The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

~~5.8.9.3~~5.10.9.3 Following AEC mode use, the system shall indicate the actual kiloVoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

~~5.8.10~~5.10.10 Automatic exposure control.

~~5.8.10.1~~5.10.10.1 Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided~~,~~ (e.g., grid, nongrid, magnification, nonmagnification and various target--filter combinations).

~~5.8.10.2~~5.10.10.2 The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

~~5.8.10.2.1~~5.10.10.2.1 The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

~~5.8.10.2.2~~5.10.10.2.2 The selected position of the detector shall be clearly indicated.

~~5.8.10.3~~5.10.10.3 The system shall provide means for the operator to vary the selected optical density from the normal (zero (0)) setting.

~~5.8.11~~5.10.11 X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

~~5.8.12~~5.10.12 Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

~~5.8.13~~5.10.13 Film processing solutions. When processing mammography films, the facility shall use chemical solutions that are capable of developing the film used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

~~5.8.14~~5.10.14 Lighting. The facility shall make special lights for film illumination~~,~~ (i.e., hot-lights), capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

~~5.8.15~~5.10.15 Film masking devices. Facilities shall ensure that filmmasking devices that can limit the illumination area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians.

RHB ~~5.9~~5.11. Medical Records and Mammography Reports.

~~5.9.1~~5.11.1 Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

~~5.9.1.1~~5.11.1.1 The name of the patient and an additional patient identifier;

~~5.9.1.2~~5.11.1.2 Date of examination;

~~5.9.1.3~~5.11.1.3 The name of the interpreting physician who interpreted the mammogram;

~~5.9.1.4~~5.11.1.4 Overall final assessment of findings, classified in one of the following categories:

~~5.9.1.4.1~~5.11.1.4.1 "Negative." Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

~~5.9.1.4.2~~5.11.1.4.2 "Benign." Also a negative assessment;

~~5.9.1.4.3~~5.11.1.4.3 "Probably Benign." Finding(s) has a high probability of being benign;

~~5.9.1.4.4~~5.11.1.4.4 "Suspicious." Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

~~5.9.1.4.5~~5.11.1.4.5 "Highly suggestive of malignancy." Finding(s) has a high probability of being malignant~~,~~;

~~5.9.1.5~~5.11.1.5 In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

~~5.9.1.6~~5.11.1.6 Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

~~5.9.2~~5.11.2 Communication of mammography results to the patient. Each facility shall send each patient a summary of the mammography report written in lay terms within thirty (30) calendar days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy.","~~,~~ the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

~~5.9.2.1~~5.11.2.1 Patients who do not name a health care provider to receive the mammography report shall be sent the report described in RHB ~~5.9.1~~5.11.1 within thirty (30) calendar days, in addition to the written notification of results in lay terms.

~~5.9.2.2~~5.11.2.2 Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

~~5.9.3~~5.11.3 Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

~~5.9.3.1~~5.11.3.1 Provide a written report of the mammography examination, including the items listed in subsection ~~5.9.1~~5.11.1 of this Section, to that health care provider as soon as possible, but no later than thirty (30) calendar days after the date of the mammography examinations; and

~~5.9.3.2~~5.11.3.2 If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

~~5.9.4~~5.11.4 Record-keeping. Each facility that performs mammograms:

~~5.9.4.1~~5.11.4.1 Shall, except as provided in RHB ~~5.9.4.2~~5.11.4.2, maintain mammography films and reports in a permanent medical record of the patient for a period of not less than five (5) years, or not less than ten (10) years if no additional mammograms of the patient are performed at the facility;

~~5.9.4.2~~5.11.4.2 Shall upon request by, or on behalf of, the patient permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly~~.~~; and

~~5.9.4.3~~5.11.4.3 Any fee charged to the patient for providing the services in RHB ~~5.9.4~~5.11.4 shall not exceed the documented costs associated with this service.

~~5.9.5~~5.11.5 Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

~~5.9.5.1~~5.11.5.1 Name of patient and an additional patient identifier.

~~5.9.5.2~~5.11.5.2 Date of examination.

~~5.9.5.3~~5.11.5.3 View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body shall be used to identify view and laterality.

~~5.9.5.4~~5.11.5.4 Facility name and location. At a minimum, the location shall include the city, state, and zip code of the facility.

~~5.9.5.5~~5.11.5.5 Technologist identification.

~~5.9.5.6~~5.11.5.6 Cassette/screen identification.

~~5.9.5.7~~5.11.5.7 Mammography unit identification, if there is more than one (1) unit in the facility.

RHB ~~5.10~~5.12. Quality Assurance Requirements.

Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

~~5.10.1~~5.12.1 Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

~~5.10.1.1~~5.12.1.1 Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of this Part. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

~~5.10.1.2~~5.12.1.2 Interpreting physicians. All physicians interpreting mammograms for the facility shall:

~~5.10.1.2.1~~5.12.1.2.1 Follow the facility procedures for corrective action when the images that they are asked to interpret are of poor quality; and

~~5.10.1.2.2~~5.12.1.2.2 Participate in the facility's medical outcomes audit program.

~~5.10.1.3~~5.12.1.3 Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in RHB ~~5.12~~5.14 and ~~RHB 5.13~~5.15.

~~5.10.1.4~~5.12.1.4 Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of RHB ~~5.11~~5.13.

~~5.10.2~~5.12.2 Quality assurance records.

~~5.10.2.1~~5.12.2.1 The lead interpreting physician~~, quality control technologist and medical physicist~~ shall ensure that the following records ~~concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions and the effectiveness of the corrective actions), safety, and protection~~ are properly maintained and updated~~.~~:

5.12.2.1.1 Employee qualifications;

5.12.2.1.2 Mammography technique and procedures;

5.12.2.1.3 Quality control (including monitoring data, problems detected by analysis of that data, corrective actions and the effectiveness of the corrective actions); and

5.12.2.1.4 Report of the medical physicist’s test results with numerical values as well as written documentation of any corrective actions taken.

~~5.10.2.2~~5.12.2.2 These quality control records shall be kept for each test specified in RHB ~~5.11~~5.13 until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two (2) additional times at the required frequency, whichever is longer.

~~5.10.2.3 A report of the medical physicist's test results with numerical values shall be submitted to the Department annually as required by RHB 5.12.~~

RHB ~~5.11~~5.13. Equipment Quality Assurance Tests.

~~5.11.1~~5.13.1 Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

~~5.11.1.1~~5.13.1.1 The base plus fog density shall be within plus 0.03 of the established operating level.

~~5.11.1.2~~5.13.1.2 The mid-density shall be within plus or minus 0.15 of the established operating level.

~~5.11.1.3~~5.13.1.3 The density difference shall be within plus or minus 0.15 of the established operating level.

~~5.11.2~~5.13.2 Weekly quality control tests. Facilities with screen-film systems shall perform a phantom image quality evaluation test, using an FDA-approved phantom, at least weekly.

~~5.11.2.1~~5.13.2.1 The optical density of the film at the center of an image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

~~5.11.2.2~~5.13.2.2 The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

~~5.11.2.3~~5.13.2.3 The phantom image shall achieve at least the minimum score established by the accreditation body.

~~5.11.2.4~~5.13.2.4 The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

~~5.11.3~~5.13.3 Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

~~5.11.3.1~~5.13.3.1 Fixer retention in film. The residual fixer shall be no more than ~~5~~five micrograms per square centimeter (5 µg/cm^2).

~~5.11.3.2~~5.13.3.2 Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than ~~2.0~~two percent (2%) of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

~~5.11.4~~5.13.4 Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

~~5.11.4.1~~5.13.4.1 Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20, is exposed to typical darkroom conditions for two (2) minutes while such film is placed on the counter top

emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

~~5.11.4.2~~5.13.4.2 Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

~~5.11.4.3~~5.13.4.3 Compression device performance. The maximum compression force for the initial power drive shall be between ~~111~~one hundred eleven newtons (111 N)(25 ~~pounds~~lbs) and ~~209~~two hundred nine newtons (209 N)(45 ~~pounds~~lbs).

~~5.11.5~~5.13.5 Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

~~5.11.5.1~~5.13.5.1 Automatic exposure control (AEC) performance.

~~5.11.5.1.1~~5.13.5.1.1 The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when the thickness of a homogeneous material is varied over a range of two to six centimeters (2 to 6 cm) and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that shall be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

~~5.11.5.1.2~~5.13.5.1.2 After October 28, 2002, the AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of two to six centimeters (2 to 6 cm) and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

~~5.11.5.1.3~~5.13.5.1.3 The optical density of the film in the center of the phantom image shall not be less than 1.20.

~~5.11.5.2~~5.13.5.2 Kilovoltage peak accuracy and reproducibility. The kVp shall be accurate within plus or minus ~~5~~five percent (5%) of the indicated or selected kVp at:

~~5.11.5.2.1~~5.13.5.2.1 The lowest clinical kVp that can be measured by a kVp test device;

~~5.11.5.2.2~~5.13.5.2.2 The most commonly used clinical kVp;

~~5.11.5.2.3~~5.13.5.2.3 The highest available clinical kVp; and

~~5.11.5.2.4~~5.13.5.2.4 At the most commonly used clinical setting of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be checked annually or upon new x-ray tube installation.

~~5.11.5.3~~5.13.5.3 Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated by measuring focal spot dimensions or by determining system resolution. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution. For focal spot dimensions, the measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the following tolerance limits:

Focal Spot Tolerance Limit

~~Nomical~~Nominal Focal Spot Size (mm)	Maximum Width (mm)	Measured Dimensions Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

~~5.11.5.3.1~~5.13.5.3.1 System Resolution.

~~5.11.5.3.1.1~~5.13.5.3.1.1 Each x-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of eleven (11) cycles per millimeter (mm)(line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode cathode axis, and a minimum resolution of thirteen (13) line-pairs/mm when the bars are parallel to that axis.

~~5.11.5.3.1.2~~5.13.5.3.1.2 The bar pattern shall be placed four and one-half centimeters (4.5 cm) above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within one centimeter (1 cm) of the chest wall edge of the image receptor.

~~5.11.5.3.1.3~~5.13.5.3.1.3 When more than one (1) target material is provided, the measurement shall be made using the appropriate focal spot for each target material.

~~5.11.5.3.1.4~~5.13.5.3.1.4 When more than one (1) source-image receptor distance is provided, the test shall be performed at the SID most commonly used clinically.

~~5.11.5.3.1.5~~5.13.5.3.1.5 Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

~~5.11.5.3.2~~5.13.5.3.2 Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in this Part. The focal spot shall be checked annually or upon new x-ray tube installation.

~~5.11.5.4~~5.13.5.4 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 for any specific combination of selected technique factors. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5$ (Emax - Emin). This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

~~5.11.5.5~~5.13.5.5 Timer Reproducibility. The coefficient of variation of the timer shall not exceed 0.05. This requirement shall be deemed to have been met if, with a selected timer setting, the average exposure

period ($\overline{T}$) shall be greater than or equal to five (5) times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four (4) timer tests are performed: $\overline{T} \geq 5$ (Tmax- Tmin). This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

~~5.11.5.6~~5.13.5.6 Timer Accuracy. Deviation of the selected time setting from indicated time values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%) of the indicated time value. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

~~5.11.5.7~~5.13.5.7 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of ~~40~~forty percent to ~~100~~one hundred percent (40% to 100%) of the maximum rated:

~~5.11.5.7.1~~5.13.5.7.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: [X1-X2] < 0.10 (X1+X2); where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two (2) tube current settings.

~~5.11.5.7.2~~5.13.5.7.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere--seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is [X1-X2] <0.10 (X1+X2); where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

~~5.11.5.7.3~~5.13.5.7.3 Measuring Compliance. Determination of compliance shall be based on four (4) exposures, at each of the two (2) settings. The two (2) settings may include any two (2) focal spot sizes provided that neither focal spot size is equal to or less than .45 millimeter, in which case the two (2) settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the tube manufacturer. Linearity shall also be checked annually or upon new x-ray tube installation.

~~5.11.5.8~~5.13.5.8 Beam quality and half-value layer (HVL). For mammography systems operating at x-ray tube potentials of less than fifty kilovoltage peak (50 kVp), the HVL in millimeters of aluminum of the useful beam shall be equal to or greater than the product of the measured tube potential in kilovolts multiplied by 0.01. The ~~half-value layer~~ HVL shall be measured with the compression device in the beam and shall be measured at the same tube potential used in Appendix A of this Part, Mammography Dose Measurement Protocol, and Appendix B of this Part, Mammography Phantom Image Evaluation. The HVL shall be checked annually and after repairs to the system have been made that could affect the filtration or upon new x-ray tube installation.

~~5.11.5.9~~5.13.5.9 Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

~~5.11.5.10~~5.13.5.10 Dosimetry. The average glandular dose delivered during a single craniocaudal view of a phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast. The average glandular dose shall be checked annually or upon new tube installation.

~~5.11.5.11~~5.13.5.11 X-ray field/light field/image receptor/compression paddle alignment.

~~5.11.5.11.1~~5.13.5.11.1 All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than ~~2~~two percent (2%) of the SID. This requirement is for both large and small cassettes sizes.

~~5.11.5.11.2~~5.13.5.11.2 If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed ~~2~~two percent (2%) of the SID.

~~5.11.5.11.3~~5.13.5.11.3 The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent (1%) of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

~~5.11.5.12~~5.13.5.12 Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

~~5.11.5.13~~5.13.5.13 System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

~~5.11.5.14~~5.13.5.14 Radiation output.

~~5.11.5.14.1~~5.13.5.14.1 The system shall be capable of producing a minimum output of 4.5 Gy air kerma per second (513 mR per second) when operating at twenty-eight kilovoltage peak (28 kVp) in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located four and one-half centimeters (4.5 cm) above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions, shall be capable of producing a minimum output of 7.0 Gy air kerma per second (800 mR per second) when operating at twenty-eight kilovoltage peak (28 kVp) in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

~~5.11.5.14.2~~5.13.5.14.2 The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0-second period.

~~5.11.5.15~~5.13.5.15 Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

~~5.11.5.15.1~~5.13.5.15.1 An override capability to allow maintenance of compression;

~~5.11.5.15.2~~5.13.5.15.2 A continuous display of the override status; and

~~5.11.5.15.3~~5.13.5.15.3 A manual emergency compression release that can be activated in the event of power or automatic release failure.

~~5.11.6~~5.13.6 The quality assurance requirements of RHB 4.2.16 and film processing requirements of RHB 4.2.17.2 shall be met except where otherwise mentioned.

~~5.11.7~~5.13.7 Quality control tests - other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the average glandular dose must meet the requirements of RHB 5.13.5.10.

~~5.11.8~~5.13.8 Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one (1) location meet the requirements in RHB ~~5.11.1~~5.13.1 through ~~5.11.7~~5.13.7. In addition, at each examination location, before any examinations are conducted, the mobile mammography system shall be tested using the mammography phantom image evaluation to establish the adequacy of the image quality produced by the unit.

~~5.11.9~~5.13.9 Use of test results.

~~5.11.9.1~~5.13.9.1 After completion of the tests specified in RHB ~~5.11.1~~5.13.1 through ~~5.11.8~~5.13.8, the facility shall compare the test results to the corresponding specified action limits; or~~,~~ for non-screen film modalities, to the manufacturer's recommended action limits; or for post-move, pre-examination testing of mobile units, to the limits established in the test method used by the facility.

~~5.11.9.2~~5.13.9.2 If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken and documented:

~~5.11.9.2.1~~5.13.9.2.1 Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests described in RHB ~~5.11.1~~5.13.1, ~~5.11.2~~5.13.2, ~~5.11.4.1~~5.13.4.1, ~~5.11.4.2~~5.13.4.2, ~~5.11.4.3~~5.13.4.3, ~~5.11.5.10~~5.13.5.10, ~~5.11.6~~5.13.6, ~~5.11.7~~5.13.7, or ~~5.11.8~~5.13.8.

~~5.11.9.2.2~~5.13.9.2.2 Within thirty (30) calendar days of the test date for all other tests described in RHB ~~5.11~~5.13.

RHB ~~5.12~~5.14. Surveys.

~~5.12.1~~5.14.1 At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests and numerical values to ensure that the facility meets the quality assurance requirements of the annual tests described in RHB ~~5.11.5~~5.13.5 and ~~RHB 5.11.6~~5.13.6 or ~~RHB 5.11.7~~5.13.7; and the weekly phantom image quality test described in ~~5.11.2~~RHB 5.13.2.

~~5.12.2~~5.14.2 The results of all these tests conducted by the facility in accordance with RHB ~~5.11.1~~5.13.1 through ~~RHB 5.11.8~~5.13.8, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

~~5.12.3~~5.14.3 The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

~~5.12.4~~5.14.4 The survey report shall be sent to the facility within thirty (30) calendar days of the date of the survey.

~~5.12.5 The facility shall send a copy of the survey report to the Department within ten days of completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must to be sent to the Department.~~

~~5.12.6~~5.14.5 The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

RHB ~~5.13~~5.15. Mammography equipment evaluations.

Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the applicable standards in RHB ~~5.8~~5.10 and ~~RHB 5.11~~5.13. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or an individual under the direct supervision of a medical physicist.

RHB ~~5.14~~5.16. Calibration of air kerma measuring instruments.

Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two (2) years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus six percent (6%) (ninety-five percent (95%) confidence level) in the mammography energy range.

RHB ~~5.15~~5.17. Additional Administrative Requirements.

Each facility where mammography services are provided shall ensure the availability for each mammography patient:

~~5.15.1~~5.17.1 Instructions on how to perform breast self-examination~~, and~~;

~~5.15.2~~5.17.2 Information that early detection of breast cancer is maximized through a combined approach, using monthly breast self-examination, a thorough physical examination performed by a physician, and mammography performed at recommended intervals; and

~~5.15.3~~5.17.3 Information that mammography is the most accurate method for making an early detection of breast cancer, however, no diagnostic tool is one hundred percent (100%) effective.

RHB ~~5.16~~5.18. Facility Cleanliness.

~~5.16.1~~5.18.1 The facility shall establish and implement written procedures for maintaining darkroom, screen, and view box cleanliness.

~~5.16.2~~5.18.2 The facility shall document that all cleaning procedures are performed at the frequencies specified in the written procedures.

RHB ~~5.17~~5.19. Infection Control.

Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

~~5.17.1~~5.19.1 Comply with the manufacturer-recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

~~5.17.2~~5.19.2 If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

RHB ~~5.18~~5.20. Mammography procedures and techniques~~,~~ for mammography patients with breast implants.

~~5.18.1~~5.20.1 Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

~~5.18.2~~5.20.2 Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

RHB ~~5.19~~5.21. Consumer Complaint Mechanism.

Each facility shall:

~~5.19.1~~5.21.1 Establish a written and documented system for collecting and resolving consumer complaints~~.~~;

~~5.19.2~~5.21.2 Maintain a record of each serious complaint received by the facility for at least three (3) years after the date the complaint was received;

~~5.19.3~~5.21.3 Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction; and

~~5.19.4~~5.21.4 Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

RHB ~~5.20~~5.22. Clinical image quality.

Clinical images produced by any certified facility shall continue to comply with the standards for clinical image quality established by that facility's accreditation body.

RHB ~~5.21~~5.23. Mammography Medical Outcomes Audit.

Each facility shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

~~5.21.1~~5.23.1 General Requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

~~5.21.2~~5.23.2 Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than twelve (12) months after the date the facility becomes certified, or twelve (12) months after April 28, 1999, whichever is later. This audit analysis shall be completed within an additional twelve (12) months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses shall be conducted at least once every twelve (12) months.

~~5.21.3~~5.23.3 Reviewing interpreting physician. Each facility shall designate at least one (1) interpreting physician to review the medical outcomes audit data at least once every twelve (12) months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

RHB ~~5.22~~5.24. Additional Mammography Review and Patient Notification.

~~5.22 .1~~5.24.1 If the Department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Department, for review by the accreditation body. The Department will determine whether the facility is in compliance with this Part and if not, whether there is a need to notify affected patients, their physicians, or the public that the liability, clarity, and accuracy of interpretation of mammograms has been compromised.

~~5.22.2~~5.24.2 If the Department determines that the quality of mammography performed by a facility, whether or not certified under RHB ~~5.3~~5.4, was so inconsistent with the quality standards established in this Part as to present a significant risk to individual or public health, the Department may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Department may require.

~~**RHB 5.23. Revocation of Accreditation.**~~

~~If a facility's accreditation is revoked by an accreditation body, the Department may conduct an investigation into the reasons for the revocation. Following such investigation, the Department may suspend or revoke the facility's certificate and take whatever other action or combination of actions to protect public health, including requiring the establishment and implementation of a corrective plan of action that shall permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.~~

RHB 5.24. Suspension or Revocation of Certificates.

5.24.1 Except as provided in 5.24.2, the Department may suspend or revoke a certificate if the Department finds that the owner, operator, or any employee of the facility:

5.24.1.1 Has been guilty of misrepresentation in obtaining the certificate;

5.24.1.2 Has failed to comply with the standards of RHB 5.2 through 5.22.

5.24.1.3 Has failed to comply with reasonable requests of the Department or the accreditation body for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of RHB 5.2 through RHB 5.22.

5.24.1.4 Has refused a reasonable request of a duly designated FDA inspector, Department inspector or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

5.24.1.5 Has violated or aided and abetted in the violation of any provision of this regulation;

5.24.1.6 Has failed to comply with prior sanctions imposed by the Department; or

5.24.1.7 Has failed to pay any required fees.

5.24.2 The Department may suspend the certificate of a facility if the Department makes a finding described in RHB 5.24.1 and also determines that:

5.24.2.1 The failure to comply with required standards present a serious risk to human health;

5.24.2.2 The refusal to permit inspection makes immediate suspension necessary; or

5.24.2.3 There is a reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

5.24.3 If the Department suspends a certificate in accordance with 5.24.2.

5.24.3.1 The facility may request a review from the Director of Health Regulation no later than thirty days from the effective date of this suspension;

5.24.3.2 The suspension shall remain in effect until the Department determines that:

5.24.3.2.1 Allegations of violations or misconduct were not substantiated;

5.24.3.2.2 Violations of required standards have been corrected to the Department's satisfaction; or

5.24.3.2.3 The facility's certificate is revoked in accordance with 5.24.4;

5.24.4 The Department may revoke the facility's certificate if the Department determines that the facility:

5.24.4.1 Is unwilling or unable to correct violations that were the basis for suspension; or

~~5.24.4.2 Has engaged in fraudulent activity to obtain or continue certification.~~

RHB 5.25. Mammography Units Used for Localization or Stereotactic Breast Biopsy Procedures.

5.25.1 Personnel. The following requirements apply to all personnel involved in localization or biopsy procedures performed with mammography units:

5.25.1.1 Interpreting Physicians. The interpreting physician shall:

5.25.1.1.1 Be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications)~~.~~;

5.25.1.1.2 Be responsible for oversight of all quality control~~.~~;

5.25.1.1.3 Be responsible for the supervision of the radiologic technologist and the medical physicist~~.~~;

5.25.1.1.4 Be responsible for post-biopsy management of the patient~~.~~; and

5.25.1.1.5 Provide ~~D~~documentation of compliance with this Part ~~shall be provided~~ to the Department upon request.

5.25.1.2 Radiologic Technologists.

5.25.1.2.1 The radiologic technologist shall be currently registered in good standing with the American Registry of Radiologic Technologists.

5.25.1.2.2 The technologist shall have previously received documented training specifically in stereotactic breast biopsy procedures and techniques along with positioning for stereotactic units. This training shall consist of fifteen (15) hours of continuing education in mammography every three (3) years and three (3) hours of Category A continuing education in stereotactic breast biopsy every three (3) years.

5.25.1.2.3 Documentation of registration and training shall be provided to the Department upon request.

5.25.1.3 Medical Physicists. The medical physicist shall:

5.25.1.3.1 Be approved by the Department as a Class IX vendor as required in ~~2.6.6.9~~RHB 2.7.8.8 and be certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR) or The American Board of Medical Physics (ABMP);

5.25.1.3.2 Meet the requirements of RHB ~~5.7.3.1.1~~5.9.3.1.1, ~~5.7.3.1.2~~5.9.3.1.2, and ~~5.7.3.1.3~~5.9.3.1.3~~.~~;

5.25.1.3.3 Have fifteen (15) hours of continuing education in mammography physics every three (3) years~~.~~;

5.25.1.3.4 Have performed at least two (2) stereotactic breast biopsy surveys per year; and~~;~~

5.25.1.3.5 Have three (3) hours of continuing education in stereotactic breast biopsy physics every three (3) years.

5.25.2 Equipment. Mammography units used for stereotactic breast biopsy or localization procedures shall meet the requirements of RHB ~~5.8~~5.10, ~~5.11.5.2~~5.13.5.2, ~~5.11.5.3~~5.13.5.3, and ~~5.11.5.8~~5.13.5.8 with the exception of RHB ~~5.11.5.10~~5.13.5.10. Digital output mammography systems that do not use screen-film image receptors are exempt from the requirements of RHB ~~5.8~~5.10 of ~~these~~this regulation~~s~~ as they relate to screen-film image receptors.

5.25.3 Quality Assurance.

5.25.3.1 Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography localization or biopsy procedures performed at the facility.

5.25.3.2 Each facility shall have the services of a medical physicist available to survey mammography equipment and to oversee the equipment-related quality assurance practices of the facility.

5.25.3.3 The quality assurance program shall be in writing and shall have been developed by a medical physicist. The program shall include, but need not be limited to, the following:

5.25.3.3.1 Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

5.25.3.3.2 Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured, and actions to be taken if tolerances are exceeded.

5.25.3.4 The medical physicist shall conduct a review of the quality assurance program each year. Such review shall include evaluation of the results of quality assurance testing and quality control tests as specified in the American College of Radiology's Stereotactic Breast Biopsy ~~Accreditation Program Overview~~QC Manual.

5.25.3.5 Each facility shall maintain written records of the radiation dose measurements and quality assurance testing performed, as required in this Part, for inspection by the Department for a period of at least one (1) year, or until the next Department inspection, whichever is later. Such records shall include, but not be limited to, the following:

5.25.3.5.1 The date of the test and identification of the person performing the test;

5.25.3.5.2 Identification of the type of testing that was performed; and

5.25.3.5.3 Notification of whether the results of the testing were within the parameters established by the medical physicist.

5.25.3.6 The facility shall ~~send~~maintain a copy of the medical physicist's survey report~~to the~~, including documentation of any required corrective action, for Department ~~within ten days of completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must to be sent to the Department~~review.

5.25.3.7 The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct

supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

RHB 5.26. Shielding.

All mammography facilities shall meet the shielding requirements specified in RHB 4.4.

RHB 5.27. Operating conditions.

All mammography facilities shall meet the requirements of RHB 4.2.3.

RHB 5.28. Notification Requirements for Mobile Mammography Facilities Certified by Another Certifying Agency.

Mobile mammography facilities that operate in South Carolina and are certified under MQSA by the FDA, or another ~~S~~state authorized by FDA to certify mammography facilities under MQSA, shall:

5.28.1 Notify the Department by telephone, facsimile, or letter of each date and location of operation of the mobile mammography facility in South Carolina prior to conducting such operation as required by RHB 2.4.2.1.4.

5.28.2 At all times while operating in South Carolina, have the following documentation available for review and inspection by the Department:

5.28.2.1 A copy of the mammography facility certificate issued by the FDA or another ~~S~~state, showing that the facility is currently certified~~.~~;

5.28.2.2 A summary of the most recent physics survey of the mammography machine(s) and documentation of any corrective actions recommended by the medical physicist who performed the physics survey~~.~~; and

5.28.2.3 Documentation that personnel meet the qualifications of RHB ~~5.7~~5.9.

5.28.3 All provisions of RHB 2.3.4 and 2.4.2 apply.

RHB 5.29. Failure of Mobile Mammography Facilities Certified by Another Certifying Entity to Meet Requirements.

The Department shall notify the certifying entity of the facts and circumstances and may take other actions as may be appropriate under the Atomic Energy and Radiation Control Act and regulations thereunder if the Department has reason to believe that the owner, operator, or any employee of a mobile facility certified by another certifying entity:

5.29.1 Has been guilty of misrepresentation in obtaining the certificate;

5.29.2 Has failed to comply with the standards of this Part;

5.29.3 Has failed to comply with reasonable requests of the Department for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of this Part; or

5.29.4 Has refused a reasonable request of a Department representative for permission to inspect the facility or the operations and pertinent records of the facility.

Appendix A. Mammography Dose Measurement Protocol.

The technique factors used for performing a mammography examination shall not permit the mean glandular absorbed dose to exceed the limits specified in RHB ~~5.11.5.10~~5.13.5.10. Radiation measurements shall be performed with an integrating radiation measuring device that is appropriate to the high beam intensity and mammographic kilovoltage peak (kVp) used, and sufficiently sensitive to determine compliance with the criteria specified in RHB ~~5.14~~5.16. The instrument shall have been calibrated as specified in RHB ~~5. 145.~~5.16.

The mammography exam dose limits are based on an average compressed breast value of 4.2 centimeters having an average density (i.e., ~~50~~fifty percent (50%) adipose and ~~50~~fifty percent (50%) glandular).

Perform the following steps to determine the mean glandular dose to a nominal 4.2 centimeter compressed breast:

a) Measure and record the x-ray system's useful beam half value layer (HVL). (See RHB ~~5.11.5.8~~5.13.5.8.) Any compression device normally in the useful beam during mammography procedures shall be required to be placed between the x-ray tube target and measuring device when determining the HVL. The useful beam shall be collimated to a size encompassing the detector.

NOTE: Filters used for the HVL evaluation should be placed as close to the target as practical. The HVL for screen-film mammography should not exceed the minimum acceptable HVL by more than 0.1 millimeter of aluminum equivalent.

b) Determine the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (see Appendix C of this Part) using the appropriate HVL, kVp, and x-ray tube target-filter material.

NOTE: The kVp of screen-film mammography systems with molybdenum target-filter combinations should be accurately measured to determine the appropriate glandular dose to entrance exposure factor from Appendix C of this Part.

c) If the equipment has the capability for variable source-to-image receptor distance (SID), set the craniocaudal ~~source to image receptor distance (~~SID~~)~~ for the image receptor system used.

d) Position in the useful beam any compression apparatus normally used.

NOTE: Some mammography systems have the capability of providing automatic adjustment of technique factors through feedback from the position of the compression device. On such systems, the compression device should be lowered to a position 4.2 centimeters above the breast support assembly (BSA). The device should then be removed, inverted, and replaced to allow placement of the phantom and measuring device on the BSA below the compression device. If the compression device cannot be replaced in an inverted position, the device should be placed in the beam using auxiliary support.

e) Placement of the Radiation Measuring Device

1) For systems equipped with automatic exposure control (AEC):

A) Place a properly loaded film cassette in the cassette holder.

NOTE: The loaded cassette is placed in the cassette holder to simulate, as much as is possible, the conditions under which actual patient exposures are made. Following radiation measurements, the film should be discarded and the cassette reloaded with unexposed film.

B) Place a mammography phantom (see the definition for "Phantom" ~~in RHB 9.168~~) on the breast support assembly (BSA). Align the phantom so that the edge of the phantom is aligned with the chest wall side of the BSA and the phantom is over the automatic exposure control device(s).

C) Place a radiation measuring device in the useful beam so the center axis of the device is parallel to the breast support assembly (~~13~~BSA). The geometric center of the measuring device shall be positioned 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA, and immediately adjacent to either side of the mammography phantom.

2) For systems not equipped with AEC, place a radiation measuring device in the useful beam so that the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned so that it is centered 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA, and at the center line of the BSA. No part of the devices detector area shall be outside of the useful beam.

f) Collimate the x-ray field to the size normally used and assure that the area covered by the useful beam includes the detector area of the radiation measuring device and the mammography phantom if the equipment is equipped with automatic exposure.

g) Set the appropriate technique factors or automatic exposure controls normally used for a nominal 4.2 centimeter compressed breast.

h) Measure and record the exposure in air with the radiation measuring device.

i) Calculate the mean glandular dose for a 4.2 centimeter compressed breast by multiplying the measured exposure in millicoulombs per kilogram or in roentgens by the glandular dose to entrance exposure factor, which was determined using the procedure described in subsection (b) of this Appendix.

EXAMPLE: A mammography system is provided with a molybdenum target-filter combination, and the HVL and kVp are determined to be 0.3 and 30, respectively. Therefore, for a 4.2 centimeter compressed breast, the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (Appendix C of this Part) would be 159 mrad. The measured roentgen output determined in subsection (h) of this Appendix is determined to be 1.8 R. Therefore, the mean glandular dose would be 1.8 R multiplied by 159 mrad/R-. This results in a mean glandular dose measurement of 286 mrad. As such, the system would be in compliance with RHB ~~5.11.5.10~~5.13.5.10.

Appendix B. Mammography Phantom Image Evaluation.

Mammography ~~P~~phantom image evaluation shall be performed using the procedure below. The evaluation shall be performed weekly as a part of the quality assurance program. The evaluation shall be performed with the mammography phantom specified in ~~RHB 9.172~~Part X.

a) Equipment necessary for mammography phantom image evaluation includes a densitometer, the mammography phantom, and mammographic cassette and film.

b) Load film in the mammographic cassette according to the manufacturer's instructions.

c) Place the properly loaded cassette in the cassette holder.

d) Place the mammography phantom on the breast support assembly (BSA) so that the edge of the phantom is aligned with the chest wall side of the BSA. Align the phantom so that the masses in the phantom are nearest the chest wall edge of the BSA and the fibers in the phantom are away from the chest wall edge of the BSA. If the mammography machine has the capability of automatic exposure control, place the phantom so that the phantom covers the phototimer sensor.

e) Position the compression device so that it is in contact with the phantom.

f) Select the technique factors used most frequently in the clinical setting for a 4.2 centimeter compressed breast and make an exposure of the phantom.

g) Process the film in the processor used for clinical mammography films.

h) Examine the processed image for areas of non-uniformity of optical density and for the presence of artifacts due to dirt, dust, grid lines, or processing.

NOTE: If any of the problems noted above are evident on the processed image, the mammography machine film processor and film cassette(s) should be evaluated and the problem corrected. The phantom image evaluation should be repeated after the problem is corrected.

i) Measure and record the optical density of the film near the center of the phantom image. The optical density of the film at the center of the image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

j) Examine the phantom image and count and record the number of masses visualized. Repeat this procedure for the speck groups and the fibrils and record the number of objects visualized. There are a total of sixteen (16) imaging objects (five (5) masses, five (5) speck groups, and six (6) fibrils) in the phantom. Evaluation criteria for objects visualized in the phantom image are in RHB ~~5.11.2.3.~~5.13.2.5 and ~~RHB 5.11.2.4~~5.13.2.4. As a minimum, the objects that must be visualized in the phantom image are:

1) The masses that are 0.75 millimeter or larger (a total of three (3) masses);

2) The speck groups that are 0.32 millimeter or larger (a total of three (3) speck groups); and

3) The fibrils that are 0.75 millimeter or larger (a total of four (4) fibrils).

NOTE: The phantom image should be compared with previous films, including the original phantom image, to determine if subtle changes are occurring from week to week.

Appendix C. Mammography Dose Evaluation Tables.

These tables are used to determine the mean glandular dose in milligrays delivered by 25.9 mC/kg (or millirad) delivered by one Roentgen (1 R) in air incident on a 4.2 centimeter thickness compressed breast of average density (~~50~~fifty percent (50%) adipose and ~~50~~fifty percent (50%) glandular tissue). Linear extrapolation or interpolation shall be made for any HVL not listed. To convert from entrance exposure in air in roentgens to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination.

GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS---50% ADIPOSE-_50% GLANDULAR BREAST TISSUE---USING A Mo/Mo TARGET-FILTER COMBINATION*

X-ray Tube Voltage (kVp)												W/Al
												Target-Filter
HVL	23	24	25	26	27	28	29	30	31	32	33	Combination
0.23	116											
0.24	121	124										
0.25	126	129	131									
0.26	130	133	135	138								
0.27	135	138	140	142	143							
0.28	140	142	144	146	147	149						
0.29	144	146	148	150	151	153	154					
0.30	149	151	153	155	156	157	158	159				170
0.31	154	156	157	159	160	161	162	163	164			175
0.32	158	160	162	163	164	166	167	168	168	170	171	180
0.33	163	165	166	168	169	170	171	173	173	174	175	185
0.34	168	170	171	172	173	174	175	176	177	178	179	190
0.35		174	175	176	177	178	179	180	181	182	183	194
0.36			179	181	182	183	184	185	185	186	187	199
0.37				185	186	187	188	189	190	191	191	204
0.38					190	191	192	193	194	195	195	208
0.39						196	197	198	198	199	200	213
0.40							201	202	203	204	204	217
0.41								206	207	208	208	221
0.42									211	212	212	225
0.43										215	216	230
0.44											220	234
0.45												238

GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS ---50% ADIPOSE 50% GLANDULAR BREAST TISSUE ---USING A Mo/Rh TARGET-FILTER COMBINATION*

X-ray Tube Voltage (kVp)											
HVL	25	26	27	28	29	30	31	32	33	34	35
0.28	149	151	154								
0.29	154	156	158	159							
0.30	158	160	162	162	163						
0.31	163	164	166	166	166	167	167				
0.32	167	169	171	171	171	171	172	172			
0.33	171	173	175	176	176	176	176	177			
0.34	176	178	179	179	180	180	180	181	181		
0.35	180	181	183	183	184	185	185	186	187		
0.36	185	186	187	187	188	188	189	190	191	191	
0.37	189	190	191	191	192	193	193	194	195	195	
0.38	193	194	196	196	197	197	197	198	199	199	200
0.39	198	199	200	200	201	201	202	202	203	203	204
0.40	202	203	204	204	205	205	206	207	208	208	208
0.41	206	207	208	208	209	209	210	211	212	212	212
0.42	211	211	212	212	213	213	214	215	216	216	217
0.43	215	216	217	217	218	218	219	219	220	220	221
0.44	220	220	221	221	222	222	223	223	224	224	225
0.45	224	224	225	225	226	226	227	227	228	228	229
0.46		228	229	229	230	231	231	232	233	233	234
0.47			233	233	234	235	235	236	237	237	238
0.48			238	238	239	240	240	241	241	242	242
0.49				242	243	243	244	244	245	245	246
0.50					247	247	248	248	249	250	251
0.51						251	252	253	254	254	255
0.52							257	257	258	258	259
0.53							261	261	262	263	264
0.54								265	266	267	268
0.55								269	270	271	272
0.56									275	276	276
0.57									279	280	281
0.58										284	285
0.59										288	289
0.60											293

GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS ---50% ADIPOSE 50% GLANDULAR BREAST TISSUE ---USING A Rh/Rh TARGET-FILTER COMBINATION*

X-ray Tube Voltage (kVp)											
HVL	25	26	27	28	29	30	31	32	33	34	35
0.28	150	155	159								
0.29	155	160	164	168							
0.30	160	164	168	172	176						
0.31	165	168	172	174	180	182					
0.32	169	173	177	181	184	186	188				
0.33	174	178	181	185	188	190	192				
0.34	179	183	186	190	193	195	196	199			
0.35	184	187	190	194	197	199	201	203			
0.36	189	192	195	198	201	204	205	207	209		
0.37	193	196	199	202	205	207	209	211	213		
0.38	198	201	204	207	209	211	213	215	217	219	221
0.39	203	206	208	211	214	216	217	219	221	223	224
0.40	208	211	213	216	218	220	221	223	224	226	228
0.41	213	215	217	220	222	224	225	227	228	230	232
0.42	218	220	222	224	226	228	229	231	232	234	236
0.43	222	224	226	228	230	232	233	235	236	238	240
0.44	227	229	231	233	235	237	238	239	240	242	243
0.45	232	234	235	237	239	241	242	243	244	246	247
0.46			239	241	243	245	246	247	248	250	251
0.47					247	249	250	251	252	254	255
0.48					251	253	254	255	256	258	259
0.49						257	258	259	260	261	262
0.50						261	262	263	264	265	266
0.51							266	267	268	269	270
0.52							270	271	272	273	274
0.53							275	276	276	277	278
0.54								279	280	280	281
0.55								283	284	284	285
0.56									288	288	289
0.57										292	293
0.58										296	297
0.59											300
0.60											304

PART VI
USE OF THERAPEUTIC EQUIPMENT

RHB 6.1. Scope.

This ~~p~~Part establishes requirements, for which the registrant is responsible, for use of therapeutic radiation equipment~~ by persons licensed to practice one or more of the health professions within the authority granted to them by statute or regulation~~. ~~Therapeutic equipment in this part will be defined as any therapeutic machine capable of producing a useful beam of x-rays, or x-rays and charged particles with energies greater than 500 keV. Particle accelerators meeting this definition will be regulated under this part while all other particle accelerators will be regulated under Title C~~. The provisions of this ~~p~~Part are in addition to, and not in substitution for, other applicable provisions of ~~these~~this regulation~~s~~. All provisions of this Part also apply to therapeutic veterinary installations.

RHB 6.2. Shielding Requirements for all Therapeutic X-ray Equipment.

6.2.1 All facilities utilizing therapy equipment shall meet the shielding requirements specified in RHB 4.4.

RHB 6.3. General Provisions for ~~A~~all Therapeutic Equipment.

6.3.1 Radiation Safety Officer.

6.3.1.1 The registrant shall designate an individual who will be responsible for radiation protection for the therapeutic equipment. Such individual may be a radiological physicist, and shall:

6.3.1.1.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the therapeutic equipment for which he or she is responsible~~.~~;

6.3.1.1.2 Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of ~~these~~this regulation~~s~~.;

6.3.1.1.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the therapeutic equipment~~.~~; and

6.3.1.1.4 ~~Make~~Ensure surveys are performed and carry out other procedures as required by ~~these~~this regulation~~s~~.

6.3.1.2 Each therapeutic machine shall be under the administrative control of the Radiation Safety Officer, who will be responsible for the safe operation of the equipment.

6.3.2 Procedures.

6.3.2.1 Written operating procedures as well as specified safety rules shall be established for each therapeutic unit facility and approved by the ~~r~~Radiation ~~s~~Safety ~~o~~Officer.

6.3.2.1.1 Operating procedures. The written operating procedures to be implemented shall include the following:

6.3.2.1.1.1 Policies and procedures for pregnant workers; ~~NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers;~~

6.3.2.1.1.2 Policies and procedures for personnel monitoring;

6.3.2.1.1.3 Policies and procedures for training new employees; ~~and~~

6.3.2.1.1.4 Policies and procedures for identifying and reporting misadministrations~~, as defined by RHB 9.153.~~; and

6.3.2.1.1.5 Policies and procedures for quality assurance addressing annual equipment performance testing on radiation therapy simulators and CT scanners used for treatment planning.

6.3.2.1.2 Emergency Procedures. The emergency procedures shall include instructions for contacting the therapeutic radiological physicist when operational problems or emergencies occur and the actions that are to be taken until the physicist can be contacted.

6.3.2.2 Operators and maintenance personnel shall be familiar with and have available a copy of the written operating and emergency procedures. Documentation must be maintained indicating that the operator or maintenance person has read and agrees to adhere to the operating procedures.

6.3.3 Operator Requirements and Training.

6.3.3.1 The registrant shall assure that all therapeutic equipment under his or her control is operated only by a radiation therapist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association. For the purpose of this Part, a radiation therapist is defined as a person who applies radiation to humans for therapeutic purposes; performs treatment setups, including, but not limited to, patient positioning, setting of treatment parameters on the control panel, and verification of treatment accessories; or documents daily treatments for a patient's chart.

6.3.3.2 In-house modification, repairs, or preventative maintenance on therapeutic equipment components or safety interlocks may be performed only by or under the direct supervision of persons who have received at least the minimum training specified in RHB 6.3.3.12 and demonstrated competence specified in RHB 6.3.3.13.

6.3.3.3 No person other than a licensed practitioner or a radiation therapist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes.

6.3.3.4 No person shall employ or designate as a radiation therapist a person who does not hold a certificate issued by the South Carolina Radiation Quality Standards Association.

6.3.3.5 No person holding a certificate issued by the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

6.3.3.6 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer," "radiographer," ~~or~~ "radiation

therapist," or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for therapeutic purposes.

6.3.3.7 A student enrolled in and attending a school or college of medicine, radiologic technology, radiation therapy, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine may apply ionizing radiation to humans without a certificate from the South Carolina Radiation Quality Standards Association, as long as the student or resident is under the direct supervision of a licensed practitioner or direct supervision of a certified radiation therapist appropriately trained to supervise the specific procedure.

6.3.3.8 The registrant shall display each operator's current certificate in public view, not obstructed by any barrier, equipment, or other object. The registrant may also post a notice to the public that South Carolina Radiation Quality Standards Association certificates are available for review upon request.

6.3.3.9 The registrant shall ensure that each operator has received training specific to the equipment and procedures in use at his or her facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 6.3.2. Documentation of this training for each operator shall be made available for Departmental review.

6.3.3.10 The registrant shall ensure ~~A~~all operators ~~shall~~ receive at least one (1) month of on-the-job training before assuming operational responsibility. Documentation of training shall include, at a minimum, the date the operator was assigned therapeutic responsibility; the training completion date; and topics covered in training.

6.3.3.11 The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection. Training records of former operators shall be retained for a period of at least two (2) years, or until the next Department inspection, whichever is later.

6.3.3.12 Training of in-house and test maintenance personnel shall include:

6.3.3.12.1 Fundamentals of Radiation Safety~~;~~.

6.3.3.12.1.1 Characteristics of radiation.

6.3.3.12.1.2 Units of radiation dose.

6.3.3.12.1.3 Hazards of excessive exposure to radiation.

6.3.3.12.1.4 Levels of radiation from therapeutic equipment.

6.3.3.12.1.5 Methods used to prevent radiation exposure including shielding, interlocks, safety rules, and radiation monitoring equipment.

6.3.3.12.2 Use and care of personnel monitoring equipment employed at the facility.

6.3.3.12.3 Location and use of all operating controls.

6.3.3.12.4 Requirements of pertinent ~~S~~state ~~R~~regulations.

6.3.3.12.5 Registrant's written operating and emergency procedures.

6.3.3.13 In-house personnel who are to perform or directly supervise modifications, tests, or maintenance work shall demonstrate the following capabilities to the ~~r~~Radiation ~~s~~Safety ~~o~~Officer:

6.3.3.13.1 Ability to read and understand electrical diagrams.

6.3.3.13.2 A thorough knowledge of the principles and operation of the therapeutic equipment.

6.3.3.13.3 A thorough knowledge of the safety interlock system.

6.3.3.13.4 Ability to understand, use, and check the operation of radiation survey instruments.

6.3.3.14 The registrant shall maintain a record of all training for in-house testing and maintenance personnel. Such records shall be made available for Departmental inspection.

6.3.4 Training for Therapeutic Radiation Machine Authorized Users.

6.3.4.1 For any therapeutic radiation machine covered in Part VI the registrant shall require the authorized user to be a licensed practitioner who~~;~~:

6.3.4.1.1 Is certified in:

6.3.4.1.1.1 Radiation ~~O~~oncology or therapeutic radiology by the American Board of Radiology, or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; ~~or~~

6.3.4.1.1.2 Radiation oncology by the American Osteopathic Board of Radiology; ~~or~~

6.3.4.1.1.3 Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; ~~or~~

6.3.4.1.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~;~~

6.3.4.1.2 Is in the active practice of therapeutic radiology and has completed two hundred (200) hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

6.3.4.1.2.1 To satisfy the requirement for instruction, the classroom and laboratory training shall include radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of ionization radiation, and radiation biology.

6.3.4.1.2.2 To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include review of the full calibration measurements and periodic quality assurance checks, evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings, using administrative controls to prevent misadministrations, implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console, and checking and using radiation survey meters.

6.3.4.1.2.3 To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral

Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

6.3.4.1.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

6.3.4.1.2.3.2 Selecting proper dose and how it is to be administered;

6.3.4.1.2.3.3 Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

6.3.4.1.2.3.4 Post-administration follow-up and review of case histories.

6.3.4.2 The registrant shall maintain a record of all training for each authorized user. Such records shall be made available for Departmental inspection.

6.3.5 Control.

6.3.5.1 The ~~radiation safety officer~~Radiation Safety Officer shall maintain a current list of all personnel who are qualified to service the therapeutic equipment.

6.3.5.2 No registrant shall permit a therapeutic unit to operate at any time with a safety interlock bypassed, except for necessary testing.

6.3.5.3 The accelerator shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient.

6.3.5.4 No individual other than the patient shall be in the therapy room during irradiation.

6.3.5.5 Individuals shall not be exposed to the useful beam except for therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.

6.3.6 Technique indicators. Instrumentation readouts and controls on the therapy control console must be clearly identified and easily discernable.

6.3.7 The accelerator is used in such a manner that patients, workers, and the general public are protected from radiation hazards and the provisions of Part III of ~~these~~this regulation~~s~~ are met.

6.3.8 No therapeutic machine shall be left unattended unless it is secured against unauthorized use.

RHB 6.4. Therapeutic X-ray Systems of Less than 1 MeV.

6.4.1 Equipment requirements.

6.4.1.1 Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the values specified at the distance stated for the classification of that x-ray system shown in Table 1.

TABLE 1. LEAKAGE LIMITS FOR THERAPEUTIC X-RAY SYSTEMS OF LESS THAN 1 MeV.

System	Leakage Limit	Measurement Location
~~Contact Therapy~~	~~100 mR/hr~~	~~5 cm from surface of tube housing~~
Contact Therapy	100 mR/hr	5 cm from surface of tube housing
0-150 kVp (manufactured or installed prior to ~~the effective date of these regulations~~January 1, 1994)	1 R in 1 hr.	1 m from source
0-150 kVp (manufactured on or after ~~the effective date of these regulations~~ January 1, 1994)	100 mR in 1 hr	1 m from source
151-500 kVp	1 R in 1 hr	1 m from source
500-999 kVp	0.1 percent of 1 R in 1 hr.	1 m from source useful beam ~~or~~

6.4.1.2 Permanent Beam-Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

6.4.1.3 Removable and Adjustable Beam-Limiting Device.

6.4.1.3.1 Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than ~~1~~one percent (1%) of the useful beam at the maximum kV and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

6.4.1.3.2 Adjustable beam-limiting devices shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than ~~5~~five percent (5%) of the useful beam at the maximum kV and maximum treatment filter.

6.4.1.3.3 Adjustable beam-limiting devices installed after May 25, 2001, shall meet the requirements of RHB 6.4.1.3.

6.4.1.4 The filter system shall be so designed that:

6.4.1.4.1 The filters cannot be accidentally displaced at any possible tube orientation;

6.4.1.4.2 For equipment installed after ~~the effective date of these regulations~~January 1, 1994, an interlock system prevents irradiation if the proper filter is not in place;

6.4.1.4.3 The radiation at ~~5~~five centimeters (5 cm) from the filter insertion slot opening does not exceed ~~30~~thirty Roentgens (30 R)(7.74 mC/kg) per hour under any operating conditions; and

6.4.1.4.4 Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

6.4.1.5 Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

6.4.1.6 Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within ~~5~~five millimeters (5 mm), and such markings shall be readily accessible for use during calibration procedures.

6.4.1.7 Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at one hundred kilovoltage peak (100 kVp) that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

6.4.1.8 Beam Monitoring System. Systems of greater than one hundred fifty (150 kVp) manufactured after ~~the effective date of these regulations~~January 1, 1994, shall be provided with a beam monitoring system which:

6.4.1.8.1 Shall have the detector of the monitor system interlocked to prevent incorrect positioning;

6.4.1.8.2 Shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;

6.4.1.8.3 Shall independently terminate irradiation when the preselected exposure has been reached;

6.4.1.8.4 Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

6.4.1.8.5 Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

6.4.1.8.6 Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero (0); and

6.4.1.8.7 Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

6.4.1.9 Timer.

6.4.1.9.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector.

6.4.1.9.2 The timer shall activate with the production of radiation and retain its reading after irradiation is interrupted. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero (0).

6.4.1.9.3 The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

6.4.1.9.4 The timer shall permit accurate presetting and determination of exposure times as short as one (1) second.

6.4.1.9.5 The timer shall not permit an exposure if set at zero (0).

6.4.1.9.6 The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer factor to compensate for mechanical lag.

6.4.1.9.7 Timers shall be accurate to within ~~1~~one percent (1%) of the selected value or one (1) second, whichever is greater.

6.4.1.10 Control Panel Functions. The control panel, in addition to the displays required in other provisions of this Part, shall have:

6.4.1.10.1 An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

6.4.1.10.2 An indication of whether x-rays are being produced;

6.4.1.10.3 Means for indicating x-ray tube potential and current;

6.4.1.10.4 Means for terminating an exposure at any time;

6.4.1.10.5 A locking device which will prevent unauthorized use of the x-ray system; and

6.4.1.10.6 For x-ray systems manufactured after May 25, 2001, a positive display of specific filters in the beam.

6.4.1.11 Multiple Tubes. When a control panel may energize more than one (1) x-ray tube:

6.4.1.11.1 It shall be possible to activate only one (1) x-ray tube at any time;

6.4.1.11.2 There shall be an indication at the control panel identifying which x-ray tube is activated; and

6.4.1.11.3 There shall be an indication at the tube housing assembly when that tube is energized.

6.4.1.12 Source-to-Skin Distance (SSD). There shall be means of determining initially the SSD to within ~~1~~one centimeter (1 cm) and of producing this measurement to within ~~2~~two millimeters (2 mm) thereafter.

6.4.1.13 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

6.4.1.13.1 After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

6.4.1.13.2 An indication of shutter position shall appear on the control panel.

6.4.2 Facility Design Requirements for Therapy X-ray Systems Capable of Operating Above 50 kVp.

6.4.2.1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

6.4.2.2 Viewing Systems.

6.4.2.2.1 Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

6.4.2.2.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.4.2.2.3 Should both systems described in RHB 6.4.2.2.2 above fail or be inoperative, treatment shall not be performed with the unit until one of the systems is restored.

6.4.2.3 Barriers. With equipment operating at voltages above fifty kilovoltage peak (50) kVp), the required barriers shall be an integral part of the building.

6.4.2.4 Multiple Access. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on.". Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3 Additional Requirements for X-ray Systems Capable of Operating Above 150 kVp.

6.4.3.1 All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.4.3.2 The control panel shall be within a protective booth equipped with an interlocked door or located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room.

6.4.3.3 Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booth, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3.4 When any door referred to in RHB 6.4.3.3 is opened while the x-ray tube is activated, the exposure at a distance of 1one meter (1 m) from the source shall be reduced to less than 100one hundred milliroentgen (100 mR) per hour.

6.4.3.5 A scram button or other emergency power cut-off switch shall be located and easily identifiable in all accessible high radiation areas.

6.4.3.6 All safety and warning devices, including interlocks, shall be tested and appropriately serviced after each five hundred (500) hours of operation or at intervals not to exceed six (6) months, whichever comes first. Documentation shall be kept and available for review of all testing and servicing.

6.4.4 Surveys, Calibrations, and Spot Checks.

6.4.4.1 Surveys.

6.4.4.1.1 All new facilities, and existing facilities not previously surveyed shall have a survey made by or under the direction of a qualified expert who is authorized by the Department to perform such surveys. Such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. A record shall be made of the therapeutic operating conditions and radiation

levels measured at specific control points. One (1) of these control points must be at the normal work station of the operator.

6.4.4.1.2 The registrant shall obtain a written report of the survey from the qualified expert. A copy of the initial report shall be transmitted by the registrant to the Department within thirty (30) calendar days of the first patient treatment following the survey. The registrant shall maintain all subsequent reports for inspection by the Department.

6.4.4.1.3 The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules or regulations.

6.4.4.1.4 The registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by ~~these~~this regulation~~s~~. Each radiation survey instrument shall meet the requirements of RHB 1.4.4.

6.4.4.2 Calibrations. Calibrations of x-ray systems subject to the requirements of this Part shall meet the following requirements:

6.4.4.2.1 The calibration of an x-ray system shall be performed at intervals not to exceed one (1) year and after any change or replacement of components which could cause a change in the radiation output on output.

6.4.4.2.2 The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.

6.4.4.2.3 Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall meet the requirements of RHB 1.4.4.

6.4.4.2.4 The calibration shall be such that the dose at a reference point in a water or tissue equivalent phantom can be calculated to within an uncertainty of ~~5~~five percent (5%). For superficial units, free-in-air calibrations are acceptable.

6.4.4.2.5 The calibration of the x-ray system shall include, but not be limited to, the following determinations:

6.4.4.2.5.1 Verification that the x-ray system is operating in compliance with the design specifications;

6.4.4.2.5.2 Half-value layer for each kV setting and filter combination used;

6.4.4.2.5.3 The exposure rates as a function of field size, technique factors, filter, and treatment distance used; and

6.4.4.2.5.4 The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present, which shall be within ~~5~~five millimeters (5 mm) for any field edge.

6.4.4.2.6 Records of calibrations shall be maintained by the registrant for five (5) years after completion of the calibration. The records shall be available for review.

6.4.4.2.7 A copy of the most recent x-ray system calibration shall be available at or in the general area of the control panel.

6.4.4.2.8 A copy of the most recent x-ray system calibration shall be submitted to the Department upon request.

6.4.4.3 Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than one hundred fifty kilovoltage peak (150 kVp). Such spot checks shall meet the following requirements:

6.4.4.3.1 The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be submitted to the Department upon request.

6.4.4.3.2 If the radiological physicist does not perform the spot check measurement, the results of the spot check measurements shall be reviewed by the radiological physicist within seven (7) treatment days and a record made of the review.

6.4.4.3.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed. The spot check procedures shall specify that the spot check shall be performed during the calibration specified in RHB 6.4.4.2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in RHB 6.4.4.2 shall be stated.

6.4.4.3.4 The written spot check procedures shall include special operating instructions which shall be carried out whenever a parameter in RHB 6.4.4.2 exceeds an acceptable tolerance.

6.4.4.3.5 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot check procedures, the system shall be recalibrated, as required in RHB 6.4.4.2.

6.4.4.3.6 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for two (2) years after completion of the spot check measurements. A copy of the most recent spot check shall be available at or in the area of the control panel.

6.4.4.3.7 Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RHB 6.4.4.2.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.4.4.4 Prohibited use. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of RHB 6.4.4.2 and ~~RHB~~ 6.4.4.3 have been met.

RHB 6.5. X-ray and Electron Therapy Systems with Energies of 1 MeV and Above.

These rules shall apply to facilities using therapy systems with energies 1 MeV and above. The records shall be maintained and available for review.

6.5.1 Leakage Radiation to the Patient Area. Equipment shall meet the following requirements:

6.5.1.1 For operating conditions producing maximum leakage radiation, the absorbed dose in rads (Grays) due to leakage radiation, including x-rays and electrons, at any point in a circular plane of ~~2~~two meters (2 m) radius centered on and perpendicular to the central axis of the beam at the isocenter or ~~normal~~nominal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent

of the maximum absorbed dose in rads (Grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, ~~100~~one hundred square centimeters (100 cm^2) at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, ~~200~~two hundred square centimeters (200 cm^2).

6.5.1.2 For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in RHB 6.5.1.1 for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Department.

6.5.2 Beam-Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than ~~2~~two percent (2%) of the useful photon beam at the ~~normal~~nominal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

6.5.3 Filters.

6.5.3.1 Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be redetermined.

6.5.3.2 If the absorbed dose rate data required by RHB 6.5.15 relates exclusively to operation with a field-flattening filter or beam scattering foil in place, such filter shall be removable only by the use of tools.

6.5.3.3 For equipment installed after May 25, 2001, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering foils:

6.5.3.3.1 Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically.

6.5.3.3.2 An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

6.5.3.3.3 A display shall be provided at the treatment control panel showing filters in use.

6.5.3.3.4 An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

6.5.3.4 Attenuation of wedges and compensator devices must be checked before the device is placed into service. A visual inspection of the mechanical integrity of these accessories must be done monthly.

6.5.4 Beam Quality. The registrant shall determine data sufficient to assure that the following beam quality requirements in tissue equivalent material are met:

6.5.4.1 The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ~~10~~ten centimeters (10 cm) greater than the practical range of the electrons shall not exceed the values stated in Table 2. Linear interpolation shall be used for values not stated.

Table 2

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose As a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

6.5.4.2 Compliance with RHB 6.5.4 shall be determined using:

6.5.4.2.1 A measurement within a tissue equivalent phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

6.5.4.2.2 The largest field size available which does not exceed ~~15~~fifteen centimeters by ~~15~~fifteen centimeters (15 cm x 15 cm); and

6.5.4.2.3 A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least ~~5~~five centimeters (5 cm) and whose depth is sufficient to perform the required measurement.

6.5.4.3 The measured ionization at the surface relative to maximum ionization along the central axis shall not exceed the limits stated in Table 3. Linear interpolation shall be used for values not stated.

Table 3

Maximum Photon Energy in MeV	Measured Ionization at surface relative to Maximum Ionization along central axis
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

6.5.4.4 Compliance with RHB 6.5.4.3 shall be determined by measurements made:

6.5.4.4.1 Within a tissue equivalent phantom using an instrument which will allow extrapolation to the surface absorbed dose;

6.5.4.4.2 Using a phantom whose size and placement meet the requirements of RHB 6.5.4.2;

6.5.4.4.3 After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam-flattening filters; and

6.5.4.4.4 Using the largest field size available which does not exceed ~~15~~fifteen centimeters by ~~15~~fifteen centimeters (15 cm x 15 cm).

6.5.5 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

6.5.5.1 Equipment manufactured after January 1, 1994, shall be provided with at least two (2) independent radiation detectors. The detectors shall be incorporated into two (2) independent dose monitoring systems.

6.5.5.2 Equipment manufactured before January 1, 1994, shall be provided with at least one (1) radiation detector. This detector shall be incorporated into a primary dose monitoring system.

6.5.5.3 The detector and the system into which that detector is incorporated shall meet the following requirements:

6.5.5.3.1 Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

6.5.5.3.2 Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

6.5.5.3.3 Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

6.5.5.3.4 For new equipment, the design of the dose monitoring systems shall assure that: a) ~~M~~malfunctioning of one (1) system shall not affect the correct functioning of the secondary system; and b) ~~F~~failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

6.5.5.3.5 Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

6.5.5.3.5.1 Maintain a reading until intentionally reset to zero (0);

6.5.5.3.5.2 Have only one (1) scale and no scale multiplying factors for each mode of operation; and

6.5.5.3.5.3 Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined~~; and~~.

6.5.5.3.6 In the event of power failure, the dose monitoring information required by RHB 6.5.5.3.5 displayed at the control panel at the time of failure shall be retrievable in at least one (1) system for a twenty (20)-minute period of time.

6.5.6 Beam Symmetry. In new equipment inherently capable of producing useful beams with unattenuated asymmetry exceeding ~~5~~five percent (5%), the asymmetry of the radiation beam in two (2) orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds ~~5~~five percent (5%) of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ~~10~~ten percent (10%), the irradiation is terminated.

6.5.7 Selection and Display of Dose Monitor Units.

6.5.7.1 Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

6.5.7.2 The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

6.5.7.3 After termination of irradiation, it shall be necessary to manually reset the dosimeter display to zero (0) before subsequent treatment can be initiated.

6.5.7.4 For new equipment, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

6.5.8 Termination of Irradiation by the Dose Monitoring System or Systems during Stationary Beam Therapy.

6.5.8.1 Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

6.5.8.2 If original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than ~~15~~fifteen percent (15%) or forty (40) dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the control panel, has been detected by the secondary dose monitoring system.

6.5.8.3 For equipment manufactured after January 1, 1994, a secondary dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than ~~10~~ten percent (10%) or twenty-five (25) dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.4 For equipment manufactured after January 1, 1994, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

6.5.9 Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

6.5.10 Termination Switches. It shall be possible to terminate irradiation and equipment movements or go from any interruption condition to termination conditions at any time from the operator's position at the treatment control panel.

6.5.11 Timer.

6.5.11.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

6.5.11.2 The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero (0).

6.5.11.3 For equipment manufactured after May 25, 2001, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

6.5.11.4 The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

6.5.12 Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

6.5.12.1 Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

6.5.12.2 An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

6.5.12.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations at the treatment control panel.

6.5.12.4 An interlock system shall be provided to prevent irradiation with x-ray except to obtain a port film when electron applicators are fitted.

6.5.12.5 An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

6.5.12.6 The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13 Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

6.5.13.1 Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

6.5.13.2 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.13.3 The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13.4 For new equipment, an interlock system utilizing monitoring of the bending magnet current shall be provided to terminate irradiation if the energy of the electrons striking the target or electron window deviates by more than ~~20~~twenty percent (20%) or three megaelectron volt (3 MeV), whichever is smaller, from the selected nominal energy.

6.5.14 Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

6.5.14.1 Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

6.5.14.2 An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

6.5.14.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.14.4 The mode of operation shall be displayed at the treatment control panel.

6.5.14.5 An interlock system shall be provided to terminate irradiation if movement of the gantry:

6.5.14.5.1 Occurs during stationary beam therapy; or

6.5.14.5.2 Stops during moving beam therapy unless such stoppage is a preplanned function.

6.5.14.6 Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:

6.5.14.6.1 An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of arc differs by more than ~~20~~twenty percent (20%) from the selected value.

6.5.14.6.2 Where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than ~~5~~five percent (5%) from the value calculated from the absorbed dose per unit angle relationship.

6.5.14.7 Where the dose monitor system terminates the irradiation in moving beam therapy, the termination of irradiation shall be as required in RHB 6.5.8.

6.5.15 Absorbed Dose Rate. A system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in RHB 6.5.5 may form part of this system. In addition:

6.5.15.1 The dose monitor rate shall be displayed at the treatment control panel.

6.5.15.2 If the equipment can deliver under any conditions an absorbed dose rate at the ~~normal~~nominal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameter utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be in a record maintained by the registrant.

6.5.16 Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

6.5.16.1 The x-ray target or the virtual source of x-rays; and

6.5.16.2 The electron window or the virtual source of electrons if the system has electron beam capabilities.

6.5.17 System Checking. Capabilities shall be provided so that all radiation safety interlocks can be checked for operation.

6.5.18 Facility and Shielding Requirements. In addition to RHB 6.2 of these rules, the following design requirements shall apply:

6.5.18.1 Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.5.18.2 Control Panel. The control panel shall be located outside the treatment room.

6.5.18.3 Viewing Systems.

6.5.18.3.1 Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the control panel.

6.5.18.3.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.5.19 Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel independent of the particle accelerator. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used. When this is the case, a description of the alternate method shall be submitted to~~,~~ and approved by the Department.

6.5.20 Room Entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all accessible doors to indicate when the useful beam is "on" and "off.~~"~~.

6.5.21 Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

RHB 6.6. Operational Requirements for X-ray and Electron Therapy Systems with Energies of 1 MeV and Above.

6.6.1 Radiological Physics Support. The services of a radiological physicist shall be utilized in facilities having therapy systems with energies of one megaelectron volt (1 MeV) and above. The radiological physicist shall be responsible for:

6.6.1.1 Calibration;

6.6.1.2 Supervision and review of patient dosimetry;

6.6.1.3 Beam data acquisition and storage for computer dosimetry, and supervision of its use;

6.6.1.4 Quality assurance, including spot check review; ~~and~~

6.6.1.5 Consultation with the radiation therapist in treatment planning, as needed~~.~~; and

6.6.1.6 ~~The radiological physicist described in RHB 6.6.1 shall also be available~~Availability and responsiveness to immediate problems or emergencies.

6.6.2 Surveys.

6.6.2.1 All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, the radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.6.2.2 The registrant shall obtain a written report of the survey and a copy of the report shall be transmitted by the registrant to the Department within thirty (30) calendar days of the first patient treatment following the survey.

6.6.2.3 The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist, is in violation of applicable rules or regulations.

6.6.3 Calibrations.

6.6.3.1 The calibration of systems subject to RHB 6.5 shall be performed in accordance with an established calibration protocol acceptable to the Department before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed twelve (12) months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The protocol used shall be a nationally accepted standard, such as one established by the American Association of Physicists in Medicine.

6.6.3.2 The calibration shall be performed by or under the direct supervision of the radiological physicist who is physically present at the facility during the calibration.

6.6.3.3 Calibration radiation measurements required by RHB 6.6.3 shall meet the requirements of RHB 1.4.4.

6.6.3.4 Calibrations shall be in sufficient detail that the dose at a reference point in tissue equivalent phantom may be calculated to within an uncertainty of ~~5~~five percent (5%).

6.6.3.5 The calibration of the therapy unit shall include, but not be limited to, the following determinations:

6.6.3.5.1 Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, all patient positioning lights, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and collimator system, and beam flatness and symmetry at the specified depth.

6.6.3.5.2 The absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

6.6.3.5.3 The uniformity of the radiation field to include symmetry, flatness, and dependence on gantry angle.

6.6.3.5.4 Verification that existing isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

6.6.3.5.5 Verification of transmission factors for all accessories such as wedges, shadow trays, and/or universal beam modifying devices.

6.6.3.6 Records of calibration measurements under RHB 6.6.3.1 and dosimetry system calibrations under RHB 6.6.3.3 shall be maintained for five (5) years after completion of the full calibration.

6.6.3.7 A copy of the latest calibrated absorbed dose rate measured pursuant to RHB 6.6.3.1 shall be available.

6.6.4 Spot Checks. Spot checks shall be performed on systems subject to RHB 6.5 during calibrations and at intervals established by the radiological physicist, not to exceed monthly, using a nationally accepted standard such as one established by the American College of Radiology, American Association of Physicists in Medicine, American College of Medical Physics, etc.

6.6.4.1 The spot check procedures shall be in writing and shall have been developed by the radiological physicist. A copy of the procedures shall be submitted to the Department upon request.

6.6.4.2 If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the radiological physicist within seven (7) treatment days.

6.6.4.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

6.6.4.4 Spot checks shall be made at a depth ~~beyond the calibration depth but no deeper than the 80% ionization depth~~consistent with a nationally accepted standard, such as one established by the American Association of Physicists in Medicine.

6.6.4.5 Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.

6.6.4.6 A parameter exceeding a tolerance set by the radiological physicist shall be corrected before the system is used for patient irradiation.

6.6.4.7 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated, as required in RHB 6.6.3.

6.6.4.8 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for a period of three (3) years after completion of the spot check measurements.

6.6.4.9 Whenever a spot check requires a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RHB 6.6.3.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.6.5 Prohibited Use. The system shall not be used in the administration of radiation therapy unless the requirements of RHB 6.6.1 through ~~RHB~~ 6.6.4 have been met.

RHB 6.7. Misadministration Report Requirements of ~~A~~all Therapeutic X-ray Systems.

All facilities utilizing therapeutic x-ray systems are subject to the misadministration reporting requirements in RHB 1.11.

PART VII
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RHB 7.1. Scope.

This ~~p~~Part establishes special requirements for analytical ~~X-ray~~x-ray equipment. The provisions of this ~~p~~Part are in addition to, and not in substitution for, other applicable provisions of ~~these~~this regulation~~s~~.

RHB 7.2. Electron Microscopes.

Electron microscopes shall be exempt from the other requirements of Part VII except that they:

7.2.1 Shall be registered with the Department; and

7.2.2 Shall be installed, shielded, and operated in such a manner that no one shall be exposed beyond the limits defined in ~~Section~~RHB 3.4.1 of ~~these~~this regulation~~s~~.

RHB 7.3. Hand-Held Analytical X-ray Equipment.

Hand-held analytical x-ray equipment shall be exempt from the other requirements of Part VII except that they:

7.3.1 Shall be registered with the Department;

7.3.2 Shall only be operated by personnel who have completed documented training as outlined in RHB 7.9;

7.3.3 Shall have an interlock system that prevents the operation of the unit unless the x-ray exit port is in contact with or in close proximity to the item being irradiated;

7.3.4 Shall be operated in accordance with the manufacturer's specifications; and

7.3.5 Shall have operating procedures in accordance with RHB 7.10.

RHB 7.4. General Requirements for all Analytical X-ray Equipment.

7.4.1 Registration. All requirements of RHB 2.3 and 2.4 apply.

7.4.2 Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION- X-RAY EQUIPMENT,"~~,~~ or words having similar intent.

7.4.3 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol, and

7.4.3.1 A label bearing the words "Caution - Radiation - This Equipment Produces Radiation When Energized," or words having a similar intent, shall be placed near any switch which energizes an x-ray tube.

7.4.3.2 A sign bearing the words “Caution- High Intensity X-ray Beam,”, or words having a similar intent, on the x-ray source housing, shall be placed in the area immediately adjacent to each tube head or on the x-ray tube housing. The sign shall be so located that it is clearly visible to any person operating, aligning, or adjusting the unit, or handling or changing a sample.

7.4.4 Warning Lights.

7.4.4.1 An easily visible warning light labeled with the words “X-RAY ON,” or words having a similar intent, shall be located near any switch that energizes an X-rayx-ray tube and shall be illuminated only when the tube is energized.

7.4.4.2 Warning lights shall have fail-safe characteristics.

7.4.5 Safety Devices.

7.4.5.1 Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding, shall be:

7.4.5.1.1 Approved in advance by the rRadiation sSafety oOfficer.;

7.4.5.1.2 Specified in writing and posted near the x-ray tube housing.;

7.4.5.1.3 Terminated as soon as possible.; and

7.4.5.1.4 Documented, and the documentation maintained for inspection by the Department. This documentation shall contain: the nature and date of the alteration, and the signature and date of the individuals who made the alteration, and the signature of who restored the unit to original condition.

7.4.5.2 Tests of all safety devices such as interlocks, shutters, and warning lights shall be conducted annually for all operable analytical x-ray equipment. Documentation of such tests shall be maintained for inspection by the Department.

7.4.5.3 The inspection and testing of safety devices shall not be a substitute for a radiation area survey.

7.4.5.4 Interlocks shall not be used to de-activatedeactivate the x-ray tube, except in an emergency or during testing of the interlock system. After such shut-off, it shall be possible to restore the machine to full operation only from the control panel.

7.4.5.5 Unused ports on radiation source housings shall be secured in the closed position in a manner to prevent inadvertent opening.

7.4.6 Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of five centimeters (5 cm) from its surface does not exceed 2.5two and one-half milliRoentgen (2.5 mR) per hour.

7.4.7 Generator Cabinet. Each X-rayx-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance from its surface to 0.25 milliRoentgen per hour.

7.4.8 Radiation in excess of the limits specified in RHB 7.4.6 and RHB 7.4.7 shall be eliminated prior to using the analytical x-ray equipment.

7.4.9 Repair or Modification of X-ray Tube System. Except as specified in ~~7.3.5.1~~RHB 7.4.5.1, no operation involving removal of covers, shielding materials, or tube housings, or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

RHB 7.5. Additional Requirements for Open-Beam Configuration X-ray Equipment.

7.5.1 Safety Device. A device which prevents the entry of any portion of an individual's body into the primary beam path, or which causes the beam to be shut off upon entry into its path, shall be provided on all open-beam configuration x-ray equipment. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:

7.5.1.1 A description of the various safety devices that have been evaluated;

7.5.1.2 The reason each of these devices cannot be used;

7.5.1.3 A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of the safety devices; and

7.5.1.4 The procedure for notifying proper persons in the event of an accident. This list shall include the names, addresses, and telephone numbers.

7.5.2 The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.

7.5.3 When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

7.5.4 Warning Devices. Open-beam configuration x-ray equipment shall be provided with a readily discernible indication of:

7.5.4.1 X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner, or

7.5.4.2 Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

7.5.5 Warning devices shall be labeled so that their purpose is easily identified.

7.5.6 Warning devices shall have fail-safe characteristics.

7.5.6.1 Where couplings exist~~,~~ (e.g., between the x-ray tube and the collimator of the diffractometer, etc.), they shall prevent radiation from escaping the coupling.

7.5.6.2 Each port of the radiation source housing shall be provided with a beam shutter interlocked with the x-ray apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place.

7.5.7 Operating Procedures. The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.5.7.1 Policies and procedures for personnel monitoring~~.~~;

7.5.7.2 Policies and procedures for controlling access to radiation areas~~.~~;

7.5.7.3 Policies and procedures for locking and securing the x-ray unit~~.~~;

7.5.7.4 Policies and procedures for pregnant employees~~.~~; and

7.5.7.5 Policies and procedures for training new employees.

7.5.8 Operator training.

7.5.8.1 No person shall be permitted to operate, repair, modify, or maintain open-beam configuration analytical x-ray equipment unless such person has received instruction in and demonstrated competence in:

7.5.8.1.1 Identification of radiation hazards associated with the use of the equipment;

7.5.8.1.2 Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.5.8.1.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures;

7.5.8.1.4 Radiation survey instruments: operation, calibration, limitations, and survey techniques, if applicable;

7.5.8.1.5 Characteristics of ionizing radiation;

7.5.8.1.6 Methods of controlling radiation dose;

7.5.8.1.7 Units of radiation dose;

7.5.8.1.8 Personnel monitoring and the use of personnel monitoring equipment;

7.5.8.1.9 Symptoms of an acute localized exposure ~~and~~;

7.5.8.1.10 Proper procedures for reporting an actual or suspected overexposure~~.~~; and

7.5.8.1.11 The regulations contained in this Part, and the applicable sections of Part III.

7.5.8.2 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.6. Additional Requirements for Enclosed Beam X-ray Equipment.

To include stationary, transportable, mobile, and portable units.

7.6.1 The radiation source, sample, detector, and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

7.6.2 The sample chamber closure shall be interlocked with the x-ray tube high voltage supply or a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a properly functioning interlock.

RHB 7.7 Area Requirements for ~~A~~all Analytical X-ray Equipment.

7.7.1 Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group ~~which~~ could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.4. These levels shall be met at any specified tube rating.

7.7.2 Surveys, Tests, and Inspections. Radiation surveys, as required by RHB 1.4, of all analytical x-ray systems to show compliance with RHB 7.7.1 shall be performed and records kept and available for review:

7.7.2.1 Upon installation of the equipment and at least once every twelve (12) months thereafter~~.~~;

7.7.2.2 Following any change in the initial arrangement, number, or type of local components in the system~~.~~;

7.7.2.3 Following any change in operating parameters~~.~~;

7.7.2.4 Following any maintenance requiring the disassembly or removal of a local component of the system~~.~~;

7.7.2.5 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed~~.~~;

7.7.2.6 Any time a visual inspection of the local components in the system reveals an abnormal condition~~.~~; and

7.7.2.7 Whenever a monitoring device~~s~~ show~~s~~ a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits specified in RHB 3.4.

7.7.3 Radiation survey measurements shall not be required if a registrant can demonstrate compliance ~~to the satisfaction of the Department with 7.7.1 in some other manner~~ with RHB 7.7.1. ~~Upon approval by the Department~~For enclosed beam analytical x-ray equipment, an area monitor or monitors may be used in place of an annual radiation survey. The area monitor shall be placed on the unit and changed on at least a quarterly basis. The results shall be documented and available for review. If an area monitor result shows a substantial increase over previous results, perform a documented investigation including a radiation area survey.

7.7.4 Tests and inspections of all safety devices shall be performed at least yearly to ensure their proper operation. ~~The results shall be documented and available for review in accordance with RHB 1.10.2.4.~~

7.7.5 All surveys, tests, and inspections shall be documented and records shall be maintained and available for Departmental review in accordance with RHB 1.10.2.4.

RHB 7.8. Radiation Survey Instruments.

All provisions of RHB 1.4.4 apply.

RHB 7.9. Minimum Personnel Radiation Safety Training Requirements ~~F~~for Radiation Safety Officers and Operators.

7.9.1 No registrant shall permit any individual to act as a ~~radiation safety officer~~Radiation Safety Officer until such person:

7.9.1.1 Has been instructed in the subjects outlined in RHB 7.9.2 of this Part;

7.9.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part ~~IX~~XI, the applicable sections of Part III, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

7.9.1.3 Has demonstrated competence to use the ~~X-ray~~x-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

7.9.2 No person shall be permitted to operate, repair, modify, or maintain analytical x-ray equipment unless such person has received instruction and demonstrated competence in:

7.9.2.1 Identification of radiation hazards associated with the use of the equipment;

7.9.2.2 Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.9.2.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures, as specified in RHB 7.10;

7.9.2.4 Characteristics of ionizing radiation; and

7.9.2.5 Personnel and/or area monitoring and the use of personnel and/or area monitoring equipment, if applicable.

7.9.3 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.10. Operating Procedures.

7.10.1 The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.10.1.1 Policies and procedures for personnel and/or area monitoring;

7.10.1.2 Policies and procedures for pregnant employees;

7.10.1.3 Policies and procedures for training new employees;

7.10.1.4 Methods and occasions for conducting radiation surveys, tests, and inspections;

7.10.1.5 Methods for controlling access to ~~radiographic~~restricted and radiation areas;

7.10.1.6 Methods for locking and securing ~~X-ray~~x-ray machines, when not in use or in storage; and

7.10.1.7 Maintenance of records.

7.10.2 A copy of operator training provided as required by RHB 7.9 and a copy of operating procedures as required by RHB 7.10 shall be provided to the Department upon request.

RHB 7.11. Personnel Monitoring.

7.11.1 Personnel monitoring shall be required as outlined in RHB 3.12.

7.11.2 Finger or wrist dosimetric devices shall be provided to and shall be used by:

7.11.2.1 Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

7.11.2.2 Personnel maintaining analytical or research and development x-ray equipment, if the maintenance procedures required the presence of a primary x-ray beam when any local component in the analytical or research and development x-ray system is disassembled or removed.

PART VIII
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL USES OF RADIOGRAPHIC SOURCES

RHB 8.1. Scope.

~~The regulations in this part~~This Part establishes radiation safety requirements for industrial uses of ~~X-ray~~x-ray machines. The requirements of this ~~p~~Part are in addition to, and not in substitution for, the other requirements of ~~these~~this regulation~~s~~.

RHB 8.2. Locking of X-ray Machines.

Each x-ray machine shall be provided with a locking device designed to prevent unauthorized or accidental production of radiation, and shall be kept locked at all times except when under the direct surveillance of a radiographer, ~~radiographer's assistant,~~ a ~~radiation safety officer~~Radiation Safety Officer, or an operator, as applicable.

RHB 8.3. Permanent Storage Precautions.

Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

RHB 8.4. Radiation Survey Instruments.

All provisions of RHB 1.4.4 apply.

RHB 8.5 Warning Devices.

Warning devices shall be labeled so that their purpose is easily identified. An easily visible warning device light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized. This warning light shall be of a fail-safe design.

RHB ~~8.5~~8.6. Labeling.

There shall be a durable permanent label indicating the maximum operating current, kVp, the standard radiation symbol, and a caution notice which shall read as follows or similarly: “CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED.” In addition, a label which reads, “CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED” shall be located near or adjacent to each switch that controls the production of x-rays.

RHB ~~8.6~~8.7. ~~Registration and~~ Posting Requirements.

~~8.6.1 Registration. Each facility shall meet the requirements of RHB 2.3 and 2.4 of these regulations.~~

~~8.6.2 Posting.~~Areas in which radiography is being performed shall be conspicuously posted as required by RHB 3.15 and 3.16.

RHB ~~8.7~~8.8. Minimum Personnel Radiation Safety Training Requirements ~~F~~for Radiation Safety Officers, Radiographers, and Operators.

~~8.7.1~~8.8.1 No registrant shall permit any individual to act as a ~~radiation safety officer~~Radiation Safety Officer until such person:

~~8.7.1.1~~8.8.1.1 Has been instructed in the subjects outlined in RHB ~~8.11~~8.12 of this Part;

~~8.7.1.2~~8.8.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part ~~IX~~XI, the applicable sections of Part III, and the registrant’s operating and emergency procedures, and shall have demonstrated understanding thereof; and

~~8.7.1.3~~8.8.1.3 Has demonstrated competence to use the ~~X-ray~~x-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

~~8.7.2~~8.8.2 No registrant shall permit any individual to act as an operator or radiographer until such person:

~~8.7.2.1~~8.8.2.1 Has been instructed in the subjects outlined in RHB ~~8.11~~8.12 of this Part;

~~8.7.2.2~~8.8.2.2 Has received copies of and instruction in: Part ~~IX,~~XI of ~~these~~this regulation~~s~~, and the registrant’s operating and emergency procedures, and shall have demonstrated understanding thereof; and

~~8.7.2.3~~8.8.2.3 Has demonstrated competence to use, under the personal supervision of the Radiation Safety Officer, the ~~X-ray~~x-ray machine, related handling tools, and survey instruments which will be employed in his or her assignment.

~~8.7.2.4~~8.8.2.4 The registrant shall have all training instruction, procedures, and ~~testing~~competencies documented in writing, and available for ~~the~~ Department~~’s~~al review.

RHB ~~8.8~~8.9. Operating and Emergency Procedures.

The registrant shall have written operating and emergency procedures. These procedures shall include instruction in:

~~8.8.1~~8.9.1 The handling and use of ~~X-ray~~x-ray machines to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in Part III of ~~these~~this regulation~~s~~;

~~8.8.2~~8.9.2 Methods and occasions for conducting radiation surveys;

~~8.8.3~~8.9.3 Methods for controlling access to radiographic areas;

~~8.8.4~~8.9.4 Methods for locking and securing ~~X-ray~~x-ray machines, when not in use or in storage;

~~8.8.5~~8.9.5 Personnel monitoring and the use of personnel monitoring equipment~~;~~, including steps that must be taken by radiography personnel in the event a pocket dosimeter is found to be off-scale;

~~8.8.6~~8.9.6 The proper handling of exposed personnel;

~~8.8.7~~8.9.7 Minimizing exposure of individuals in the event of an accident;

~~8.8.8~~8.9.8 The procedure for notifying proper persons in the event of an accident~~. This shall include the listing~~, including a list of names, addresses, and telephone numbers; and

~~8.8.9~~8.9.9 Maintenance of records.

RHB ~~8.9~~8.10. Inspection~~s~~ and Maintenance.

Each registrant shall ensure that checks for obvious defects in radiation machines are made at the beginning of each day of equipment use.

~~8.9.1~~8.10.1 At least annually, each registrant shall inspect and repair components associated with radiation safety of the machines. Records of inspection and maintenance shall be maintained for the Department's inspection.

~~8.9.2~~8.10.2 If any inspection conducted by the registrant reveals damage to the components affecting radiation safety, the radiation machine shall not be used and shall be labeled as defective until repaired.

RHB ~~8.10~~8.11. Personnel Monitoring.

No registrant shall permit any individual to act as a Radiation Safety Officer~~,~~ ~~or as an~~ operator, or radiographer unless, at all times during radiographic operations, each such person wears a film badge, thermoluminescent dosimeter (TLD), or other dosimeters approved by the Department. All provisions of Part III of ~~these~~this ~~R~~regulation~~s~~ apply.

RHB ~~8.11~~8.12. Minimum Subjects ~~T~~to ~~B~~be Covered ~~I~~in Training Radiation Safety Officers~~, and~~ Radiographers, and Operators.

~~8.11.1~~8.12.1 Fundamentals of Radiation Safety:

~~8.11.1.1~~8.12.1.1 Characteristics of ionizing radiation;

~~8.11.1.2~~8.12.1.2 Units of radiation dose (rem or Sievert);

~~8.11.1.3~~8.12.1.3 Hazards of exposure to radiation;

~~8.11.1.4~~8.12.1.4 Levels of radiation from sources of radiation;

~~8.11.1.5~~8.12.1.5 Methods of controlling radiation dose;

~~8.11.1.5.1~~8.12.1.5.1 Working time;

~~8.11.1.5.2~~8.12.1.5.2 Working distances; and

~~8.11.1.5.3~~8.12.1.5.3 Shielding.

~~8.11.2~~8.12.2 Radiation Detection Instrumentation to be Used:

~~8.11.2.1~~8.12.2.1 Use of radiation survey instruments;

~~8.11.2.1.1~~8.12.2.1.1 Operation;

~~8.11.2.1.2~~8.12.2.1.2 Calibration; and

~~8.11.2.1.3~~8.12.2.1.3 Limitations.

~~8.11.2.2~~8.12.2.2 Survey techniques; and

~~8.11.2.3~~8.12.2.3 Use of personnel monitoring equipment:

~~8.11.2.3.1~~8.12.2.3.1 Film badges or other approved dosimeters; and

~~8.11.2.3.2~~8.12.2.3.2 Pocket dosimeters or pocket chambers, if applicable.

~~8.11.3~~8.12.3 Operation and control of ~~X-ray~~x-ray machines.

~~8.11.4~~8.12.4 The requirements of pertinent state regulations.

~~8.11.5~~8.12.5 The registrant's written operating and emergency procedures.

~~RHB 8.12~~8.13. Special Requirements for Certain Industrial Radiographic Techniques.

~~8.12.1~~8.13.1 Cabinet Radiography.

~~8.12.1.1~~8.13.1.1 Upon installation, a cabinet radiography unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. A radiation survey of the unit and area adjacent to the unit shall also be performed at least annually, and after any repair modification, or maintenance on the system.

~~8.12.1.2~~8.13.1.2 Tests for proper operation of high radiation area control devices, alarm systems, or interlocks must be conducted~~,~~ at least annually, recorded, and maintained in accordance with RHB ~~8.9~~8.10.

~~8.12.1.3~~8.13.1.3 Radiation emitted from the cabinet x-ray unit shall not exceed ~~0.5~~one-half milliRoentgen (0.5 mR) per hour at any point five centimeters (5 cm) from the external surface.

~~8.12.1.4~~8.13.1.4 A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

~~8.12.1.5~~8.13.1.5 The insertion of any part of the human body through any port into the primary beam or through any aperture shall not be possible.

~~8.12.1.6~~8.13.1.6 Interlocks.

~~8.12.1.6.1~~8.13.1.6.1 Each door of a cabinet x-ray system shall have a minimum of two (2) safety interlocks. One (1), but not both, of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

~~8.12.1.6.2~~8.13.1.6.2 Each access panel shall have at least one (1) safety interlock.

~~8.12.1.6.3~~8.13.1.6.3 Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with RHB ~~8.12.1.8.2~~8.13.1.8.2 shall be necessary for resumption of x-ray generation.

~~8.12.1.6.4~~8.13.1.6.4 Failure of any single component of the cabinet x-ray system shall not cause failure of more than one (1) required safety interlock.

~~8.12.1.7~~8.13.1.7 A ground fault, or an accidental electrical grounding of an electrical conductor, shall not result in the generation of x-rays.

~~8.12.1.8~~8.13.1.8 Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable, there shall be provided:

~~8.12.1.8.1~~8.13.1.8.1 A key actuated control to ~~insure~~ensure that x-ray generation is not possible with the key removed.

~~8.12.1.8.2~~8.13.1.8.2 A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

~~8.12.1.8.3~~8.13.1.8.3 Two (2) independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half (0.5) second in which case the indicators shall be activated for one-half (0.5) second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One (1), but not both, of the indicators required by this regulation may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON."

~~8.12.1.8.4~~8.13.1.8.4 Additional means, other than milliammeters, which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half (0.5) second, in which case the indicators shall be activated for one-half (0.5) second, as needed to ~~insure~~ensure that at least one (1) indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON."

~~8.12.1.9~~8.13.1.9 Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans, there shall also be provided:

~~8.12.1.9.1~~8.13.1.9.1 A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden, or bypassed from the outside of the cabinet.

~~8.12.1.9.2~~8.13.1.9.2 No means by which x-ray generation can be initiated from within the cabinet.

~~8.12.1.9.3~~8.13.1.9.3 Audible and visible warning signals within the cabinet which are actuated for at least ten (10) seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause the failure of both the audible and visible warning signals.

~~8.12.1.9.4~~8.13.1.9.4 A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated~~,~~ unless the x-ray generation period is less than one-half (0.5) second, in which case the indicator shall be activated for one-half (0.5) second.

~~8.12.1.9.5~~8.13.1.9.5 Signs indicating the meaning of the warning signals required by RHB ~~8.12.1.9.3~~8.13.1.9.3 and ~~8.12.1.9.4~~8.13.1.9.4 and containing instructions for the use of the control required by RHB ~~8.12.1.9.1~~8.13.1.9.1. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

~~8.12.1.10~~8.13.1.10 Warning labels. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED." There shall also be a permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement: "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED-X-RAY HAZARD."

~~8.12.1.11~~8.13.1.11 Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-rays.

~~8.12.1.11.1~~8.13.1.11.1 During an exposure or preset succession of exposures of one-half (0.5) second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

~~8.12.1.11.2~~8.13.1.11.2 During an exposure or preset succession of exposures of less than one-half (0.5) second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

~~8.12.1.12Exemptions. To qualify for this exemption, registrant must provide documentation regarding the certified and/or certifiable status of each device.~~

~~8.12.1.12.1Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Part except for the following:~~

~~8.12.1.12.1.1For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:~~

~~8.12.1.12.1.1.1No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this requirement shall be maintained for Departmental review.~~

~~8.12.1.12.1.1.2Tests for proper operation of interlocks must be conducted and documented at intervals not to exceed six months. Records of these tests shall be maintained in accordance with RHB 1.10.2.4.~~

~~8.12.1.12.1.1.3The registrant shall perform an evaluation of the radiation dose limits to determine compliance with Part III of this Regulation and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not exceed one year. Records of these evaluations shall be maintained in accordance with RHB 1.10.2.4.~~

~~8.12.1.12.1.2Cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, and no modification shall be made to the system unless prior Departmental approval has been granted.~~

~~8.12.2~~8.13.2 Shielded Room Radiography.

~~8.12.2.1~~8.13.2.1 Each registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, every individual who operates, makes "set-ups," or performs maintenance on a radiation machine for shielded room radiography.

~~8.12.2.2~~8.13.2.2 A physical radiation survey shall be conducted to determine that the ~~X-ray~~x-ray machine is ~~"off"~~off prior to each entry into the shielded room. Such surveys shall be made with a radiation measuring instrument capable of measuring radiation of the energies and at the dose rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding ~~twelve~~twenty-four (24) months or following the last instrument servicing, whichever is later.

~~8.12.2.3~~8.13.2.3 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to assure compliance with RHB 3.4~~,~~ and ~~RHB~~ 3.9.

~~8.12.2.4~~8.13.2.4 Shielding. All provisions of RHB 4.4 apply.

8.13.2.5 Entrance Interlocks. All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.

8.13.2.6 Audible Warning Device. A shielded room shall be provided with an audible warning signal within the shielded room which is actuated for at least ten (10) seconds immediately prior to the first initiation of x-ray generation after closing any door.

8.13.2.7 Visible Warning Signal. A shielded room shall be provided with visible warning signals which remain actuated when and only when x-rays are being generated. These visible warning signals shall be located so that they can be observed from any position or orientation within the room and at each entrance.

8.13.2.8 Signs indicating the meaning of the warning signals required by RHB 8.13.2.6 and 8.13.2.7 shall be legible and conspicuously posted.

8.13.2.9 Emergency Shut-off. An emergency shut-off switch shall be provided for preventing and terminating x-ray generation, which cannot be reset, overridden, or bypassed from the outside of the shielded room. Emergency shut-off switches shall be:

8.13.2.9.1 Accessible within ten (10) seconds to individuals therein;

8.13.2.9.2 Identified by a legible, conspicuously posted sign adjacent to the switch which includes instructions for the use of the emergency shut-off switch;

8.13.2.9.3 Designed with a manual reset that must be activated at the switch before x-rays can again be produced from the control panel; and

8.13.2.9.4 Designed such that it shall be possible to produce x-rays again only from the control panel after an emergency shut-off switch has been activated.

8.13.2.10 Separate Electrical Systems. The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.

8.13.2.11 X-ray generation shall not be possible from within the shielded room.

~~8.12.3~~8.13.3 Field Radiography.

~~8.12.3.1~~8.13.3.1 Utilization Logs. Each registrant shall maintain current logs, which shall be kept available for inspection by the Department, showing for each ~~X-ray~~x-ray machine the following information:

~~8.12.3.2~~ 8.13.3.1.1 A description (or make and model number) of each ~~X-ray~~x-ray machine;

~~8.12.3.3~~ 8.13.3.1.2 The identity of the radiographer to whom assigned;

~~8.12.3.4~~ 8.13.3.1.3 The plant or site where used and dates used; and

~~8.12.3.5~~ 8.13.3.1.4 The dates each radiation machine is energized or used and number of exposures made.

~~8.12.3.6~~8.13.3.2 Security. During each radiographic operation, the radiographer ~~or radiographer's assistant~~ shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except a) where the high radiation area is equipped with a control device which turns the ~~X-ray~~x-ray machine off upon unauthorized entry into the high radiation area or an alarm system which visibly or audibly signals the presence of a high radiation area, or b) where the high radiation area is locked to protect against unauthorized or accidental entry.

~~8.12.3.7~~8.13.3.3 Radiation Surveys and Survey Records. No radiographic operation shall be conducted unless calibrated, operable radiation survey instrumentation is available and used at each site where radiographic exposures are made, as described in RHB 8.4.

~~8.12.3.7.1~~8.13.3.3.1 A physical radiation survey shall be conducted to determine that the radiation machine is ~~"off"~~off prior to each entry into the radiographic exposure area.

~~8.12.3.7.2~~8.13.3.3.2 Survey results and records of boundary locations shall be maintained and kept available for inspection by the Department.

~~8.12.3.8~~8.13.3.4 Personnel Monitoring. In addition to the requirements of ~~8.10~~RHB 8.11, each radiographer ~~or radiographer's assistant~~ shall wear a pocket dosimeter or pocket chamber along with a film badge during all radiographic operations. Pocket chambers or dosimeters shall be:

~~8.12.3.8.1~~8.13.3.4.1 Capable of measuring doses from zero (0) to at least ~~200~~two hundred milliRoentgen (200 mR);

~~8.12.3.8.2~~8.13.3.4.2 Read and doses recorded daily; ~~and~~

~~8.12.3.8.3~~8.13.3.4.3 Recharged daily or at the start of each shift;

~~8.12.3.8.4~~8.13.3.4.4 Reports received from the dosimeter processor and records of the pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Department; and

~~8.12.3.8.5~~8.13.3.4.5 Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one (1) year. Acceptable dosimeters shall read within plus or minus thirty percent (30%) of the true exposure. Instrument calibration records shall be maintained by the registrant for the Department's inspection.

~~8.12.4~~8.13.4Gauging Devices Radiography and Other Industrial Applications. The source shall be such that no radiation is emitted except by application of an electric current through an x-ray tube. Provisions shall be made to limit both the current through the tube and the voltage across the tube, so that radiation levels do not exceed the device classification under use conditions or through circuit component failures. In the event of fire or abnormal elevated temperatures, provisions shall be made to ~~insure~~ensure the high voltage is automatically disabled before loss of any integral shielding. This provision exempts x-ray tube sources from accident classification conditions.

~~8.12.4.1~~8.13.4.1 A useful beam control system shall be provided in gauges whenever the useful beam is accessible and the radiation levels exceed one hundred millirem per hour (100 mrem/h) (1 mSv/h) at five centimeters (5 cm) from any accessible surface or five millirem per hour (5 mrem/h) (.05 mSv/h) at thirty centimeters (30 cm). The useful beam controls may include ~~(~~, but not be limited to~~)~~, a moving shutter, a moving source, or a high voltage power supply.

~~8.12.4.2~~8.13.4.2 A yellow or amber warning light with the radiation "High Voltage On" shall be located on the control panel and on or adjacent to the source housing and shall light only when power is applied to the x-ray tube high voltage circuit.

~~8.12.4.3~~8.13.4.3 Radiation levels. The local components of an industrial x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group could result in a dose to an individual present therein in excess of the dose limits given in RHB ~~3.3.2~~3.4. These levels shall be met at any specified tube rating.

PART IX
PERSONNEL SECURITY SCREENING SYSTEMS USING X-RAY EQUIPMENT

RHB 9.1. Scope.

This Part establishes radiation safety requirements, for which a registrant is responsible, for use of personnel security screening systems using x-ray equipment. The requirements of this Part are in addition to, and not in substitution for, the other requirements of this regulation.

RHB 9.2. Operation.

Each system shall be maintained and operated solely for security screening purposes in compliance with, and fully according to, the most restrictive standards found in the American National Standards Institute (ANSI) publication ANSI/HPS N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation" and subsequent revisions.

RHB 9.3. Utilization.

The registrant utilizing a personnel security screening system shall be a correctional institution, detention center, prison, or jail.

RHB 9.4. Shielding.

Prior to installation or replacement, the registrant shall submit a floor plan and equipment arrangement which has been prepared by a registered Class II vendor and submitted to the Department for review and acceptance.

9.4.1 The floor plan must include, at a minimum:

9.4.1.1 The proposed location of the system;

9.4.1.2 Surrounding and adjacent areas with occupancies;

9.4.1.3 General direction of the useful beam; and

9.4.1.4 Location of the control panel and operator.

9.4.2 An inspection zone shall be established around the personnel security screening system where bystanders are prohibited during the operation of the device. A means shall be provided for any operator responsible for initiating a scan to maintain full visual surveillance of the inspection zone. The registrant shall ensure only the scanned individual is within two meters (2 m) of the scanner when in operation.

9.4.3 The Department may require a shielding plan, as described in RHB 4.4.

RHB 9.5. Notifications.

The registrant shall inform each person being screened that the system emits radiation and that more information is available. Posters, signs, and handouts, of a sufficient size and in a location so as to be readily visible, are examples of appropriate means to provide this information. At a minimum, the following information shall be available to screening subjects prior to scanning:

9.5.1 The estimated effective dose from one (1) screening;

9.5.2 An example shall be provided to compare the dose to a commonly known source of radiation; and

9.5.3 Confirmation the screening complies with the ANSI/HPS Standard N43.17; if requested, information on how to acquire this standard shall be provided.

RHB 9.6. Radiation Safety Program.

The registrant shall institute a radiation safety program which includes, but is not limited to, written operating procedures and area monitoring.

9.6.1 Operating procedures shall include all requirements of ANSI/HPS Standard N43.17.

9.6.2 Area monitoring devices shall be located at the operator's location and areas surrounding the unit routinely occupied during the scan.

9.6.3 Records of operating procedures and dosimetry shall be adhered to and maintained for Departmental review.

RHB 9.7. Radiation Safety Officer.

The registrant shall appoint a Radiation Safety Officer (RSO) who is qualified by training and experience for all hazards and precautions involved in operation of the system.

9.7.1 The RSO shall have completed a forty (40)-hour radiation safety course, which shall include, but is not limited to, instruction in radiation protection, biological effects of radiation, personnel monitoring, digital imaging acquisition, machine safety and operation, general operating procedures, and machine maintenance.

9.7.2 Training shall be documented and maintained for Departmental review.

RHB 9.8. Operator Training.

Each operator shall be provided with training on the operation and use of the system prior to performing security screening operations.

9.8.1 At a minimum, this training shall include all requirements of ANSI/HPS Standard N43.17.

9.8.2 Training shall be documented and maintained for Departmental review.

9.8.3 Refresher training shall be provided every twelve (12) months and documented for Departmental review.

9.8.4 Training records shall contain the date of training, an outline of the training, and the names of those in attendance.

RHB 9.9. Installation.

The system shall be stationary and installed in a manner in which the exposure switch is located behind a protective barrier requiring the operator to remain behind the barrier during the entire exposure while still being able to view the individual being scanned, surrounding areas, and any access doors. Mobile or portable x-ray controls, including wireless or remote exposure switches, are not permitted.

RHB 9.10. Surveys.

Radiation surveys shall verify the reference effective dose, radiation leakage, inspection zone, and other parameters specified by the manufacturer. Records of radiation surveys shall include all requirements of ANSI/HPS Standard N43.17. Surveys shall be performed:

9.10.1 Upon installation;

9.10.2 At least once every twelve (12) months;

9.10.3 After any maintenance that affects the radiation shielding, shutter mechanism, or x-ray producing components; and

9.10.4 After any incident that may have damaged the system in such a way that unintended radiation emission occurs.

RHB 9.11 Dose.

9.11.1 The radiation dose delivered to a scanned individual shall be as low as reasonably achievable and shall not exceed limits required by ANSI/HPS Standard N43.17.

9.11.2 The dose outside of the inspection zone shall not exceed twenty microsieverts (20 µSv) (2 mrem) in any one (1) hour.

PART ~~I~~X
DEFINITIONS

~~RHB 9.~~

As used in ~~these~~this regulation~~s~~, the following definitions apply:

~~9.1~~10.1 "Absorbed ~~D~~dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special units of absorbed dose are the rad or the gray.

~~9.2~~10.2 "Accessible ~~S~~surface" means the external surface of the enclosure or housing provided by the manufacturer.

~~9.3~~10.3 "Accreditation body" or "body" means an entity that has been approved by the FDA to accredit mammography facilities.

~~9.4~~10.4 "Act" means Act No. 223, Atomic Energy and Radiation Control Act enacted by the 1967 Session South Carolina Legislature. [Section 13-7-40 *et seq*., S.C. Code of Laws (1976, as amended)].

~~9.5~~10.5 "Action limits" or "action levels" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action shall be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

~~9.6"Added filtration" means any filtration which is in addition to the inherent filtration.~~

~~9.7~~10.6 "Adverse event" means an undesirable experience associated with mammography activities that include, but are not limited to: poor image quality; failure to send mammography reports within thirty (30) calendar days to the referring physician or in a timely manner to the self-referred patient; and use of personnel that do not meet the requirements.

~~9.8~~10.7 “Adult” means an individual eighteen (18) ~~or more~~ years of age or older.

~~9.9~~10.8 “Air kerma” means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than ~~300~~three hundred kiloelectronvolts (~~9~~300 keV), 1Gy=100rad. In air, 1Gy of absorbed dose is delivered by one hundred fourteen roentgens (114 R) of exposure.

~~9.10~~10.9 “ALARA” (acronym for “as low as is reasonably achievable”) means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits in ~~the Rules in this Chapter~~this regulation as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

~~9.11~~10.10 “Aluminum equivalent” means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

~~9.12~~10.11 “Analytical x-ray equipment” means any machine utilizing x-rays for examination of the microscopic structure, or elemental or chemical composition of materials. This includes x-ray equipment used for x-ray diffraction, fluorescence analysis, or spectroscopy.

~~9.13~~10.12 “Analytical ~~X~~x-ray ~~S~~system” means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

~~9.14~~10.13 “Annually” means at intervals not to exceed twelve (12) consecutive months.

~~9.15~~10.14 “Applicator” means a structure which determines the extent of the treatment field at a given distance from the virtual source.

~~9.16 “Assembler” means any person engaged in the business of assembling, reassembling, replacing, installing, or reinstalling one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system, his employee, or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.~~

~~9.17~~10.15 “Attenuation block” means a block or stack~~having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.~~ of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions twenty (20) centimeters (cm) or larger by twenty (20) cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

~~9.18~~10.16 “Authorized representative” means an employee of the Department, or an individual outside the Department when the individual is specifically so designated by the Department.

~~9.19~~10.17 “Automatic exposure control” means a device which automatically controls one (1) or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also “Phototimer”).

~~9.20~~10.18 "Average ~~G~~glandular dose" means, in mammography, the value in millirad for a given breast or phantom thickness which estimates the average absorbed dose to the glandular tissue extrapolated from free air exposures and based on fixed filter thickness and target material.

~~9.21~~10.19 "Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation regulated by the ~~agency~~Department.

~~9.22~~10.20 "Barrier" (See "Protective Barrier").

~~9.23~~10.21 "Beam ~~A~~axis" means a line from the source through the centers of the x-ray fields.

~~9.24~~10.22 "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

~~9.25~~10.23 "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

~~9.26~~10.24 "Beam scattering foil" means a ~~foil used in order to scatter a beam of electrons~~ thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

10.25 "Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues.

~~9.27~~10.26 "Breast implant" means a prosthetic device implanted in the breast.

~~9.28~~10.27 "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits as specified in Part III of ~~these~~this ~~R~~regulation~~s~~.

~~9.29~~10.28 "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during x-ray production. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

~~9.30~~10.29 "Calendar ~~Q~~quarter" means not less than twelve (12) consecutive weeks nor more than fourteen (14) consecutive weeks. The first calendar quarter of each year shall begin in January; and subsequent calendar quarters shall be such that no day is included in more than one (1) calendar quarter or omitted from inclusion within a calendar quarter. No registrant shall change the method observed by him of determining calendar quarters for purposes of ~~these~~this regulation~~s~~, except at the beginning of a calendar year. For the purpose of Part V, "Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

~~9.31 "Calibration" means:~~

~~a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or~~

~~b) the strength of a source of radiation relative to a standard.~~

~~9.32~~10.30 "Category I" means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society or an equivalent organization.

~~9.33~~10.31 "C-~~A~~arm" means a~~n~~ fluoroscopic x-ray system in which the image receptor and x-ray tube housing assembly are connected ~~by a common mechanical support system in order to maintain a desired spatial relationship~~or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

~~9.34~~10.32 "Central axis of the ~~B~~beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

~~9.35~~10.33 "Cephalometric" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

~~9.36 "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.~~

~~9.37~~10.34 "Certification" for Part V, means the process of approval of a facility by the Department to provide mammography services.

~~9.38 "Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.~~

~~9.39~~10.35 "Certified components" means components of x-ray systems which are subject to the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968, promulgated under Public Law 90-602.

~~9.40~~10.36 "Certified system" means any x-ray system which has one (1) or more certified component(s).

~~9.41 "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.~~

~~9.42~~10.37 "Change of ~~S~~status" means transfer of ownership, change of address, or disposal of any ~~X~~x-ray system.

~~9.43~~10.38 "Clinical image" means a mammogram.

~~9.44~~10.39 "Coefficient of ~~V~~variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \sum \frac{(x_i - \bar{x})^2}{n-1}$$

where:
s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
Xi = ith observation in sample.
n = Number of observations in sample.

$$c = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \sum \frac{(X_i - \bar{X})^2}{n-1}$$

where:
s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = *i*th observation in sample.
n = Number of observations in sample.

~~9.45~~10.40 "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

~~9.46~~10.41 "Committed dose equivalent" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the fifty (50)-year period following the intake.

~~9.47~~10.42 "Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

10.43 "Contact hour" means an hour of training received through direct instruction.

~~9.48~~10.44 "Continuing education unit or continuing education credit" means one (1) contact hour of training.

~~9.49 "Contact hour" means an hour of training received through direct instruction.~~

~~9.50~~10.45 "Controlled area" means an area outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

~~9.51 "Coulomb per Kilogram" (C/kg) is the unit of exposure. One Roentgen is equal to 2.58 × 10-4 Coulomb per kilogram. Submultiples of this unit are the milliCoulomb per kilogram (mC/kg) and the microCoulomb per kilogram (uC/kg).~~

~~9.52~~10.46 "CT" (See "Computed Tomography")

~~9.53 "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 8.173.~~

~~9.54 "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.~~

~~9.55~~10.47 “Computed ~~T~~tomography (CT)” means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

~~9.56~~10.48 “Contact ~~T~~therapy ~~S~~system” means an x-ray system used for therapy with the x-ray tube port placed in contact with or within ~~5~~five centimeters (5 cm) of the surface being treated.

~~9.57~~10.49 “Control ~~P~~panel” means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, keypads, touchscreens, and other hardware necessary for manually setting the technique factors.

~~9.58~~10.50 “Cooling ~~C~~curve” means the graphical relationship between heat units stored and cooling time.

10.51 “CT conditions of operation” means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors.

10.52 “CT Gantry” means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components within a computed tomography system.

10.53 “Coulomb per Kilogram” (C/kg) is the unit of exposure. One Roentgen is equal to $2.58 \times 10\text{-}4^{-4}$ Coulomb per kilogram. Submultiples of this unit are the milliCoulomb per kilogram (mC/kg) and the microCoulomb per kilogram (uC/kg).

~~9.59~~10.54 “~~Dead-man~~Dead man’s ~~S~~switch” means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

~~9.60~~10.55 “Declared pregnant woman” means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

~~9.61~~10.56 “Deep-dose equivalent~~”~~ (H_d),” which applies to external whole-body exposure, is the equivalent at a tissue depth of one centimeter (1 cm) (1000 mg/cm^2).

~~9.62~~10.57 “Department” means the South Carolina Department of Health and Environmental Control.

~~9.63~~10.58 “Detector” (See “Radiation detector”).

~~9.64~~10.59 “Diagnostic mammography” means mammography performed on a patient with:

(a) Clinical signs, symptoms, or physical findings suggestive of breast cancer;

(b) An abnormal or questionable screening mammogram;

(c) A history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms, or physical findings; or

(d) Augmented breast regardless of absence of clinical breast signs, symptoms, or physical findings.

~~9.65~~10.60 “Diagnostic source assembly” means the tube housing assembly with a beam-limiting device attached.

~~9.66~~10.61 “Diagnostic x-ray imaging system” means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

~~9.67~~10.62 “Diagnostic x-ray system” means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

~~9.68~~10.63 “Diaphragm” means a device or mechanism by which the x-ray beam is restricted in size.

~~9.69~~10.64 “Direct instruction” means face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

~~9.70~~10.65 “Direct scattered radiation” means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See “Scattered Radiation”).

~~9.71~~10.66 “Direct supervision”~~,~~ means overall direction, control, and training of an individual by a qualified person who shall be physically present and provide constant feedback during the activities as they occur. ~~i~~In Part V, means that~~:~~ ~~D~~during joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient’s records; or ~~D~~during the performance of a mammography examination or survey of the facility’s equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

~~9.72~~10.67 “Dose” is a generic term which means absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent as defined in ~~these~~this regulation~~s~~.

~~9.73~~10.68 “Dose ~~E~~equivalent~~"~~ (H_T)” means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent ~~at~~ are the rem and sievert (Sv).

~~9.74~~10.69 “Dose limits” (See Limits)

~~9.75~~10.70 “Dose monitoring system” means a system of devices for the detection, measurement, and display of quantities of radiation.

~~9.76~~10.71 “Dose monitor unit” means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

~~9.77~~10.72 “Dosimetry processor” means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

~~9.78~~10.73 “Effective dose equivalent~~"~~ (H_E)” is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = w_T H_T$).

~~9.79~~10.74 “Embryo~~/~~ or fetus” means the developing human organism from conception until the time of birth.

10.75 “Enclosed beam x-ray equipment” means an analytical x-ray system in which the beam path cannot be entered by any part of the body during normal operation.

~~9.80~~10.76 “Entrance or access point” means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

~~9.81~~10.77 “Entrance exposure rate” means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

~~9.82~~10.78 “ESE” means the exposure at skin entrance where the center of the useful beam enters the patient.

~~9.83~~10.79 “Equipment” (See “X-ray system”).

~~9.84~~10.80 “Established operating level” means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility’s quality assurance program.

~~9.85~~10.81 “Exposure” is the amount of ionization per unit mass of air due to x-rays. It is the quotient of dQ by dm where “dQ” is the absolute value of the total charge of the ions of one (1) sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “dm” are completely stopped in air. The special units of exposure are the Roentgen (R), or the coulomb per kilogram (C/kg).

~~9.86~~10.82 “Exposure rate” means the exposure per unit of time, such as R/min and mR/h.

~~9.87~~10.83 “External dose” means that portion of the dose equivalent received from radiation sources outside the body.

~~9.88~~10.84 “Extremities” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

~~9.89~~10.85 “Eye dose equivalent” applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2)

~~9.90~~10.86 “Facility” means:

1) the location at which one (1) or more x-ray machines are installed or located within one (1) building, vehicle, or under one (1) roof and are under the same administrative control.

~~9.91 “Facility” or “mammography installation” means~~ 2) in Part V, a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram and maintaining viewing conditions for that interpretation.

~~9.92~~10.87 “Fail-safe characteristics” means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

~~9.93~~10.88 “FDA” means the U.S. Food and Drug Administration.

~~9.94~~10.89 “Field emission equipment” means equipment which uses an x-ray tube in which an electron emission from the cathode is due solely to the action of an electric field.

~~9.95~~10.90 “Field-flattening filter” means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

~~9.96~~10.91 “Field ~~R~~radiography” means the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation in a non-fixed or non-permanent location.

~~9.97~~10.92 “Field size” means the dimensions along the major axes of an area in a plane perpendicular to the central axis of the useful beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the ~~50~~fifty percent (50%) isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

~~9.98~~10.93 “Filter” means material placed in the useful beam to preferentially absorb selected radiation.

~~9.99~~10.94 “First allowable time” means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

~~9.100~~10.95 “Fluoroscopic imaging assembly” means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

10.96 “Fluoroscopy” means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

~~9.101~~10.97 “Focal spot (actual)” means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

~~9.102 “Fog test” means an evaluation of increased density and reduced contrast on film which has not been exposed to the radiation field. This is usually done by processing unexposed film and measuring the density.~~

~~9.103~~10.98 “Gantry” means that part of the system supporting and allowing possible movements of the radiation head.

~~9.104~~10.99 “Gauge” means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative chemical composition. It may include components such as radiation shields and useful beam controls incorporated into the gauge in order to meet the requirements or specifications of this regulation.

~~9.105~~10.100 “General purpose ~~radiographic~~ x-ray system” means any radiographic x-ray which, by design, is not limited to radiographic examination of specific anatomical regions.

~~9.106 “Gonadal shield” means a protective barrier for the testes or ovaries.~~

~~9.107~~10.101 “The ~~“~~Gray” is the unit of absorbed dose. It is equal to ~~1~~one joule per kilogram (1 J/kg). One rad is equal to 1×10^{-2} Gray. Submultiples included in this ~~document~~regulation are the milliGray (Gy) and the microGray (uGy).

~~9.108~~10.102 “Half-value layer (HVL)” means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

~~9.109~~10.103 “Healing arts” means any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

~~9.110~~10.104 “Healing arts screening” means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner ~~of the healing arts~~ legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

~~9.111~~10.105 “Health ~~P~~professions” means the professional persons authorized by the laws of the ~~S~~state to use x-rays in the diagnosis or treatment of human or animal disease.

~~9.112~~10.106 “Heat unit” means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds~~,~~ (i.e., kVp × mA × second).

~~9.113~~10.107 “High radiation area” means any area, accessible to individuals, in which there exists radiation at such levels that the whole body could receive in any one (1) hour, a dose in excess of 0.1 rem (mSv) in one (1) hour at ~~30~~thirty centimeters (30 cm) from the radiation source or from any surface that the radiation penetrates.

~~9.114~~10.108 “HVL” (See “Half-value layer”).

~~9.115~~10.109 “Image intensifier” means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

~~9.116~~10.110 “Image receptor” means any device, such as radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.

~~9.117 “Image receptor support” means, for mammographic systems, that part of the system designed to support the image receptor during mammography.~~

~~9.118~~10.111 “Individual” means any human being.

~~9.119~~10.112 “Individual monitoring” means:

~~(a)~~1) the assessment of dose equivalent by the use of devices designed to be worn by an individual; or

~~(b)~~2) the assessment of dose equivalent by the use of survey data.

~~9.120~~10.113 “Individual ~~M~~monitoring ~~D~~devices” ~~or “individual monitoring equipment”~~ means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), and pocket ionization chambers.

~~9.121~~10.114 “Industrial x-ray ~~equipment~~system” means any machine utilizing x-rays for examination of the macroscopic structure of materials. This includes x-ray equipment used for cabinet radiography, shielded room radiography, field radiography, and gauges.

~~9.122~~10.115 “Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

~~9.123~~10.116 “Inoperative” means any x-ray machine or device that is temporarily or permanently rendered incapable of producing x-rays.

~~9.124~~10.117 “Inspection” means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

10.118 “Inspection zone” means the general area established by the operating institution for the purpose of limiting or controlling access to the area where personnel security screening systems using x-ray equipment will be located. This includes, but is not limited to, any ingress, egress, gate, portal, traffic path, and areas, access to which is restricted due to the presence of radiation.

10.119 “Instrument calibration” means the determination of:

1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

2) the strength of a source of radiation relative to a standard.

~~9.125~~10.120 “Interim regulations” means the regulations entitled “Requirements for Accrediting Bodies of Mammography facilities” (58 FR 67558-67565) and “Quality Standards and Certification Requirements for Mammography Facilities”(58 FR 67565-67572), published by the FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994 and April 28, 1999.

~~9.126~~10.121 “Interlock” ~~means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.~~means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

~~9.127~~10.122 “Interpreting physician” means a licensed physician who interprets mammograms and who meets the requirements of ~~Section~~RHB ~~5.7.1~~5.9.1and 5.25.1.1.

~~9.128~~10.123 “Irradiation” means the exposure of matter to ionizing radiation.

~~9.129~~10.124 “Isocenter” means the intersection of the collimator axis of rotation and the gantry axis of rotation.

~~9.130~~10.125 “Kilovolt~~s~~age peak” (See “Peak tube potential”).

~~9.131~~10.126 “kV” means kilovolts.

~~9.132~~10.127 “kVp” (See “Peak tube potential”).

~~9.133~~10.128 “Lead interpreting physician” means the interpreting physician assigned the general responsibility for ensuring that a facility’s quality assurance program meets all of the requirements of ~~Sections~~RHB 5.9, 5.10.1, 5.10.2, 5.10.4, 5.10.5, 5.10.6, and 5.10.7 of ~~this Part~~this regulation. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

10.129 “Leakage radiation (diagnostic)” means radiation emanating from the diagnostic source assembly except for:

1) the useful beam, and

2) radiation produced when the exposure switch or timer is not activated.

~~9.134~~10.130 “Leakage radiation (non-diagnostic)” means all radiation coming from within the tube housing complex except the useful beam(s).

~~9.135 “Leakage radiation (diagnostic)” means radiation emanating from the diagnostic source assembly except for:~~

~~1) the useful beam, and~~

~~2) radiation produced when the exposure switch or timer is not activated.~~

~~9.136~~10.131 “Leakage technique factors” means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ~~10~~ten millicoulombs (10 mC)~~,~~ (i.e., ~~10~~ten milliampere seconds~~,~~ (10 mAs)) or the minimum obtainable from the unit, whichever is larger.

2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

~~9.137~~10.132 “Licensed practitioner” means ~~an individual with professional specialization who has met the criteria as outlined by the South Carolina Department of Labor, Licensing, and Regulation~~a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state.

~~9.138~~10.133 “Light field” means that area of the intersection of the light beam from the beam-limiting device and one (1) of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth (1/4) of the maximum in the intersection.

~~9.139~~10.134 “Limits” or “Dose ~~L~~limits” means the permissible upper bounds of radiation doses.

~~9.140 "Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.~~

~~9.141 "Line voltage regulation" means the difference between the no load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation.~~

~~Percent line voltage regulation = 100 (Vn-Vl)/Vl where~~

~~Vn = No load line potential and~~

~~Vl = Load line potential.~~

~~9.142~~10.135 "mA" means milliAmpere.

~~9.143~~10.136 "Mammogram" means a radiographic image produced through mammography.

~~9.144~~10.137 "Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography and digital mammography.

~~9.145~~10.138 "Mammography" means radiography of the breast.

~~9.146~~10.139 "Mammography equipment evaluation" means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in ~~this Part~~this regulation.

~~9.147~~10.140 "Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

~~9.148~~10.141 "Mammography unit" or "units" means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum, an x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

~~9.149~~10.142 "mAs" means milliAmpere second.

~~9.150 "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.~~

~~9.151~~10.143 "Mean optical density" means the average of the optical densities (OD) measured using phantom thicknesses of two (2), four (4), and six (6) centimeters with values of kilovoltage peak (kVp) clinically appropriate for those thicknesses.

~~9.152 "Medical device" means an instrument, tool, machine, test kit, or implant that is used to prevent, diagnose, or treat disease or other medical conditions.~~

~~9.153~~10.144 "Medical physicist," for the purpose of Part V, means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications set forth in RHB 5.7.3.

9.15410.145 “Member of the public” means an individual ~~in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose~~except when that individual is receiving an occupational dose

9.15510.146 “Minor” means an individual ~~less~~younger than eighteen (18) years of age.

9.15610.147 “Misadministration” means the administration of:

~~9.156.~~1) Radiation to the wrong patient, wrong treatment site, or wrong mode of treatment;

~~9.156.~~2) Performance of a diagnostic or therapeutic procedure other than that ordered by the prescribing physician.

~~9.156.~~3) A therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than ~~20~~twenty percent (20%).

~~9.156.~~4) When the treatment consists of three (3) or fewer fractions, a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than ~~10~~ten percent (10%).

~~9.156.~~5) When the calculated weekly treatment dose exceeds the weekly prescribed dose by ~~30~~thirty percent (30%) or more of the weekly prescribed dose.

9.15710.148 “Mobile x-ray equipment” (See “X-ray equipment”).

9.15810.149 “Monitoring,”~~,~~ "radiation monitoring," or “radiation protection monitoring” means the measurement of radiation levels~~, concentrations, surface area concentrations or quantities of radioactive material~~ and the use of the results of these measurements to evaluate potential exposures and doses.

10.150 “Moving beam therapy” means radiation therapy with relative displacement of the useful beam or the patient during irradiation. It includes arc therapy, skip therapy, conformational therapy, and rotational therapy.

9.15910.151 “MQSA” means the federal Mammography Quality Standards Act of 1992.

9.16010.152 “Multi-reading” means two (2) or more physicians, at least one (1) of whom is an interpreting physician, interpreting the same mammogram.

~~9.161 “Nonstochastic effect” means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of nonstochastic effect (also called a deterministic effect).~~

~~9.162 “Moving beam therapy” means radiation therapy with relative displacement of the useful beam or the patient during irradiation. It includes arc therapy, skip therapy, conformational therapy, and rotational therapy.~~

9.16310.153 “~~Normal~~Nominal treatment distance” means:

1) For electron irradiation, the distance from the scattering foil or exit window of the electron beam to the surface along the central axis of the useful beam, or from the virtual source to the surface along the central axis of the useful beam as specified by the manufacturer.

2) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be specified by the manufacturer.

~~9.164~~10.154 "Occupational dose" means, for the purpose of Part IV, the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation, whether in the possession of the registrant or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

~~9.165~~10.155 "Open beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his or her body in the primary beam path during normal operation.

~~9.166~~10.156 "Operating ~~C~~conditions," for the purpose of Part IV, means circumstances required to maintain a radiation protection program sufficient to ensure compliance with the provisions of this ~~R~~regulation. Conditions include, but are not limited to, patient holding, pregnant workers, use of shielding and barriers, pregnant patients, use of personnel monitoring devices, employee training, and quality assurance methods.

~~9.167~~10.157 "Operating procedures" means detailed written instructions including, but not limited to, use of the x-ray equipment, use of shielding and barriers, quality assurance methods, occasions and methods for conducting area surveys, use of personnel monitoring devices, and alignment, calibration, or preventative maintenance of x-ray equipment. Routine and emergency radiation safety considerations are part of these procedures. Emergency procedures shall include methods of notifying proper persons in the event of an emergency, to include the listing of names, addresses, and phone numbers.

~~9.168~~10.158 "Operative" means any x-ray machine or device that is capable of producing x-rays.

~~9.169~~10.159 "Out-of-~~S~~state ~~F~~facility" means any person proposing to bring an x-ray machine into the ~~S~~state for any temporary use.

~~9.170~~10.160 "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment, including a mammography evaluation.

~~9.171~~10.161 "PBL" (See "Positive Beam Limitation").

~~9.172~~10.162 "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

~~9.173~~10.163 "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than entities over which a federal government agency has exclusive jurisdiction.

~~9.174~~10.164 "Personnel monitoring equipment" means devices designed to be carried or worn by a~~n~~ single individual for the purpose of measuring the dose which an individual receives (e.g., film badges, thermoluminescence (TLDs) dosimeters, optically stimulated luminescence (OSL) dosimeters, pocket chambers, pocket dosimeters).

10.165 “Personnel security screening system” means any x-ray equipment used on humans for security evaluation.

~~9.175 “Phantom” in Part VI, means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of the tissue.~~

~~9.176 “Phantom” in Part V, means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. This definition does not apply to phantoms used for Quality Assurance testing of stereotactic biopsy units. It is equivalent to a nominal 4.2 centimeter compressed breast of average density (i.e., 50 percent adipose and 50 percent glandular tissue) and shall contain the following objects:~~

~~1) Spherical masses, composed of phenolic plastic with thicknesses of: 2.00, 1.00, 0.75, 0.50 and 0.25 millimeter;~~

~~2) Specks, composed of aluminum oxide, with diameters of: 0.54, 0.40, 0.32, 0.24 and 0.16 millimeter~~

~~3) Fibers composed of nylon, with thicknesses of: 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeter.~~

10.166 “Phantom” means:

1) in Part V, a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. This definition does not apply to phantoms used for Quality Assurance testing of stereotactic biopsy units. It is equivalent to a nominal 4.2 centimeter compressed breast of average density (i.e., fifty percent (50%) adipose and fifty percent (50%) glandular tissue) and shall contain the following objects:

a) Spherical masses, composed of phenolic plastic with thicknesses of: 2.00, 1.00, 0.75, 0.50, and 0.25 millimeter;

b) Specks, composed of aluminum oxide, with diameters of: 0.54, 0.40, 0.32, 0.24, and 0.16 millimeter

c) Fibers composed of nylon, with thicknesses of: 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeter.

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

~~9.177~~10.167 “Phantom image” means a radiographic image of a phantom.

~~9.178~~10.168 “Phototimer” means a method for controlling radiation exposure to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See “Automatic exposure control”).

~~9.179~~10.169 “Physical science” means, for the purpose of this regulation, physics, chemistry, ~~radiation~~radiologic science (including medical physics and health physics), and engineering.

~~9.180~~10.170 “PID” (See “Position indicating device”).

~~9.181~~10.171 “Planned special exposure” means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

~~9.182~~10.172 “Portable x-ray equipment” (See “X-ray equipment”).

~~9.183~~10.173 “Position indicating device (PID)” means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

~~9.184~~10.174 “Positive ~~B~~beam ~~L~~limitation” means the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustments.

~~9.185~~10.175 “Positive mammogram” means a mammogram that has an overall assessment of findings that are either “suspicious” or “highly suggestive of malignancy.”

~~9.186~~10.176 “Primary beam” means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

~~9.187~~10.177 “Primary dose monitoring system” means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

~~9.188~~10.178 “Primary protective barrier” (See “Protective barrier”).

~~9.189~~10.179 “Protective apron” means an apron made of radiation absorbing material used to reduce radiation exposure.

~~9.190~~10.180 “Protective barrier” means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1) “Primary protective barrier” means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

2) “Secondary protective barrier” means a barrier sufficient to attenuate the stray radiation to the required degree.

~~9.191 “Protective glove” means a glove made of radiation absorbing materials used to reduce radiation exposure.~~

~~9.192~~10.181 “Provisional certificate” means the provisional certificate described in RHB 5.3.3.

~~9.193~~10.182 “Public dose” means the dose received by a member of the public from exposure to radiation by a registrant, or to another source of radiation either within a registrant’s controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

~~9.194~~10.183 “Qualified expert” means an individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

~~9.195~~10.184 “Qualified instructor” means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of ~~Section 5.7~~RHB 5.9 and 5.25.1 of this Part would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the requirements of this Part include, but are not limited to, instructors in a post-high school training institution and manufacturer’s representatives.

~~9.196~~10.185 “Quality ~~A~~assurance” is a program designed to produce high quality radiographs at minimal cost and minimal patient exposure.

~~9.197~~10.186 “Quality ~~C~~control” is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

~~9.198~~10.187 “Quality control technologist” means an individual meeting the requirements of RHB 5.7.2 who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

~~9.199~~10.188 “Quality ~~F~~factor~~”~~ (Q)” means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem.

~~9.200~~10.189 The “rad” is a measure of the absorbed dose of any radiation to body tissue in terms of the energy absorbed per unit mass of the tissue. One rad is the absorbed dose corresponding to one hundred (100) ergs per gram of tissue. (One millirad {mrad} = 0.001 rad.)

~~9.201~~10.190 “Radiation” means ionizing radiation, including gamma rays, x-rays, alpha particles, beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles capable of producing ions, but not sound or radio waves, or visible, infrared, or ultraviolet light.

~~9.202~~10.191 “Radiation area” means any area accessible to individuals in which there exists radiation at such levels that the whole body could receive in any one (1) hour, a dose in excess of ~~5~~five millirem (5 mrem) (.05 mSv) at ~~30~~thirty centimeters (30 cm) from the radiation source or from any surface that the radiation penetrates.

~~9.203~~10.192 “Radiation detector” means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one (1) or more quantities of incident radiation.

~~9.204~~10.193 “Radiation dose” means dose.

~~9.205 “Radiation Installation” is any location or facility where radiation machines are used.~~

~~9.206~~10.194 “Radiation Safety Officer” means one who has the knowledge and responsibility to apply appropriate radiation protection regulations, and has been assigned such responsibility, ~~is approved~~ in writing, by the registrant.

~~9.207~~10.195 “Radiation therapy simulation system” means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

~~9.208~~10.196 “Radiograph” means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

~~9.209~~10.197 “Radiographer” means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises field radiography operations, and who is responsible to the registrant for assuring compliance with the requirements of ~~these~~this regulation~~s~~.

~~9.210 “Radiographer’s Assistant” means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in field radiography.~~

~~9.211 “Radiographic imaging system” means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.~~

~~9.212~~10.198 “Radiological physicist” means an individual who is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma ray physics; or certified by the American Board of Medical Physicists in radiation oncology physics, or have the equivalent training experience as approved, or have the following minimum training and experience:

~~9.212.~~1) A Master’s or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one (1) year full-time training in therapeutic radiological physics;

~~9.212.~~2) One (1) year full-time experience in a therapeutic facility where the individual’s duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one (1) machine.

~~9.213~~10.199 “Radiologic technologist,”~~,~~ in Part V, means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and, when performing mammography without direct supervision, also meets the requirements set forth in RHB ~~5.7.2~~5.9.2.

~~9.214~~10.200 “Rating” means the operating limits as specified by the component manufacturer.

~~9.215~~10.201 “Recording” means producing a permanent form of an image resulting from x-ray photons.

~~9.216~~10.202 “Registrant” means any person who is registered with the Department or is legally obligated to register with the Department pursuant to the Act and ~~these~~this regulation~~s~~.

~~9.217~~10.203 “Registration” means registering with the Department in accordance with ~~these~~this regulation~~s~~ and the Act.

~~9.218~~10.204 “Rem” is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). The quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X-, gamma, or beta radiation	1	1
		a Unit Dose Equivalent*

Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

~~9.219~~10.205 "Response time" means the time required for an instrument system to reach ~~90~~ninety percent (90%) of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation flux from zero (0) sufficient to provide a steady step midscale reading.

~~9.220~~10.206 "Restricted area or controlled area" ~~(controlled area)~~ means any area, access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation. A "restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

~~9.221~~10.207 "Roentgen~~"~~ (R)" is the special unit of exposure. One Roentgen equals 2.58 x 10^{-4} Coulombs/kilogram of air. (See "exposure.")

~~9.222~~10.208 "Safety device" means a device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path.

~~9.223~~10.209 "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one (1) or more tomograms.

~~9.224~~10.210 "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system or between successive scans measured along the direction of such displacement.

~~9.225~~10.211 "Scan sequence" means a preselected set of two (2) or more scans performed consecutively under preselected CT conditions of operation.

~~9.226~~10.212 "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

~~9.227~~10.213 "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

~~9.228~~10.214 "Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.

~~9.229~~10.215 "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

~~9.230~~10.216 "Secondary protective barrier" (See "Protective barrier").

~~9.231~~10.217 "Serious adverse event" means an adverse ~~advent~~event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

~~9.232~~10.218 "Serious complaint" means a report of a serious adverse event.

~~9.233~~10.219 “Shadow tray” means a device attached to the radiation head to support auxiliary beam blocking material.

~~9.234~~10.220 “Shallow- dose equivalent~~”~~ (H_S)”, which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of ~~1~~one square centimeter (1 cm^2).

~~9.235~~10.221 “Shielded room radiography” means industrial radiography using radiation machines, which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets conditions for an unrestricted area and the only access to which is through openings which are interlocked so that the radiation machine will not operate unless all openings are securely closed.

~~9.236~~10.222 “Shutter” means a device attached to the tube housing assembly which can totally intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

~~9.237~~10.223 “SID” (see Source to Image Receptor Distance).

~~9.238~~10.224 “Sievert (Sv)” is the unit of dose equivalent. The dose equivalent ~~is~~in Sieverts is equal to the absorbed dose in grays multiplied by the quality factor. (1 Sv = 100 rems). Submultiples included in this ~~document~~regulation are the milliSievert (mSv) and the microSievert (uSv).

~~9.239~~10.225 “Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

~~9.240~~10.226 “Source” means the focal spot of the x-ray tube.

10.227 “Source of radiation” means any device or equipment emitting or capable of producing x-ray radiation.

~~9.241~~10.228 “Source-to-image receptor distance (SID)” means the distance from the source to the center of the input surface of the image receptor.

10.229 “Source-to-skin distance (SSD)” means the distance between the source and the skin entrance plane of the patient.

~~9.242 “Source of radiation” means any device or equipment emitting or capable of producing x-ray radiation.~~

~~9.243 “Special procedures” means the application of special x-ray equipment and specialized techniques to obtain required diagnostic information. This usually provides enhanced detail of a given anatomical structure but with reduced visualization of others. Special procedures include, but are not limited to, angiography, cardiac catheterization, myelogram, and surgery.~~

~~9.244~~10.230 “Special purpose x-ray system” means any radiographic x-ray system which is limited, by design, to radiographic examinations of specified anatomical regions. Special purpose x-ray systems include, but are not limited to, mammography units, dedicated chest units, cystography units, and head and skull units.

~~9.245~~10.231 “Spot check” means a procedure which is performed to assure that a previous calibration continues to be valid.

~~9.246~~10.232 “Spot film” means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

~~9.247~~10.233 “Spot film device” means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

~~9.248 “SSD” means the distance between the source and the skin entrance plane of the patient.~~

~~9.249~~10.234 “Standard breast” means a 4.2 centimeter (cm) thick compressed breast consisting of ~~50~~fifty percent (50%) glandular and ~~50~~fifty percent (50%) adipose tissue.

~~9.250 “Stationary x-ray equipment” (See “X-ray equipment”).~~

~~9.251 “Stochastic effects” means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects (also called a probabilistic effect).~~

~~9.252~~10.235 “Stray radiation” means the sum of leakage and scattered radiation.

~~9.253~~10.236 “Supervision” means the delegating of the task of applying radiation pursuant to ~~this part~~this regulation by persons, not licensed in the healing arts or veterinary medicine, who provide services under the practitioner’s control. The licensed practitioner assumes full responsibility for these tasks and must assure that the tasks will be administered correctly.

~~9.254 “Survey” means an evaluation of the use, of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation.~~

~~9.255 “Survey” in Part V, means an onsite physics consultation and evaluation of a facility’s quality assurance program performed by a medical physicist.~~

10. 237 “Survey” means:

1) an evaluation of the use, of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation.

2) in Part V, an onsite physics consultation and evaluation of a facility’s quality assurance program performed by a medical physicist.

~~9.256~~10.238 “Target” means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

~~9.257~~10.239 “Technique factors” means the following conditions of operations:

1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

~~9.258~~10.240 "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

~~9.259~~10.241 "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.

~~9.260 "Therapeutic type protective tube housing" (1) For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed one Roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential. (2) For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation at a distance of one meter from the source does not exceed an exposure of one Roentgen in an hour or 0.1 percent of the useful beam dose rate at one meter at its maximum rated continuous current for the maximum rated accelerating potential.~~

~~9.261 "Time cycle" means the film development time.~~

~~9.262~~10.242 "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

~~9.263~~10.243 "Total Effective Dose Equivalent~~"~~ (TEDE)" means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

~~9.264~~10.244 "Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two (2) years and the results of the proficiency test conducted within twenty-four (24) months of calibration show agreement within plus or minus ~~3~~three percent (3%) of the national standard in the mammography energy range.

~~9.265~~10.245 "Tube" means an x-ray tube, unless otherwise specified.

~~9.266 "Tube housing apparatus complex" means those parts of an analytical x-ray device in which x-rays are produced and utilized for a useful purpose. This includes the x-ray tube housing, shutter or port assemblies, collimators, cameras, goniometers, and electronic radiation detectors.~~

~~9.267~~10.246 "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

~~9.268~~10.247 “Unrestricted area or uncontrolled area” ~~(uncontrolled area)~~ means any area to which access is not controlled by the registrant for purposes of protection of individuals from exposure to radiation, and any area used for residential quarters.

~~9.269~~10.248 “Vendor” means a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish x-ray machine services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of x-ray equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning and maintenance, and health physics consultations.

~~9.270~~10.249 “Very high radiation area” means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five hundred (500) rads (5 grays) in one (1) hour at ~~1~~one meter (1 m) from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

~~9.271~~10.250 “Virtual source” means a point from which radiation appears to originate.

~~9.272~~10.251 “Whole body” means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

~~9.273~~10.252 “Worker” means an individual engaged in work under a license or registration issued by the ~~agency~~Department and controlled by a licensee or registrant, but does not include the licensee or registrant.

10.253 “X-ray control” means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

~~9.274~~10.254 “X-ray equipment” means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

~~9.274.~~1) Mobile means ~~X~~x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

~~9.274.~~2) Portable means ~~X~~x-ray equipment designed to be hand carried to the location of use, but not operated while being held by an individual.

~~9.274.~~3) Stationary means ~~X~~x-ray equipment ~~designed~~ which is installed in a fixed location.

~~9.274.~~4) Transportable means ~~X~~x-ray equipment installed in a vehicle or trailer.

5) Hand-held means x-ray equipment that is designed to be hand-held during operation.

~~9.275~~10.255 “X-ray system” means an assemblage of components for the controlled production of x-rays. It includes, minimally, an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

~~9.276 "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.~~

~~9.277~~10.256 "X-ray subsystem" means any combination of two (2) or more components of an x-ray system.

~~9.278~~10.257 "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

~~9.279~~10.258 "Year" means the period of time beginning in January used to determine compliance with the provisions of ~~this part~~this regulation. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

PART X**I**
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS:INSPECTIONS

RHB ~~10.1~~11.1. ~~Purpose and~~ Scope.

This Part establishes requirements for notices, instructions, and reports by registrants to individuals employed by them, and options available to such individuals in connection with Department inspections of registrants to ascertain compliance with the provisions of the Act and regulations issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, or transfer radiation producing equipment registered by the Department pursuant to the regulation in Part II.

RHB ~~10.2~~11.2. Posting of Notices to Workers.

~~10.2.1~~11.2.1 Each registrant shall post current copies of the following documents: 1) the regulations in this Part and in Part III; and 2) ~~"Notice to Employees" Form SC-RHA-20; 3)~~ any notice of violation involving radiological working conditions; or order issued pursuant to Part I and any response from the registrant.

~~10.2.2~~11.2.2 If posting of a document required by RHB 11.2.1 is not practicable, the registrant ~~may~~ shall make documents electronically available or post a notice which describes the document and states where it may be examined.

11.2.3 Each Registrant shall post "Notice to Employees" Form 3A-17 as required by this regulation.

~~10.2.3~~11.2.4 Documents, ~~or~~ notices, of~~r~~ forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work associated with the ~~X~~x-ray equipment to observe them on the way to or from any equipment location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

~~10.2.4~~11.2.5 ~~Department~~ ~~d~~Documents posted pursuant to RHB ~~10.2.3~~11.2.4~~,~~ of this section shall be posted within five (5) working days after receipt of the documents from the Department; the registrant's response, if any, shall be posted within five (5) working days after dispatch from the registrant. Such document shall remain posted for a minimum of five (5) working days or until action correcting the violation has been completed, whichever is later.

RHB ~~10.3~~11.3. Instructions to Workers.

All individuals working in or frequenting any portion of a restricted area shall: be kept informed of the use of x-ray equipment or of radiation in portions of the ~~un~~restricted area; s~~hall~~ be instructed in the health protection problems associated with exposure to ~~such~~ x-ray equipment or radiation~~,~~ and in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; ~~shall~~ be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Department regulations for the protection of personnel from radiation occurring in such areas; ~~shall~~ be instructed of their responsibility to report promptly to the registrant any conditions which may lead to or cause a violation of Department regulations or unnecessary exposure to radiation; s~~hall~~ be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation; and ~~shall~~ be advised as to the radiation exposure ~~requests~~reports which workers may request pursuant to RHB ~~10.4~~11.4. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

RHB ~~10.4~~11.4. Notification and Reports to Individuals.

~~10.4.1~~11.4.1 The Registrant shall report to the individual, ~~R~~radiation exposure data ~~for an individual~~ and the results of any measurements, analyses, and calculations of radiation exposure to the body ~~of an individual shall be reported to the individual~~ as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or inspections. Each notification and report shall: be in writing~~;~~, include appropriate identifying data such as the name of the registrant, the name of the individual, ~~the individual's social security number~~an additional personal identifier for the individual~~;~~, ~~include~~ the individual's exposure information~~;~~, and contain the following statement: "This report is furnished to you under the provisions of the South Carolina Department of Health and Environmental Control's Radiation Control Regulations. You should preserve this report for future reference."

~~10.4.2~~11.4.2 At the request of any worker, each registrant shall advise such worker annually of the worker's exposure to radiation as shown in records maintained by the registrant pursuant to RHB ~~3.22~~3.27.

~~10.4.3~~11.4.3 At the request of the worker formerly engaged in work controlled by the registrant, each registrant shall furnish to the worker a report of the workers' exposure to radiation. Such report shall be furnished within thirty (30) calendar days from the time the request is made, or within thirty (30) calendar days after the exposure of the individual has been determined by the registrant, whichever is later~~;~~ and shall cover~~,~~ ~~within~~ the period of time specified in the request, each calendar quarter in which the workers' activities involved exposure to radiation from x-ray producing equipment registered by the Department; and shall include the dates and locations of work under the registrant in which the worker participated during this period.

~~10.4.4~~11.4.4 When a registrant is required pursuant to RHB 3.24, 3.25, or 3.26 to report to the Department any exposure of an individual to radiation, the registrant shall also provide the individual a report on his or her exposure data included therein. Such reports shall be ~~transmitted~~submitted to the individual at a time not later than the ~~transmittal~~ date of notification to the Department.

RHB ~~10.5~~11.5. Presence of Registrants and Workers During Inspections.

~~10.5.1~~11.5.1 Each registrant shall afford to the Department, at all reasonable times, opportunity to inspect machines, activities, facilities, premises, and records pursuant to ~~these~~this regulation~~s~~.

~~10.5.2~~11.5.2 During an inspection, the registrant shall permit Department inspectors ~~may~~ to consult privately with workers as specified in RHB ~~10.6~~11.6. The registrant may accompany Department inspectors during other phases of an inspection.

~~10.5.3~~11.5.3 If, at any time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of the physical working conditions.

~~10.5.4~~11.5.4 Each workers' representative shall be routinely engaged in work under control of the registrant and shall have received instructions as specified in RHB ~~10.3~~11.3. With written approval ~~of~~from the registrant, the workers' representative may be an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

~~10.5.5~~11.5.5 Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection.

~~10.5.6~~11.5.6 Notwithstanding the other provisions of this section, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for the area shall be an individual previously authorized by the registrant to enter that area.

RHB ~~10.6~~11.6. Consultation with Workers During Inspections.

~~10.6.1~~11.6.1 The Registrant shall permit Department inspectors ~~may~~to consult privately with workers concerning matters of occupational radiation protection and other matters related to the extent of an effective and thorough inspection.

~~10.6.2~~11.6.2 During the course of an inspection, the registrant shall allow any worker ~~may~~to bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, or ~~these~~this regulation~~s~~, or any unnecessary exposure of an individual to radiation from x-ray producing equipment under the registrant's control. Any such notice in writing shall comply with the requirements of RHB ~~10.7.1~~11.7.1.

~~10.6.3~~11.6.3 The provisions of RHB ~~10.6.2~~11.6.2 of this section shall not be interpreted as authorization to disregard instructions pursuant to RHB ~~10.3~~11.3.

RHB ~~10.7~~11.7. Request by Workers for Inspections.

~~10.7.1~~11.7.1 Any worker or representative of workers who believes that a violation of the Act, or ~~these~~this regulation~~s~~ exists or has occurred in work under a registrant ~~with regard to~~regarding radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. ~~Any such notice shall be in writing~~ Notification shall be made on the current version of the form provided by the Department and shall set forth the specific grounds for the notice. ~~A copy shall be provided to the registrant by the Department no later than at the time of inspection.~~

~~10.7.2~~11.7.2 If, upon receipt of such notice, the ~~Director of Health Regulation or the Chief of the Bureau of Radiological Health~~Department determines that the complaint meets the requirements set forth in RHB

~~10.7.1~~11.7.1 of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, ~~he shall cause~~ an inspection ~~to be made~~may be conducted as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in this complaint.

~~10.7.3~~11.7.3 No registrant shall discharge or in any manner discriminate against any worker because such worker has filed any ~~compliant~~ complaint or instituted or caused to be instituted any proceeding under ~~these~~this regulation~~s~~ or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of the worker or others of any option afforded by this Part.

RHB ~~10.8~~11.8. Inspections not Warranted.

~~Informal Review.~~

~~10.8.1. If t~~The ~~Chief of the Bureau of Radiological Health~~Department may determine~~s~~, with respect to a complaint under RHB ~~10.7~~11.7 that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred~~,~~. ~~the Bureau Chief shall notify the complainant, if identified, in writing of such determination. The complainant, if identified, may obtain a review of such determination by submitting a written statement of position with the Director of Health Regulation, who will provide the registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position with the Bureau of Radiological Health who will provide the complainant with a copy of such statements by certified mail. Upon the request of the complainant, the Bureau of Radiological Health may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant will be made only following receipt written authorization from the complainant. After considering all written or oral views present, the Director of Health Regulation shall affirm, modify, or reverse the determination of the Chief of the Bureau of Radiological Health and furnish the complainant and the registrant a written notification of the decision and the reason therefore.~~

~~10.8.2 If the Chief of the Bureau of Radiological Health determines that an inspection is not warranted because the requirements of RHB 10.7.1 have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of RHB 10.7.1.~~

RHB ~~10.9~~11.9. Right to ~~i~~Inspect and ~~i~~Investigate.

The Department of Health and Environmental Control is the state agency responsible for the control and regulation of radiation sources. Section 13-7-40(A), S.C. Code of Laws (1976, as amended). By statute, the Department is authorized to enter, at all reasonable times, private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of its regulations. Section 13-7-40(A), S.C. Code of Laws (1976, as amended). Because the Department is authorized by law to enter and inspect property in order to determine compliance with Department regulations, such entry and inspection falls under the health oversight activities exception of Health Insurance Portability and Accountability Act (HIPAA). Therefore, where protected health information is necessary for determining compliance with Department regulations, protected health information may be used and disclosed to the Department without the subject's authorization under HIPAA.

~~PART XI~~
~~REGIONAL CALIBRATION LABORATORY~~

RHB 11.1. Scope.

This part establishes operating requirements and fees for the South Carolina Regional Calibration Laboratory (SCRCL).

RHB 11.2. Operations.

11.2.1 The SCRCL shall maintain a current accreditation status as directed by the Conference of Radiation Control Program Directors.

11.2.2 The SCRCL shall perform accredited calibration procedures that will be traceable to the National Institute of Standards and Technology.

11.2.2.1 The SCRCL shall perform yearly proficiency tests under the guidance of, and in coordination with, the National Institute of Standards of Technology.

11.2.3 The SCRCL shall maintain current written operating procedures. The policies of the operating procedures will be followed for all instruments entrusted to the SCRCL for calibration.

11.2.4 Each instrument received shall be surveyed for contamination. Contaminated instruments will not be calibrated at the South Carolina Regional Calibration Laboratory.

11.2.5 Each Geiger-Mueller, Ion Chamber and R Meter will be calibrated at two (2) points on each scale.

RHB 11.3. Fees.

11.3.1 A fee shall be charged for each instrument and probe calibrated at the SCRCL. The following table shall be used by the Department to determine calibration fees:

Type of Instrument	Fees
-	-
Geiger-Mueller (GM)	$75
-	-
Ion Chamber	-
First mode	$75
Second mode	$18.75
-	-
R Meter	$50
-	-
MDH 1015 or 1515	-
One probe-five calibration points	$250
Additional probe-five calibration points	$106.25
-	-
MDH 2025	-
One probe- five calibration points	$106.25
Additional probe-five calibration points	$75
-	-
Dosimeter test - analog and digital	$18.75 Per mode of operation
-	-
Replacement Carbon Zinc Batteries	-

~~15 volts (NEDA 220)~~	~~Market price plus tax~~
~~22.5 volts (NEDA 221)~~	~~-~~
~~22.5 volts (NEDA 215)~~	~~-~~
~~30 volts (NEDA 210)~~	~~-~~
~~67.5 volts (NEDA 416)~~	~~-~~
~~300 volts (NEDA 722)~~	~~-~~
~~-~~	~~-~~
~~Replacement desiccant pellets~~	~~Market price plus tax~~
~~-~~	~~-~~
~~Minimum handling fee, any instrument no calibration~~	~~$18.75~~
~~-~~	~~-~~

~~11.3.2 Shipping and insurance charges will be added to calibration fees for instruments requiring mail services. Charges will be the same as the cost to the Department.~~

~~11.3.3 An invoice for calibrations and other services will be issued to the person or organization requesting the calibration. All fees are due upon receipt of the invoice.~~

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.61-64, X-Rays (Title B). Interested persons may submit written comments to the Office of Policy and Communications, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Healthcare Quality Public Comment Form. To be considered, the Department must receive comments no later than 5:00 p.m. on March 28, 2022, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to S.C. Code Section 13-7-40 et seq., the Department promulgates, amends, and repeals regulations relating to the control of ionizing and nonionizing radiation, the qualifications of operators applying ionizing or nonionizing radiation to humans, and registration of radiation sources or devices or equipment utilizing these sources. The Department proposes comprehensive amendment to R.61-64, X-Rays (Title B). General areas of this revision include, but are not limited to, clarifying and simplifying the regulation, adding new definitions as required, deleting requirements that are no longer applicable, and to ensure the regulation is in alignment with the current statute. The Department may also amend requirements regarding registration, inspections, violations, enforcement, equipment, and mammography. The proposed amendments will also update vendor classes, add requirements for personnel security screening systems using x-ray, and clarify, organize, and update the Radiation Safety Officer requirements. The Department may also include changes such as corrections for readability, grammar, punctuation, codification, and other such regulatory text improvements.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-64, *X-Rays (Title B)*

As of the March 28, 2022, close of the Notice of Drafting comment period:

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	1.11.1 and 3

Comment:
Misadministration Documentation.
Add to 1.11.2 the requirement for 3 years of record retention.Then remove that from 1.11.3. In that way, 1.11.2 will relate to Diaganostic Misamins, and 1.11.3 will refer just to Therapy Misadmins. This will clarify that the extra record elements, like patient ID will just be required for therapy misadministrations. This will keep patient IDs out of these non-clinical records which is preferred under HIPAA, and will be more appropriate for the low, if not zero, risk associated with diagnostic misadministrations.

Department Response:
Adopted.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	1.11.2 and 1.11.3

Comment:
Record information and retention for Misadministrations.
Remove the requirement to maintain patient information and identification for diagnostic misadministrations in Section 1.11.3. Section 1.11.3 should be for therapeutic misadministrations only. Diagnostic misadministrations have little to no patient health effects risk and therefore patient identification is not needed. This will allow registrants to refrain from including protected patient information out of non-clinical documents in accordance with HIPAA. Add any needed diagnostic misadministrations record information to Section 1.11.2. For example, date of exam, performing individual, referring physician, description of event, estimated radiation exposure and actions taken to prevent re-occurrence as appropriate.

Department Response:
Adopted.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	1.11.2 and 1.11.3

Comment:

Record Information and Retention for Misadministrations.

We recommend that 1.11.2 and 1.11.3 be dedicated to Diagnostic Misadministrations and Therapy Misadministrations, respectively. This could help avoid confusion and potential misinterpretation. Additionally, since Diagnostic Misadministrations are typically not as significant as Therapy Misadministrations, we recommend removing the requirement to include patient identification in the documentation for diagnostic misadministrations. This will better assist facilities in maintaining compliance with HIPAA requirements.

The CRCPD SSR do not include misadministrations for diagnostic radiology procedures. This regulation could be removed altogether or revised as recommended below.

Current Versions:

1.11.2 Diagnostic Misadministrations. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for the Department review, and maintain the record as directed in RHB 1.11.3.

1.11.3 Each registrant shall retain a record of each therapy misadministration for ten (10) years and three (3) years for each diagnostic misadministration. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.

Recommended versions:

1.11.2 Diagnostic Misadministrations. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for the Department review, and shall retain a record of each diagnostic misadministration for three (3) years. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, and the patient's referring physician), a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.

1.11.3 Each registrant shall retain a record of each therapy misadministration for ten (10) years. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.

Department Response:

Adopted.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	1.2.7

Comment:
Hand-Held Radiographic Prohibited.
Section 1.2.7 prohibits the use of hand-held radiographic equipment. However, Section 4.6.4 allows for the use of hand-held intraoral dental radiographic equipment. Recommend adding a clarification to Section 1.2.7 that exempts hand-held intraoral dental radiographic equipment from this section.

Department Response:
Adopted. Sections related to hand-held were amended.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	General and 1.2.8 - 9

Comment:
Licensed Practitioners (LPs).
Better define WHICH LPs can perform fluoro and other radiological procedures, as the number of "LPS" is increasing greatly. NPs, PAs, and SLPs do not have defined rad training. Rad PA's do. Explicitly state that LPs that do not have formal and appropriate rad training should not be allowed to operate rad units. Engage SCRQSA as needed to help define. See also definitions in 9.127 and 4.2.2

Department Response:
Partially Adopted. Updated definition of Licensed Practitioner to match Title 44, Chapter 74 Medical Radiation Health and Safety Act.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	1.2.8.9, 4.2.2 and 9.137

Comment:
Licensed Practitioners Operating X-ray Producing Equipment
Better define Licensed Practitioners that can operate x-ray producing equipment. There are an increasing number of “Licensed Practitioners” as listed in South Carolina Labor and Licensing such as Physicians, Nurse Practitioners, Physician Assistants, Speech Language Pathologists, etc. It is understood that Physicians, Dentists, Podiatrists, Chiropractors and Radiology Physician Assistants

can operate x-ray producing equipment. For example, physicians have training on x-ray producing equipment through residency and fellowship programs. Radiology Physician Assistants have an approved Scope of Practice through the South Carolina Board of Medical Examiners requiring formal radiation safety training and specific training for each procedure they perform.
However, other types of Licensed Practitioners (e.g., Nurse Practitioners, Non-Radiology Physician Assistants, Speech Language Pathologists) do not have this type of training and/or scope of practice approval required. It would be appropriate to clarify this part of the regulation to ensure Licensed Practitioners that do not meet this advanced training and/or scope of practice are not able to operate x-ray producing equipment.

Department Response:
Partially Adopted. Updated definition of Licensed Practitioner to match Title 44, Chapter 74 Medical Radiation Health and Safety Act.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	1.6.3

Comment:
Guidance for Equipment not covered in regulations.
This reg states that BRH publishes guidance documents used to assess new modalities. This is great, but these cannot be found. If they exist, a link to them should be emailed to registrants now and when additions or changes are made.

Department Response:
Adopted. The requirement for the guidance document was removed from the regulation.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	1.6.3

Comment:
Equipment Not Covered in Regulations.
While the Department develops guidance documents for x-ray producing equipment not currently covered in regulation, that guidance documentation is not readily available and/or provided to the end user of that equipment. It is recommended that the Department send these guidance documents and their revisions electronically to all X-ray registrants in the state and/or publish on the Department's website in an easy to identify location.

Department Response:
Adopted. The requirement for the guidance document was removed from the regulation.

Name	Section
Laura Srebnik Manager, Government Relations Medical Imaging & Technology Alliance	2.5.1.3

Comment:
Vendor Obligation: Registration stickers on controls.
Currently, Class I/II Vendors are required by 2.5.1.3 to confirm that a registration sticker is present on a control and that it contains the appropriate information. MITA recommends that this should be the sole responsibility of the Facility/Registrant per 2.5 Equipment Registration Requirements, Users of X-ray Machines. Class I/II Vendors do not have ownership/control of Facility/Registrant related items.

Department Response:
Not Adopted. Allows vendors to use the registration sticker to confirm the unit is registered prior to providing service. Removing would cause possible citations to the vendor.

Name	Section
Laura Srebnik Manager, Government Relations Medical Imaging & Technology Alliance	2.6

Comment:
Registration Requirements – Servicing and Services (VENDOR).
Currently, Vendors are required to complete and submit DHEC D-0825 Vendor Employee Registration form incorporating education, training, and experience requirements of each service technician performing installation and/orservicing of devices.

With respect to Class I/II Vendors, MITA recommends elimination of DHEC D-0825 as this requirement causes undue burden as compliance may be demonstrated by alternative means (e.g., ISO 13485:2016 Certification). These records can be provided upon request.
In addition, with respect to Class I/II Vendors, this requirement would prohibit use of a National Service Team which may be leveraged for disaster relief purposes or to support surge demand. Delays caused by this requirement would likely prevent use of non-local employees in an event of disaster and/or other similar conditions (e.g., storms and hurricanes) and could be a detriment to Facilities and/or Patients.

Department Response:
Not Adopted. Certifications and training are to be documented on the application. Exemption from requirements for emergency situations will be reviewed at the discretion of the Department.

Name	Section
Laura Srebnik Manager, Government Relations Medical Imaging & Technology Alliance	2.7.1

Comment:
Vendor Obligation.
Currently, Class I/II Vendors are required by 2.7.1.4 to submit DHEC Form D-0823 Report of Sale or Installation of X-ray Equipment monthly, regardless of whether X-ray equipment was sold that

month. This requirement is an undue burden as the information provided within is redundant to FDA Form 2579 which is submitted by Class I/II Vendors to both the Facility/Registrant as well as the State. MITA recommends including a provision regarding the use of assembler's reports, which will provide relief from the submission of duplicate information at monthly intervals:
"In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal diagnostic x-ray standard (21 CFR 1020.30(d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler."
Additionally, a single Facility/Registrant may have multiple Vendors selling/installing X-ray equipment. In these instances, if this requirement is deemed necessary, the Facility/Registrant is best positioned to provide a cohesive list for state review.

Department Response:
Partially Adopted. The requirement to submit the form when no machines were sold for the month has been removed. FDA Form 2579 is not required for all x-ray types making the monthly notification to the Department necessary.

Name	Section
Laura Srebnik Manager, Government Relations Medical Imaging & Technology Alliance	2.7.2

Comment:
Vendor Obligation: Facility Registrations, Installation Shielding Plans, Equipment Replacement/Repairs Notification.

Currently Class I/II Vendors are required by 2.7.2 to:
• Verify State approval of customer Facility Registrations prior to installations.
• Verify State approval of Facility/Registrant submitted shielding plans prior to installations (4.4.1.1).
• Verify State approval of Facility/Registrant submitted documentation (4.4.2.1) for Equipment Replacement/Repairs.

Vendors should not be involved with matters between the Facility/Registrant and the State. The industry standard which has been adopted by other States, is that these requirements are and should be the sole responsibility of the Facility/Registrant per 2.4 Facility Registration Approval and 2.5 Equipment Registration Requirements, Users of X-ray Machines and/or that appropriate classification of Vendor. Class I/II Vendors do not oversee or manage the Facility/Registrant activities and processes and don't have visibility into documents/submissions or state approvals.
Additionally, Class I/II Vendors are not involved with matters between the Facility/Registrant and the State. This requirement represents an undue complication for the Vendor as they are not engaged in the process, nor can the Vendor complete any of the activities that may be required.

This requirement introduces undue potential delays in installation and servicing activities.
Additionally, according to Regulatory Guide B6, X-Ray Facility Shielding Plans, the State requires DHEC Form D-2779 to be submitted prior to replacement of like-for-like components (generators and controls) by a Class III or higher Vendor, referencing section 4.4.2. Form DHEC 2779 requires Vendors to include information around equipment orientation, maximum technique factors, workloads, and occupiancies of surrounding areas. All of these changes would require extensive

changes to an X-ray system and to existing software which would not be considered a like-for-like exchange and would be covered under 4.4.2.2. This process is duplicative and dependent on the availability of the Facility physicist, leading to Vendor delays which could be detrimental to patients. MITA recommends that, in all sections of the new rule, verification of Facility/Registrant and activities that are subcontracted to other Vendor classifications are the sole responsibility of that Facility/Registrant and/or Vendor.

Department Response:
Partially Adopted. Equipment stickers provide vendor visibility as to state approvals. Additionally, agency website lists registered facilities in real time. Equipment must be installed in accordance with Department accepted shielding plan. Thus, the installation vendor must review the Department accepted shielding plan prior to installation. Requirements surrounding DHEC Form D-2779 have been revised.

Name	Section
Laura Srebnik Manager, Government Relations Medical Imaging & Technology Alliance	2.7.2

Comment:
Vendor Obligation: Paper copies.
Currently, Class I/II Vendors are required by 2.7.3.3 and 2.7.3.4 to provide copies of records to the registrant at the time of service including signature of the person performing the service. MITA recommends clarifying that appropriate electronic records are sufficient and acceptable as they are readily available and indefinitely retained.

Department Response:
Adopted. See Section 1.10.5

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	3.12.3.1.3

Comment:
Stop work for lost badges.
Should only apply to those are chronically exposed above 10% MPD. For too disruptive to suspend workers for trivial exposures, especially now with COVID staffing issues.

Department Response:
Adopted.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands	3.12.3.1.3

Prisma Health-Upstate	

Comment:
Ceasing Radiation Work Due to Lost or Damaged Radiation Monitor.
This section requires that an individual stop work if their radiation monitor is lost or damaged. Radiation exposure is cumulative and therefore this regulation should allow for the ability to estimate exposure for individuals for short periods of time in the cases of a lost or damaged monitor until another monitor can be assigned. This will avoid potential patient safety issues should personnel lose or otherwise have a damaged monitor during a procedure. Spare monitors are not always immediately available and an appropriate number of days to assign another monitor (e.g., up to five days) would be appropriate.

Department Response:
Adopted.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	3.12.3.1.3

Comment:
Ceasing Radiation Work Due to Lost or Damaged Radiation Monitor.
We believe that this is a disruptive process for individuals who receive low level exposures. We support this regulation when a dosimeter is lost or damaged for individuals that are likely to receive greater than 10% of the maximum permissible dose. We recommend removing this requirement or revising as recommended below.

Current Version:
3.12.3.1.3 If a personnel monitoring device is lost or damaged, the worker shall cease work immediately until a replacement badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the badge. In the event a replacement badge is not available, the Radiation Safety Officer shall be contacted immediately to evaluate the probable radiation exposure to the worker until a replacement device is received.

Recommended Version:
Remove 3.12.3.1.3 or
3.12.3.1.3 If a personnel monitoring device is lost or damaged, the worker who is likely to receive greater than 10% of the maximum permissible dose shall cease work immediately until a replacement badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the badge. In the event a replacement badge is not available, the Radiation Safety Officer shall be contacted immediately to evaluate the probable radiation exposure to the worker until a replacement device is received.

Department Response:
Adopted. Amended for clarity.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	3.12.3.1.4

Comment:
Requires monitors be returned/analyzed within 45 days of monitoring period end.
Remove the 45 day late requirement. Allow internal processes to handle late/unreturned monitors. If not removed entirely, at least have it only apply to those receiving more than 10% MPD. The monitoring is still continous; the dose just has a different date range assigned to it.

Department Response:
Not Adopted. Threshold required to determine compliance with the regulation.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	3.12.3.1.4 and 3.12.3.1.5

Comment:
Radiation Monitor Returns and Documentation.
These regulations require that radiation monitors be returned within 45 days of the end of the monitoring period and that an explanation be documented for any late, unreturned and/or unused monitors for Department inspection. These requirements are not found in the Conference of Radiation Control Program Directors (CRCPD)1 recommend state regulations. The CRCPD regulations stipulate that radiation monitors be used to ensure compliance with the annual radiation exposure limits. It is recommended that these portions of the regulation be removed. This allows for the registrant's radiation protection operational conditions as required by these regulations to stipulate the radiation monitoring program and any follow-up needed for monitors not being returned and/or analyzed timely.

Department Response:
Not Adopted. Threshold required to determine compliance with the regulation.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	3.12.3.1.4 and 3.12.3.1.5

Comment:
Radiation Monitor Returns and Documentation.
These regulations require that radiation monitors be returned within 45 days of the end of the monitoring period and that an explanation be documented for any late, unreturned and/or unused monitors for Department inspection. We believe that this is excessive and unnecessarily

burdensome to facilities. It should be noted that while they may be returning their dosimeter late, they continue to be monitored. We recommend that these rules be removed.

Current Versions:
3.12.3.1.4 The Registrant shall ensure that personnel monitoring devices are returned within 45 days of the end of the monitoring period. Direct read dosimeters must be read according to the manufacturer specifications and the results from the readings recorded and available for departmental review

3.12.3.1.5 Documentation providing explanation of any late, absent or unused personnel monitoring devices must be recorded and available for Departmental review
Recommended Version:

3.12.3.1.4 – Remove.

3.12.3.1.5 – Remove.

Department Response:
Not Adopted. Threshold required for evaluation of compliance with regulation. Refer to RHB 3.12.4.1.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	3.12.3.1.5

Comment:
Document late badges.
Remove this. Burden with no value. Dose assignment by RSO and other internal procedures can handle this. At least restrict this only to those chronically exposed at 10% of MPD rate or higher.

Department Response:
Partially Adopted. Addressed in RHB 3.12.4.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	3.12.4.1.3.1

Comment:
Badges for all "working with" fluoro.
This is vague and produces too many low-yield monitored individuals. Change to "chronically working directly adjacent to patients undergoing fluoroscopy." Will also reduce the burden of 3.20.1 for onboarding new people. Such tracking is not found in CRCPD recommendations. We have years of data at SRHS that show those circulating in an even a busy fluoro room like OR and Cath, don't collect even 10% of MPD. We must reduce burden with no benefit by not regulating doses less than natural background in Denver. So we can focus on the "heavy-hitters".

Department Response:
Not Adopted. The wording is consistent with the Suggested State Regulations.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	3.12.4.1.3.1 and 3.12.4.1.4

Comment:
Personnel Radiation Monitoring Requirements.
Section 3.12.4.1.3.1 requires monitors for any individual working with fluoroscopy. This allows for a wide variety of interpretation and thus individuals being monitored for radiation exposure that do no need to be monitored. This results in additional operational aspects of tracking individuals who receive significantly less than 10% of the annual regulatory limits. These operational aspects cause additional personnel resources and financial resources for registrants. It is recommended that the Department remove this section and only require those likely to exceed 10% of the annual regulatory limits, Minors/declared pregnant workers likely to exceed 10% of RHB 3.7 or 3.8 or those entering a high radiation area to be monitored. Making this change would be consistent with SC DHEC Title A, Regulation No. R61-63, Radioactive Materials, Section 3.17.12. This would also allow the Radiation Safety Officer to implement an appropriate monitoring program for exposed groups/individuals, analyze the data and deem if they are likely to exceed 10% of the annual limit. The Department could review these determinations during inspections as appropriate.

Section 3.12.4.1.4 specifies that radiation monitoring is required as the Department deems necessary. This section is not required since all appropriate scenarios for monitoring would be covered in Section 3.12.4.1.3. It is recommended that section 3.12.4.1.4 be removed.

Department Response:
Not Adopted. The wording is consistent with the Suggested State Regulations.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	3.12.4.1.3.1

Comment:
Working with Fluoroscopy.
We believe that this regulation needs to be clarified to require that personnel monitoring devices be worn by personnel working with medical fluoroscopic equipment that is likely to result in 10% of the maximum permissible dose. There may be cases when individuals work with fluoroscopy devices (i.e., mini c-arms, routine fluoro procedures, nurses in OR) that don't receive exposures > 10% of the maximum permissible dose. These individuals do not need to be monitored.

Current Version:

3.12.4.1.3 Individuals entering a high or very high radiation area.
3.12.4.1.3.1 Personnel monitoring devices shall be worn appropriately by personnel working with medical fluoroscopic equipment.

Recommended Version:
3.12.4.1.3 Individuals entering a high or very high radiation area.
3.12.4.1.3.1 – Remove Or
3.12.4.1.3.1 Personnel monitoring devices shall be worn appropriately by personnel working with medical fluoroscopic equipment that is likely to result in greater than 10% of the maximum permissible dose to that individual.

Department Response:
Not Adopted. The wording is consistent with the Suggested State Regulations.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	3.12.5.2

Comment:
Determination of Dose.
We believe that the documentation requirements for this section are unnecessary and overly burdensome. We recommend that the documentation requirements be removed. It is currently required that protective devices be worn and failure to wear them would be out of compliance. The periodic review of personnel dosimetry records is sufficient to successfully execute EDE. The CRCPD Suggested State Regulations provide an excellent model for this requirement.

Current Version:
3.12.5 Determination of Dose
3.12.5.1 When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual.
3.12.5.2 The Radiation Safety Officer may give consideration that an Effective Dose Equivalent be used as the permanent record provided that all provisions of RHB 3.3 apply. The Radiation Safety Officer must ensure individuals utilizing the Effective Dose Equivalent shall meet the following requirements:
3.12.5.2.1 Protective equipment must be used. The use of protective equipment shall be routinely documented in each room and this documentation shall periodically be reviewed by the Radiation Safety Officer, or other responsible persons to determine if it is being completed correctly.
3.12.5.2.2 Periodic visits must be made by the radiation safety officer or his designee for personal observation adherence to proper radiation safety practices. Documentation of these reviews must be available for Departmental review. 3.12.5.2.3 The Department may immediately revoke the use of the Effective Dose Equivalent upon determination that a violation of RHB 3.12.5 has occurred.
3.12.5.3 Adjustments to the dose of permanent record shall be determined by the Radiation Safety Officer prior to any changes to the record. Records of these actions shall be maintained for Departmental review.

Recommended Version:

3.12.5 Determination of Dose
3.12.5.1 When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual.
3.12.5.2 The Radiation Safety Officer may give consideration that an Effective Dose Equivalent be used as the permanent record provided that all provisions of RHB 3.3 apply. The Radiation Safety Officer must ensure individuals utilizing the Effective Dose Equivalent shall meet the following requirements:
3.12.5.2.1 Protective equipment must be used.
3.12.5.2.2 - Remove
3.12.5.2.3 (change to 3.12.5.2.2?) The Department may immediately revoke the use of the Effective Dose Equivalent upon determination that a violation of RHB 3.12.5 has occurred.
3.12.5.3 Adjustments to the dose of permanent record shall be determined by the Radiation Safety Officer prior to any changes to the record. Records of these actions shall be maintained for Departmental review.

Or replace with CRCPD Suggested State Regulation:
3.12.5.2 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure:
3.12.5.2.1 When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in 3.12.3.1.2 and 4.2.9.2, the effective dose equivalent for external radiation shall be determined as follows:
(1) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or
(2) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in 3.4, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or
(3) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

Department Response:
Partially Adopted. Revised to be substantially the same to CRCPD SSR. Removed requirement for observation of the use of protective apparel.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	3.12.5.2
Comment:	

Determination of Dose.
Regulation 3.12.5.2 allows for registrants to use the Effective Dose Equivalent (EDE) as a permanent record of an identified individual's exposure. The EDE calculation takes the lead protective apparel worn by individuals into account of their whole-body exposure. However, regulation 3.12.5.2.1 requires the registrant to routinely document that protective equipment is being worn by individuals included in their effective dose equivalent program. The Radiation Safety Officer (RSO) is also required to periodically review this documentation. Regulation 3.12.5.2.2 requires documented periodic visits by the RSO to these individuals' departments to confirm adherence with these requirements. While the CRCPD recommended state regulations allows for EDE programs like 3.12.5.2, they do not require routine documentation of protective equipment utilization, review of this documentation nor periodic visits to observe for compliance. This documentation and periodic reviews add additional work to the registrant but provides no identified benefit to the actual implementation to the radiation monitoring program. Lead aprons and radiation monitoring are required by Regulation 61-64 for individuals in these procedures outside of Section 3.12.5.2. It recommended to replace Section 3.12.5.2 with the CRCPD suggested state regulation D.120.c. as follows:
3.12.5.2 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure:
3.12.5.2.1 When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in 3.12.3.1.2 and 4.2.9.2, the effective dose equivalent for external radiation shall be determined as follows:
(1) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or
(2) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in 3.4, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or
(3) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04

Department Response:
Partially Adopted. Revised to be substantially the same to CRCPD SSR. Removed requirement for observation of the use of protective apparel.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	3.12.5.2.1

Comment:
Documentation of protective equipment used by individual on EDE for each case.

Remove documentation of lead apron use under EDE. Wearing a lead apron is already required in regulation. With or without EDE. CRCPD does not require this as part of their EDE recommended regs.

Department Response:
Adopted.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	3.12.5.2.2

Comment:
Periodic audits of individauls on EDE program to ensure protective equipment is worn.
Remove periodic review requirements for same reasons as above. If they must remain, allow tapering off. For example, for each new person, review monthly for 3 mo, then quarterly for 3Qs, then stop, unless lapses are observed.

Department Response:
Not Adopted. Quarterly visits ensure compliance with ALARA practices.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	4.10.3

Comment:
Bone Densitometry Systems.
We feel that 1 meter from the patient is an arbitrarily determined distance. If the operator is positioned where scatter measurements obtained under operational conditions is below the maximum permissible dose for occupational workers, then the distance is acceptable. If the measured exposure levels exceed the maximum permissible levels, then mobile shields should be permitted to be used to protect the operator. Radiation monitoring devices are used to demonstrate that the exposure to the operator is maintained below the maximum permissible limit.

Current Version:
4.10.3 Location. The bone densitometry system shall be placed in a controlled area. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during examination.

Recommended version:
4.10.3 Location. – Remove Or
4.10.3 Location.
The bone densitometry system shall be placed in a controlled area. The operator, ancillary personnel, and members of the general public shall be positioned such that the radiation levels to

that position are less than the maximum permissible limit. This must be demonstrated with radiation scatter measurements or measurements from stationary area monitoring devices.
Mobile shields may be employed to ensure that these radiation levels are maintained to below the maximum permissible limit.

Department Response:
Not Adopted. This would cause an undue burden on facilities.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	4.11.2.1

Comment:
CT Control in protected area outside control room conflicts with FDA -approved in-room control.
Add: "except during special procedures when an available in-room exposure switch may be used".
Newer scanners have an FDA-cleared way activate beam near the doughnut that are important to certain, especially contrast-administering procedures. This old rule conflicts with best patient care.
More info available on request.

Department Response:
Adopted. Part IV. Appendix C.3.a.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	4.11.2.1

Comment:
CT Facility Design.
This section requires that the x-ray control for a CT unit be placed in a protected area outside the room. Most modern CT units have an X-ray exposure switch on the CT gantry in addition to the x-ray exposure switch in the control room. These gantry exposure switches are for delayed exposure and are used by CT Technologists to confirm that a patient does not have a contrast infiltration at the start of a CT procedure with remote contrast injection. Once the patient is connected to the contrast injector, the gantry exposure switch is activated by the technologist and the contrast starts to inject. No radiation is present during this portion. The technologist verifies proper contrast flow and then immediately exits the room. The contrast still flows and then the CT protocol automatically energizes the x-ray tube for the procedure at the pre-set time per protocol. This is after the technologist has exited the room into the control room and is shielded. The exposure on delay range is based on protocol and are typically about 45 – 60 seconds after the exposure switch is depressed. Not allowing these exposure switches on the CT gantry could allow for unnecessary contrast infiltrations for patients potentially leading to compromised patient care and additional CT scans of the patient. It is recommended that these delay exposure switches be exempted from this regulation.

Department Response:
Adopted. Part IV. Appendix C.3.a.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	4.11.2.1

Comment:
CT Facility Design.
We believe that this regulation is dated and does not apply to modern CT equipment. Controls are no longer incorporated with the generators and are often simply a keyboard. These keyboards are not fixed behind the operator barrier and can be placed in many positions behind the control barrier. The CRCPD SSR do not include CT's in this requirement. Current CT's also have exposure switches that are located inside of the scan room. Administrative controls are used to prevent personnel exposure during any exposure. We recommend that this requirement for CT controls be removed or revised to allow for special procedures which require an individual's presence (i.e., biopsies).

Current Version:
4.11.2.1 The control panel and x-ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

Recommended Version:
4.11.2.1 – Remove. Or
4.11.2.1 The operator is required to remain in that protected area during the entire exposure, except during special applications or procedures (i.e., biopsies) when an in-room exposure switch may be used. Any individual remaining in the room during any exposure must use protective devices.

Department Response:
Partially Adopted. See amendment in Part IV. Appendix C.3.a.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	4.2.10

Comment:
Gonadal/fetal/scatter shielding.
Current national standards recommend against use of supplemental shielding in-field. Recommend delete. Consortium submitted before. Delete/modify same in Dental regs as well.

Department Response:
Adopted.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	4.2.10 and 4.5.12.4

Comment:
Patient Shielding.
Current national standards recommend against use of supplemental patient gonadal and fetal shielding due to improvement in imaging technology, minimal exposure from scatter radiation, minimal exposure reduction it provides and the potential to increase exposure if the supplemental shielding is incident to primary radiation field. It is recommended to delete this. Please see our more detailed regulatory request submitted to the Department on December 21, 2021 for more information on this specific regulation.

Department Response:
Adopted.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	4.2.10 and 4.5.12.4

Comment:
Patient Shielding.
This regulation has been discussed and decided by many professional Radiology organizations (AAPM, ACR, ASRT, RSNA, etc). They agree that patient shielding is ineffective and is no longer recommended. We recommend that this requirement be removed.

Current Version:
4.2.10 Shielding of not less than 0.5 mm lead equivalent material shall be used for patients during x ray procedures except in cases where the shielding would interfere with the diagnostic image desired.
4.5.12.4 Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25-millimeter lead equivalent to cover the gonadal area unless the patient refuses.

Recommended Version:
4.2.10 – Remove.
4.5.12.4 – Remove.

Department Response:
Adopted.

Name	Section
David Vassy	4.2.14.3

Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	

Comment:
Pregnant/fetal Monitorinig.
Monitoring pregnant persons should not be limited to Health Professions (Part IV). So this monitoring requirement should be moved and added to Part III (3.12.4.1.2) where it will have more general applicability.

Department Response:
Not Adopted. This requirement is in 3.12.6.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	4.2.14.3

Comment:
Declared Pregnant Worker Radiation Monitoring.
The requirements in Section 4.2.14.3 for providing a fetal monitor to a declared pregnant occupationally exposed worker is already addressed by 3.12.4.1.2. Recommend removing Section 4.2.14.3.

Department Response:
Not Adopted. This requirement is in 3.12.6.

Name	Section
Glenn Goudy President Health Physics Consultants, LLC	4.2.16.1.3.1

Comment:
Nomad or handheld dental units frequency of equipment performance testing should be changed from annual to biannual same as the intra oral, pan, and pan ceph, Dental CT frequency of EPT should remain the same.

Department Response:
Not Adopted. Portability and hand-held use warrants annual calibration.

Name	Section
Robert Owen Owner X-Ray Compliance Solutions, LLC	4.2.16.1.3.1

Comment:

We have found that hand held dental x-ray units rarely have non-compliance issues. In seven years, I have only tested one that had a problem. Please change the frequency of performance testing to every two years.

Department Response:
Not Adopted. Portability and hand-held use warrants annual calibration.

Name	Section
Michael F. Tkacik Radiological Physicist	4.2.16.1.3.2

Comment:
RHB 4.2.16.1.3.2 requires that the annual testing frequency for all medical x-ray equipment, including fluoroscopic, computerized tomography, and radiation therapy simulators, shall be tested annually. Please consider changing the interval from annual to 14 months. This is a perfectly sensible adjustment and one that has already been adopted by the FDA (if not by DHEC) for surveys required under MQSA. This change would not affect health or safety. Please amend RHB 4.2.16.1.3.2 to read: "RHB 4.2.16.1.3.2 All medical x-ray equipment, including fluoroscopic, computerized computed tomography, and radiation therapy simulators, shall be tested at intervals not to exceed fourteen months. Self calibrating bone densitometry systems are exempt from this requirement. Mammography units shall meet the requirements of Part V.

Department Response:
Not Adopted. Annual is defined in regulation.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	4.2.2 and others

Comment:
Licensed Practitioner.
See comment # (General and 1.2.8 - 9)

Department Response:
Partially Adopted. Updated definition of Licensed Practitioner to match Title 44, Chapter 74 Medical Radiation Health and Safety Act.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	4.2.9.1

Comment:
Requirement for 0.5mm lead use should not apply to hands.
Change to "no part of the body, excluding extremities, will be struck..." Direct hand exposure happens only fleetingly. Proceduralists need dexterity that thick gloves cannot provide, and thin

gloves don't attenuate much. Any gloves in beam drive up patient dose. (Refs available). Based on ring badge data, extremity doses rarely approach limit, which is higher for extremities.

Department Response:
Adopted. See RHB 4.2.9.2.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	4.2.9.1

Comment:
Lead Protective Equipment in Primary Beam.
This section states that individuals should not be exposed to primary x-ray beam unless those body parts are shielded with at least 0.5 mm lead equivalency. There are multiple procedures that require a physician's hands to be in primary beam temporarily to properly execute the procedure (e.g., insert catheter, adjust a screw, etc.) and requires a significant level of dexterity as well as sterility. Shielded surgical gloves can be used but are not typically available in 0.5 mm lead equivalency. Even with the lower attenuation of shielded surgical gloves, dexterity of the physician can be significantly reduced causing additional use of fluoroscopy. In addition, with modern fluoroscopic equipment, when shielding material is placed in the primary beam, the x-ray technique automatically increases. Thus, providing more radiation exposure to the individual's hands, to the patient and to the remaining personnel present during the procedure. It is recommended that this regulation provide an exemption for these interventional/surgical fluoroscopic cases where sterility and dexterity are required. See proposed regulation below:
4.2.9.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.
4.2.9.1.1 Temporary placement of the physician's and/or assistant's hands in primary beam during interventional fluoroscopy procedures and/or surgical procedures that require sterility and increased dexterity are exempt from 4.2.9.1.

Department Response:
Adopted. See RHB 4.2.9.2.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	4.2.9.1

Comment:
Lead Protective Equipment in Primary Beam.
We believe that this regulation does not permit the use of shielded gloves or other apparel that may provide more dexterity to the fluoro user (physician) during complex procedures while providing sufficient protection. There should be some latitude given to permit the use of gloves with less shielding if they use an extremity monitor. This can result in a more efficient procedure

time resulting in less dose to the patient and physician. If the physician maintains an exposure less than 10% of the maximum permissible dose to their extremity using no glove or a glove with less shielding, then this should be deemed acceptable. If an extremity monitor (i.e., ring dosimeter) is worn, then no shielded glove would be required unless monitoring results indicate otherwise. This process should be monitored by the RSO.

Current Version:
4.2.9.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.
Recommended Version:
4.2.9.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.
4.2.9.1.1 If the facility can demonstrate that physicians who use gloves with less shielding than 0.5 mm lead and wear an extremity dosimeter on the applicable extremity are exposed to less than 10% of the maximum permissible dose to their extremity, then the alternative gloves may be used.
or
4.2.9.1.1 Temporary placement of the physician's and/or assistant's hands in primary beam during interventional fluoroscopy procedures and/or surgical procedures that require sterility and increased dexterity are exempt from 4.2.9.1.

Department Response:
Adopted. See RHB 4.2.9.2.

Name	Section
Adam Larck Vice President Radon Medical Imaging	4.4.2.1

Comment:
The question/comment I have is in regards to the 2779 process. I think filling out the 2779 form and having a physicist review a shielding plan with current patient volumes is a good idea. The concept I don't like is requiring the approval of the 2779 before a service can be performed on a customer's equipment. For example, if a customer has a generator console that has a problem and needs replaced rendering the customer down until the console is replaced. The customer has to fill out the 2779 get a physicist to review their shielding plan with update volumes, the physicist has to submit to the SC DHEC and receive approval via a log number before the console can be replaced. That process creates a lot of downtime and lost revenue for the facility. Also incurring additional cost for a return service trip. I like the theory of the process but my recommendation is to allow the customer to get their console replaced, as long as the replacement does not provide more functionality or increase dose output, so they do not have extended downtime. Then allow the customer 30 days to have their shielding plan reviewed by a physicist and submitt the 2779 for approval.

Department Response:
Adopted.

Name	Section
David Vassy	4.4.2.1

Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	

Comment:
Approve Repairs?
BRH has interpreted this to require that registrants must get clearance from BRH before equipment can be repaired sometimes and there has been confusion, even within BRH, as to what replaced part triggers this rule--example HV Tank on CT. Having to apply and wait for clearance from DHEC delays the return of the machine to patient care schedule. "Repairs" nearly always serve to return the machine to original performance. So add "shall notify the Department within 30 days regarding such replacement". Also, tracking changed shielding log numbers has been a problem both for BRH and this large registrant. Don't change the log number UNLESS it is determined the shielding DOES need to be re-evaluated.

Department Response:
Partially Adopted. Reworded for clarity. Log numbers required for tracking purposes.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	4.4.2.1

Comment:
Like Equipment Replacement Requirements.
Department interpretations of this section have required that the registrant provide the Department a notification of like equipment replacement prior to the date of the replacement/repair. However, most replacements of controls, generators, and other repairs of an x-ray producing unit will not render the original shielding plan ineffective. It can take several days to get a new shielding log from the Department in order to proceed with a needed control/generator replacement (essentially a repair). This can delay patient care since the unit cannot be repaired and made operational until a new shielding log is issued by the Department. It is recommended that the Department allow a 30-day notification for replacement of controls, generators and other parts. We agree that notification prior to complete unit replacement is appropriate.

Department Response:
Adopted.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	4.4.2.1

Comment:
Like Equipment Replacement Requirements.

We believe that this requirement is confusing, overly burdensome and interferes with patient care. Component replacements can occur within hours of discovery of a component failure. These component replacements do not change the overall equipment scatter profile and therefore immediate notification is not necessary. Significant delays in gathering the necessary documentation for notification can result in significant and unnecessary patient procedure delays. We recommend that this regulation be changed to permit this process to be completed as soon as possible but within 30 days of the equipment or component change.

Current Version:
4.4.2.1 A shielding plan is not required upon the replacement of an existing x-ray machine, control, or generator with like equipment and when there are no other changes which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor. The appropriate vendor shall notify the Department regarding such replacement. A form shall be provided by the Department for this notification and shall be exempt from RHB 2.3.2.

Recommended Version:
4.4.2.1 A shielding plan is not required upon the replacement of an existing x-ray machine, control, or generator with like equipment and when there are no other changes which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor. The appropriate vendor shall notify the Department regarding such replacement. A form shall be provided by the Department for this notification and shall be exempt from RHB 2.3.2. This form shall be used to notify the Department as soon as possible but within 30 days of the replacement.

Department Response:
Partially Adopted. Reworded to clarify qualifying replacements.

Name	Section
John Kennedy Owner Bella Vista Dental	4.5.12.4

Comment:
Shielding/lead apron.
Given the growing body scientific body of evidence showing little to no benefit, and in some cases harm, of lead apron usage in dental, I would request the department take a hard scientific look at making lead aprons optional. Additionally please consider removing the requirement and documentation of annual inspection as the current evidence shows little to no benefit of aprons in the first place.

Department Response:
Partially Adopted. Section was amended to align with National Council on Radiation Protection and Measurements (NCRP).

Name	Section
Michael F. Tkacik Radiological Physicist	4.9.4.3.7

Comment:
Title B 4.9.4.3.7 requires that the results of the most recent measurements in eachmode used clinically shall be posted where any fluoroscopist may have readyaccess to such results while using the fluoroscope and be included in the records required in RHB 4.2.16.1.
I would like to bring to your attention that modern fluoroscopic equipment displays live, during fluoroscopy, the Air Kerma and the Air Kerma Rate. This has been amanufacturer's requirement since 2005.
Please consider revising paragraph 4.9.4.3.7 to read, "For fluoroscopic units that do not display Air Kerma, Air Kerma Rate, or Dose Area Product, fluoroscopic results of the most recent measurements in each mode used clinically shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and be included in the records required in RHB 4.2.16.1. The name of the person performing the measurements and the date the measurements were performed shall be included in the results."

Department Response:
Adopted. Removed requirement from the regulation.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	6.6.4.4

Comment:
Spot Check Depths.
Cal depth<check depth<80% is not appropriate for all photon and electron energies. Contradicts other references. Recommend this: ..shall be made depths determined by the qualified medical physicist consistent with AAPM recommendations."

Department Response:
Adopted. Revised language to allow spot checks be made at depths specified by a nationally accepted standard.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	6.6.4.4

Comment:
Therapy Spot Checks.
This section requires that spot checks be made at a depth beyond the calibration depth but no deeper than the 80% ionization depth. However, the 80% value is not practical and contradicts suggestions in other parts of the regulations. It is recommended that we follow the American Association of Physicists in Medicine (AAPM) recommendations. For example, the current AAPPM recommendation by Task Group 51 (TG51) is to verify output at 10 cm depth which is deeper than 80%.

Department Response:
Adopted. Revised language to allow spot checks be made at depths specified by a nationally accepted standard.

Name	Section
Bryan Bagg Radiation Safety Officer Department of Environmental Health and Safety University of South Carolina	7.9.1.3

Comment:
With regards to RHB 7.9.1.3; Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in the assignment; there are many scientific parameters in the operation of an analytical x-ray machine that do not have an impact on Radiation Safety, such as goiniometer angles of diffraction in an enclosed chamber; vacuum pressures, and other items that significantly impact the analysis of the diffraction patters of materials but do not impact radiation safety.
I encourage the revision to this language that Radiation Safety Officers should only be competent on the radiation safety parameters with regards to analytical X-ray machines. The current language implies that use of an X-ray machine also includes the scientific analysis of diffraction patterns.

Department Response:
Not Adopted. Radiation Safety Officers are not required to be competent in scientific analysis.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	9.137

Comment:
Licensed Practitioner.
Needs to be more tightly defined for purposes of being allowed to use rad-producing equipment. Or add a mandate for radiation training. The only non-MD practitioners that get formal rad training are Radiology PAs (that were RTs first).

Department Response:
Partially Adopted. Updated definition of Licensed Practitioner to match Title 44, Chapter 74 Medical Radiation Health and Safety Act.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	Part IV, Appendix D

Comment:
Average Patient Exposure Guide.

We believe that Appendix D when Applied in complying with Appendix F can be confusing and difficult to obtain particularly with facilities who use consultants. We recommend that it be the facility's responsibility to have the Patient exposure at skin entrance, for most common exams performed (4.2.13.2). Personnel change, personnel use various techniques, techniques are often changed after the physicist conducts this evaluation. Consulting physicists are often cited when facilities change their techniques after the annual survey is completed, personnel present during SCDHEC inspections may use techniques different than this provided to the physicists, service may be performed on equipment that results in technique changes. The current requirement results in physicist citations and not necessarily improvement in facility technique management. We recommend that the wording in Appendix D be revised and that an asterisk (*) be placed by this test in Appendix F similar to test 16.

Current Version:
Appendix D. Average Patient Exposure Guide.
Medical ESE's
Compliance with RHB 4.2.13.2 may be determined if the patient's exposure at skin entrance (ESE) does not vary from the national averages listed below by more than 50%. Facilities should strive for an ESE that does not vary from the national average by more than 20%. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a 200 speed system.

Recommended Version:
Appendix D. Average Patient Exposure Guide.
Compliance with RHB 4.2.13.2 may be determined if the patient's exposure at skin entrance (ESE) does not vary from the national averages listed below by more than 50%. Facilities should strive for an ESE that does not vary from the national average by more than 20%. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a 200 speed system. It is the responsibility of the facility to provide the techniques used for these select patient procedures to the vendor that is used in the determination of ESEE in Appendix F.

Special Comments for Appendix F: The average patient dose guide was developed through the CRCPD NEXT committee reports. This is a compilation of exposure results from various facilities across the country. While it is important that patient procedure exposure results be known at each facility that performs these studies, it is also important to note that these results were intended to be used for guidance in optimizing techniques and not for absolute or regulatory use. We believe that facilities in South Carolina would be better served if the regulations require that these procedures be evaluated and compared to national averages rather than specific "old" published data. Facilities should be required to establish a process to evaluate patient dose and justify any results that may exceed a national average or large database. The current results in Appendix D were published in 2003. I believe that an absolute exposure may or may not be a problem. There should be a process to gather data, evaluate it and discuss it. Facilities should be able to choose various sources (i.e, Radimetrics, ACR Dose Registries, NEXT studies, etc)

This would involve removing Test 13 from Appendix F.

Current Version:

4.2.13.2 The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality. Appendix D provides patient exposures that are typical of good practices. These shall be used by the registrant in evaluating patient exposure.

Recommended Version:
4.2.13.2 – Remove
or
4.2.13.2 The radiation exposure to the patient shall be as low as reasonably achievable that is required to produce images of good diagnostic quality. Appendix D provides patient exposures that are typical of good practices. These can be used by the registrant in evaluating patient exposure. Other national dose databases or registries can be used. The database or registry used must be documented and justified. If facility results exceed recommended ranges, then the techniques should be revised, equipment should be adjusted, or the technique justified.

Department Response:
Not Adopted. It is the vendor's responsibility to obtain clinically used techniques for the evaluation of patient dose by a qualified expert. Dose limit threshold required to determine compliance with regulations.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	Appendix F

Comment:
Requires consultant to confirm that unit adheres to shielding plan upon initial testing/after certain repairs.
Since the registrant is responsible for shielding plan and area survey, require registrant to document adherence to shielding plan. This is a registrant responsibility not easily passed off onto outside consultants. If you have to keep some version of this, at least allow it to be documented another way, like a comment in the post-installation Radiation Safety Survey, or even a posted statement in the room. More info on request.

Department Response:
Adopted. Removed requirement from Part IV, Appendix F.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	Appendix F

Comment:
Has lead apron testing and bucky slot cover/lead drapes (fluoro only) noted, but then states can be performed and docuemtned by facility.
Since this is already in regulation for registrant, remove from Appendix F.

Department Response:

Partially Adopted. Not all registrants have the means to evaluate buck slot covers-lead drapes.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	Part IV, Appendix F

Comment:

Minimum Criteria for Performance Tests.

Appendix F stipulates the minimum criteria for performance testing of Medical Radiographic Equipment, Fluoroscopic Equipment, Radiation Therapy Simulation Equipment, Computed Tomography (CT) Equipment and Dental X-Ray Equipment. While most items in Appendix F are performed by a single individual/vendor during performance testing, some items may not be. For example, Appendix F stipulates that the registrant may document lead apparel quality control testing, fluoroscopic bucky slot cover shielding and fluoroscopic unit lead drape integrity themselves. The individual/vendor performing the other tests required by Appendix F is not required to confirm these three (3) items. Since these three (3) items are required in 4.2.8 and specified that the registrant is responsible for them. It is recommended that they be removed from Appendix F.

Appendix F also requires that the individual/vendor is required to document that the unit generally adheres to the shielding plan required by RHB 4.4 during the initial performance testing and any testing after a maintenance/repair that may affect its status. However, documentation that the unit is installed in accordance with the shielding plan and that the shielding is adequate is the registrant's responsibility per RHB 4.4.6 and 4.47. The registrant is required to provide a copy of the area survey and as-built noting the location of the unit and the resulting annual exposures are also provided to the Department by the. Therefore, requiring the
individual/vendor performing the performance testing to document that the unit also generally adheres to the shielding plan is duplicative. In addition, another individual may have performed the shielding plan and/or area survey. It is best for the individual completing the area survey to confirm that it adheres to the shielding plan. It is recommended that the shielding plan references be removed from all modalities in Appendix F. Regulation RHB 4.4 is adequate documentation for adherence to the shielding plan.

Department Response:

Partially Adopted. Removed lead apparel testing. Removed requirement for vendor to document adherence to shielding. Fluoroscopic shielding retained because it requires testing by a qualified expert.

Name	Section
Thomas G. Ruckdeschel, MS, DABR, FACR President Certified Medical Physicist Alliance Medical Physics LLC	Part IV, Appendix F

Comment:

Minimum Criteria for Performance Tests.
We believe that the responsibility for completing Test 13 in Appendix F is the registrant. As discussed above. We recommend that Appendix F be revised with an asterisk (*) after Test 13.

Current Version:
Appendix F
13. Patient exposure at skin entrance, for most common exams performed at the facility (except veterinary facilities) (4.2.13.2)

Recommended Version:
13. Patient exposure at skin entrance, for most common exams performed at the facility (except veterinary facilities) (4.2.13.2)*****
Note from Title B Appendix F:
Items marked with an asterisk (*) indicate that this item is not necessarily required to be tested by the vendor, but must be tested in order for the facility to meet the requirements of RHB 4.2.16.1

Department Response:
Not Adopted. Facility personnel are not qualified to perform this testing. Appropriately calibrated equipment would also be required to perform the testing.

Name	Section
Michael F. Tkacik Radiological Physicist	Part IV, Appendix F

Comment:
There is a Title B requirement that on the initial equipment testing report there be a statement to the effect that the unit "Generally adheres to the approved shielding plan." This should be the responsibility of the person performing the shieldingarea survey and not the person who conducts the equipment performance survey. These are two separate surveys. If this statement is to be anywhere, it should be in the radiation area survey. Please delete this requirement from Appendix F.

Department Response:
Adopted. Removed requirement from Part IV, Appendix F.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	General

Comment:
Re-activate TARCC.
TARCC, has not been meeting as required by statute. It should be re-activated, and membership of physicists and vendors increased. TARCC could be helpful with new modalities and licensure issues, and I expect members would be willing to serve without per deims.

Department Response:
Acknowledged.

Name	Section
David Vassy Medical Physics/Radiation Management Imaging Services Administration Spartanburg Regional Health Care System	General

Comment:
Podiatry X-ray Units.
Needs to move into more like dental equipment regulation and less like x-ray equipment regulation. The weak tubes and low techniques don't justify more.

Department Response:
Acknowledged.

Name	Section
Dr. Luke Henry Chiropractic Physician Henry Chiropractic Clinic, LLC	General

Comment:
Healthcare providers have already suffered enough hardship during the coronavirus pandemic, labor shortage and increased inflation. Adding unannounced x-ray inspections may disrupt the normal schedule and cause further distress for our staff and the public we serve. The existing regulations already provide ample means of punishing intentional noncompliance. I do not agree with increasing regulatory burden through random, unannounced inspections.

Department Response:
Acknowledged.

Name	Section
Kevin M. Lee Travis L. White, MS, DABR Health Physicist/RSO Diagnostic Medical Physicist/RSO Prisma Health-Midlands Prisma Health-Upstate	General

Comment:
Technical Advisory Radiation Control Committee:
While there is not a specific reference to the Technical Advisory Radiation Control Council in Title B, Regulation 61-64, the council would be appropriate to implement for medical use. And other uses of radioactive material in the State. The Technical Advisory Radiation Control Council should consist of end users, registered vendors and radiation/radioactive material field experts in the state of South Carolina. This council would work with the Department on guidance and positions relating to x-ray producing equipment and radioactive material use. This is similar to what other states already have in place throughout the country.

Department Response:
Acknowledged.

Name	Section
Shannon Barnett Imaging Manager Bon Secours Medical Group	General

Comment:
Anything Time stamped.
I would like to have a chart that states annual or bi-annual for the items needed. I would like to know how long to keep paperwork on hand in the chart. I want anything that has a time stamp on it for radiology in that chart. It makes sense to know to have a cheat sheet of main points to follow. I get questioned at my practices, how long do we keep this. Can I shred this, ` and we keep it out of an abundance of caution? Please see this as an excellent opportunity for other establishments to lead staff to the correct regulations.

Department Response:
Acknowledged.

Name	Section
Valerie Fantino Owner WellnessPlus	General

Comment:
Annual Fees.
Why do we need to pay an annual fee to have an x-ray machine?

Department Response:
Acknowledged. Statutory requirement.

Name	Section
John Kennedy Owner Bella Vista Dental	General

Comment:
Hand held xray units
I am unsure if this is still applicable but several years ago Nomad was the only approved handheld unit. I also heard rumors or potential conflicts of interest due to Nomad company affiliations with the state etc. Please consider approval (if not already approved) for other manufacturers which may produce better and more affordable units.

Department Response:
Acknowledged. If a hand-held dental unit meets the requirements of R.61-64 and have FDA approval, they may be utilized in South Carolina.

Name	Section
John Kennedy Owner Bella Vista Dental	General

Comment:
CBCT annual inspections.
Please make it easier for dental equip suppliers to provide annual CBCT inspections vs dedicated only radio graphic companies. There is lack of competition in this space resulting in high costs to operators.

Department Response:
Acknowledged. Current requirements are in line with Suggested State Regulations.

Name	Section
Tracy Schening, MS,DABR Certified Diagnostic Physicist	General

Comment:
Cabinet/faxitron/specimen units should only be tested upon installation. We do the same thing with bone density units.

Department Response:
Not Adopted. Current requirements are in line with suggested state regulations.

Name	Section
Tracy Schening, MS,DABR Certified Diagnostic Physicist	General

Comment:
Have verification of the adherence of the room to the approved shielding plan be the responsibility of the person who performs the shielding integrity/scatter survey instead of the person who does the equipment performance test. This makes more sense, since the tests could be (and often are) done by different people at different times. In addition, the scatter survey is a verification that the shielding is appropriate. This has nothing to do with the performance of the equipment.

Department Response:
Adopted. Removed requirement from Part IV, Appendix F.

Name	Section
Tracy Schening, MS,DABR Certified Diagnostic Physicist	General

Comment:
Specify that equipment testing be done within 14 months to align with the federal mandate of 14 months for mammography. I believe the regs currently say annually.

Department Response:
Not Adopted. The federal mandate for mammography is testing be performed every 12 months. The 14-month timeframe is in policy, which DHEC already follows. Annual is defined in regulation.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 8, 2022

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

From: Bureau of Air Quality

Re: Notice of Proposed Regulation Amending Regulation 61-62, *Air Pollution Control Regulations and Standards.*

I. Introduction

The Bureau of Air Quality (Bureau) proposes the attached Notice of Proposed Regulation amending R.61-62, *Air Pollution Control Regulations and Standards,* for publication in the September 23, 2022, *South Carolina State Register* (*State Register*). Legal authority for these amendments resides in the South Carolina Pollution Control Act, S.C. Code Sections 48-1-10 *et seq.* (Pollution Control Act), which authorizes the Department to adopt emission control regulations, standards, and limitations, and take all actions necessary or appropriate to secure to the state the benefits of federal air pollution control laws. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal air pollution control laws.

II. Facts

1. Pursuant to the Pollution Control Act and the federal Clean Air Act, 42 U.S.C. Sections 7410, 7413, and 7416, the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations pursuant to 42 U.S.C. Section 7416.

2. The United States Environmental Protection Agency (EPA) promulgates amendments to the Code of Federal Regulations (CFR) throughout each calendar year. Recent federal amendments at 40 CFR Parts 60 and 63 include revisions to New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories.

3. The Department proposes amending R.61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*, and R.61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*, to incorporate by reference federal amendments promulgated from January 1, 2021, through December 31, 2021.

4. The Department proposes amending R.61-62.70, *Title V Operating Permit Program,* to correct an error in an earlier amendment as required by the EPA to maintain compliance with federal law.

5. The Department also proposes other changes to R.61-62, *Air Pollution Control Regulations and Standards*, as deemed necessary to maintain compliance with federal law. These changes may include corrections or other changes for internal consistency, clarification, reference, punctuation, codification, formatting, spelling, and overall improvement to the text of R.61-62.

6. The Department had a Notice of Drafting published in the June 24, 2022, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Bureau also had the Notice of Drafting published

on the Department's Regulatory Information website in the *DHEC Monthly Regulation Development Update*. The Bureau sent a copy of the Notice of Drafting to interested stakeholders *via* Department email list on June 27, 2022. The Department received no public comments by the July 25, 2022, close of the public comment period.

7. Appropriate Department staff conducted an internal review of the proposed amendments on July 12, 2022.

8. South Carolina industries are already subject to national air quality standards and NSPS, NESHAP, and Title V requirements as a matter of federal law. The Department must incorporate amendments to the federal regulations because the EPA has delegated South Carolina authority for implementation and enforcement of these federal regulations. Thus, there will be no increased cost to the state or its political subdivisions resulting from adoption of these federal amendments beyond those mandated by federal law. South Carolina is already reaping the environmental benefits of these amendments.

9. In accordance with S.C. Code Section 1-23-120(H)(1), legislative review is not required because the Department proposes promulgating the amendments to maintain compliance with federal law. As such, neither a preliminary assessment report nor a preliminary fiscal impact statement is required.

III. Request for Approval

The Bureau of Air Quality respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 23, 2022, *State Register*.

Rhonda B. Thompson, P.E.
Chief
Bureau of Air Quality

Myra C. Reece
Director
Environmental Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the June 24, 2022, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-62, AIR POLLUTION CONTROL REGULATIONS AND STANDARDS

September 8, 2022

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 48-1-10 et seq.

61-62. Air Pollution Control Regulations and Standards.

Preamble:

Pursuant to the Pollution Control Act and the federal Clean Air Act, 42 U.S.C. Sections 7410, 7413, and 7416, the Department of Health and Environmental Control (Department) must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations pursuant to 42 U.S.C. Section 7416.

The United States Environmental Protection Agency (EPA) promulgates amendments to the Code of Federal Regulations (CFR) throughout each calendar year. Recent federal amendments at 40 CFR Parts 60 and 63 include revisions to New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department proposes amending R.61-62.60, South Carolina Designated Facility Plan and New Source Performance Standards, and R.61-62.63, National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories, to incorporate by reference federal amendments promulgated from January 1, 2021, through December 31, 2021.

The Department proposes amending R.61-62.70, Title V Operating Permit Program, at 70.5(c), to correct an error in an earlier amendment as required by the EPA to maintain compliance with federal law.

The Department also proposes additional changes to R.61-62, Air Pollution Control Regulations and Standards, for overall quality of regulatory text as deemed necessary to maintain compliance with federal law. These changes may include corrections or other changes for internal consistency, clarification, reference, punctuation, codification, formatting, spelling, and overall improvement to the text of R.61-62.

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 June 24, 2022, *South Carolina State Register*.

Section-by-Section Discussion of Proposed Amendments:

Section	**Type of Change**	**Purpose**
R.61-62.60		
Subpart Kb	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.

Subpart IIII	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart JJJJ	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
R.61-62.63		
Subpart A	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart YY	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart IIII	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart KKKK	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart VVVV	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart KKKKK	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart MMMMM	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart SSSSS	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
Subpart OOOOOO	Revision	Amended to incorporate federal revisions by reference for compliance with federal law.
R.61-62.70		
70.5(c)	Revision Technical Correction	Amended to correct an error in an earlier amendment as required by EPA for compliance with federal law. Amended to correct punctuation and number formatting for accuracy.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Holly Randolph of the Air Regulation, Data Analysis, and SIP Management Section, Bureau of Air Quality; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; randolhk@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. October 24, 2022, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 8, 2022, 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. 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. Public hearing procedures are subject to change in response to COVID-19 protocols. If applicable, the Department will provide notice of these changes twenty-four (24) hours in advance of the public hearing.

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: R.61-62, Air Pollution Control Regulations and Standards

Purpose: The EPA promulgated amendments to federal air quality regulations in 2021. The recent federal amendments include revisions to New Source Performance Standards (NSPS) mandated by 42 U.S.C. Section 7411; and revisions to federal National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories mandated by 42 U.S.C. Section 7412. The Department, therefore, proposes amending R.61-62 to incorporate these amendments to federal standards promulgated from January 1, 2021, through December 31, 2021. The Department further proposes amending R.61-62.70, Title V Operating Permit Program, at 70.5(c), to correct an error in an earlier amendment as required by the EPA to maintain compliance with federal law. The Department also proposes to make corrections for internal consistency, clarification, and codification to improve the overall text as necessary for compliance with federal law.

Legal Authority: 1976 Code Sections 48-1-10 et seq., and the Clean Air Act, 42 U.S.C. Sections 7410, 7413, and 7416.

Plan for Implementation: The amendments will take legal effect upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendments. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, 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 EPA promulgates amendments to its air quality regulations throughout each calendar year. Federal amendments in 2021 included revised NSPS rules and NESHAPs for Source Categories. The Department is adopting these federal amendments to maintain compliance with federal law, as the EPA has delegated South Carolina authority for implementation and enforcement of these federal regulations. These amendments are reasonable, as they promote consistency and ensure compliance with both state and federal

regulations. The proposed amendments also include the correction of an error in an earlier amendment as required by the EPA to maintain compliance with federal law.

DETERMINATION OF COSTS AND BENEFITS:

There is no anticipated increase in costs to the state or its political subdivisions resulting from these proposed revisions. The amendments to be adopted are already in effect and applicable to the regulated community as a matter of federal law, thus the amendments do not present a new cost to the regulated community. The proposed amendments incorporate the revisions to the EPA regulations, which the Department implements pursuant to federal delegation and the authority granted by Section 48-1-50 of the Pollution Control Act. The proposed amendments will benefit the regulated community by clarifying and updating the regulations and increasing their ease of use.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the state or its political subdivisions.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Adoption of the recent changes in federal regulations through the proposed amendments to R.61-62 will provide continued protection of the environment and public health.

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

The state's authority to implement federal requirements, which are beneficial to the public health and environment, would be compromised if these amendments were not adopted in South Carolina.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-62. Air Pollution Control Regulations and Standards.

Statutory Authority: 1976 Code Section(s) 48-1-10 et seq.

61-62.60, South Carolina Designated Facility Plan and New Source Performance Standards.

Regulation 61-62.60, Subpart Kb, shall be revised as follows:

Subpart Kb - "Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984"

The provisions of 40 CFR Part 60 Subpart Kb, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 60 Subpart Kb			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 52	April 8, 1987	[52 FR 11429]
Revision	Vol. 52	June 16, 1987	[52 FR 22780]
Revision	Vol. 54	August 11, 1989	[54 FR 32973]
Revision	Vol. 62	October 8, 1997	[62 FR 52641]
Revision	Vol. 65	October 17, 2000	[65 FR 61744]
Revision	Vol. 65	December 14, 2000	[65 FR 78268]
Revision	Vol. 68	October 15, 2003	[68 FR 59328]
Revision	Vol. 86	January 19, 2021	[86 FR 5013]

Regulation 61-62.60, Subpart IIII, shall be revised as follows:

Subpart IIII - "Standards of Performance for Stationary Compression Ignition Internal Combustion Engines"

The provisions of 40 CFR Part 60 Subpart IIII, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 60 Subpart IIII			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 71	July 11, 2006	[71 FR 39154]
Revision	Vol. 76	June 28, 2011	[76 FR 37954]
Revision	Vol. 78	January 30, 2013	[78 FR 6674]
Revision	Vol. 79	February 27, 2014	[79 FR 11228]
Revision	Vol. 81	July 7, 2016	[81 FR 44212]
Revision	Vol. 85	December 4, 2020	[85 FR 78412]
Revision	Vol. 86	June 29, 2021	[86 FR 34308]

Regulation 61-62.60, Subpart JJJJ, shall be revised as follows:

Subpart JJJJ - "Standards of Performance for Stationary Spark Ignition Internal Combustion Engines"

The provisions of 40 CFR Part 60 Subpart JJJJ, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 60 Subpart JJJJ			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 73	January 18, 2008	[73 FR 3568]
Revision	Vol. 73	October 8, 2008	[73 FR 59034]
Revision	Vol. 78	January 30, 2013	[78 FR 6674]
Revision	Vol. 79	February 27, 2014	[79 FR 11228]
Revision	Vol. 81	August 30, 2016	[81 FR 59800]
Revision	Vol. 85	October 7, 2020	[85 FR 63394]

40 CFR Part 60 Subpart JJJJ			
Federal Register Citation	**Volume**	**Date**	**Notice**
Revision	Vol. 85	December 4, 2020	[85 FR 78412]
Revision	Vol. 86	June 29, 2021	[86 FR 34308]

61-62.63, National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories

Regulation 61-62.63, Subpart A, shall be revised as follows:

Subpart A - "General Provisions"

The provisions of 40 Code of Federal Regulations (CFR) Part 63 Subpart A, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 59	March 16, 1994	[59 FR 12430]
Revision	Vol. 59	April 22, 1994	[59 FR 19453]
Revision	Vol. 59	December 6, 1994	[59 FR 62589]
Revision	Vol. 60	January 25, 1995	[60 FR 4963]
Revision	Vol. 60	June 27, 1995	[60 FR 33122]
Revision	Vol. 60	September 1, 1995	[60 FR 45980]
Revision	Vol. 61	May 21, 1996	[61 FR 25399]
Revision	Vol. 61	December 17, 1996	[61 FR 66227]
Revision	Vol. 62	December 10, 1997	[62 FR 65024]
Revision	Vol. 63	May 4, 1998	[63 FR 24444]
Revision	Vol. 63	May 13, 1998	[63 FR 26465]
Revision	Vol. 63	September 21, 1998	[63 FR 50326]
Revision	Vol. 63	October 7, 1998	[63 FR 53996]
Revision	Vol. 63	December 1, 1998	[63 FR 66061]
Revision	Vol. 64	January 28, 1999	[64 FR 4300]
Revision	Vol. 64	February 12, 1999	[64 FR 7468]
Revision	Vol. 64	April 12, 1999	[64 FR 17562]
Revision	Vol. 64	June 10, 1999	[64 FR 31375]
Revision	Vol. 65	October 17, 2000	[65 FR 61744]
Revision	Vol. 67	February 14, 2002	[67 FR 6968]
Revision	Vol. 67	February 27, 2002	[67 FR 9156]
Revision	Vol. 67	April 5, 2002	[67 FR 16582]
Revision	Vol. 67	June 10, 2002	[67 FR 39794]
Revision	Vol. 67	July 23, 2002	[67 FR 48254]
Revision	Vol. 68	February 18, 2003	[68 FR 7706]
Revision	Vol. 68	April 21, 2003	[68 FR 19375]
Revision	Vol. 68	May 6, 2003	[68 FR 23898]
Revision	Vol. 68	May 8, 2003	[68 FR 24653]

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
Revision	Vol. 68	May 20, 2003	[68 FR 27646]
Revision	Vol. 68	May 23, 2003	[68 FR 28606]
Revision	Vol. 68	May 27, 2003	[68 FR 28774]
Revision	Vol. 68	May 28, 2003	[68 FR 31746]
Revision	Vol. 68	May 29, 2003	[68 FR 32172]
Revision	Vol. 68	May 30, 2003	[68 FR 32586]
Revision	Vol. 68	November 13, 2003	[68 FR 64432]
Revision	Vol. 68	December 19, 2003	[68 FR 70960]
Revision	Vol. 69	January 2, 2004	[69 FR 130]
Revision	Vol. 69	February 3, 2004	[69 FR 5038]
Revision	Vol. 69	April 9, 2004	[69 FR 18801]
Revision	Vol. 69	April 19, 2004	[69 FR 20968]
Revision	Vol. 69	April 22, 2004	[69 FR 21737]
Revision	Vol. 69	April 26, 2004	[69 FR 22602]
Revision	Vol. 69	June 15, 2004	[69 FR 33474]
Revision	Vol. 69	July 30, 2004	[69 FR 45944]
Revision	Vol. 69	September 13, 2004	[69 FR 55218]
Revision	Vol. 70	April 15, 2005	[70 FR 19992]
Revision	Vol. 70	May 20, 2005	[70 FR 29400]
Revision	Vol. 70	October 12, 2005	[70 FR 59402]
Revision	Vol. 71	February 16, 2006	[71 FR 8342]
Revision	Vol. 71	April 20, 2006	[71 FR 20446]
Revision	Vol. 71	July 28, 2006	[71 FR 42898]
Revision	Vol. 71	December 6, 2006	[71 FR 70651]
Revision	Vol. 72	January 3, 2007	[72 FR 26]
Revision	Vol. 72	January 23, 2007	[72 FR 2930]
Revision	Vol. 72	July 16, 2007	[72 FR 38864]
Revision	Vol. 72	October 29, 2007	[72 FR 61060]
Revision	Vol. 72	November 16, 2007	[72 FR 64860]
Revision	Vol. 72	December 26, 2007	[72 FR 73180]
Revision	Vol. 72	December 28, 2007	[72 FR 74088]
Revision	Vol. 73	January 2, 2008	[73 FR 226]
Revision	Vol. 73	January 9, 2008	[73 FR 1738]
Revision	Vol. 73	January 10, 2008	[73 FR 1916]
Revision	Vol. 73	January 18, 2008	[73 FR 3568]
Revision	Vol. 73	February 7, 2008	[73 FR 7210]
Revision	Vol. 73	March 7, 2008	[73 FR 12275]
Revision	Vol. 73	July 23, 2008	[73 FR 42978]
Revision	Vol. 73	December 22, 2008	[73 FR 78199]
Revision	Vol. 74	June 25, 2009	[74 FR 30366]
Revision	Vol. 74	October 28, 2009	[74 FR 55670]
Revision	Vol. 75	September 9, 2010	[75 FR 54970]
Revision	Vol. 75	September 13, 2010	[75 FR 55636]

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
Revision	Vol. 76	February 17, 2011	[76 FR 9450]
Revision	Vol. 77	February 16, 2012	[77 FR 9304]
Revision	Vol. 77	April 17, 2012	[77 FR 22848]
Revision	Vol. 77	September 11, 2012	[77 FR 55698]
Revision	Vol. 78	January 30, 2013	[78 FR 6674]
Revision	Vol. 78	January 31, 2013	[78 FR 7138]
Revision	Vol. 78	February 1, 2013	[78 FR 7488]
Revision	Vol. 78	June 20, 2013	[78 FR 37133]
Revision	Vol. 79	February 27, 2014	[79 FR 11228]
Revision	Vol. 79	March 27, 2014	[79 FR 17340]
Revision	Vol. 80	June 30, 2015	[80 FR 37365]
Revision	Vol. 80	August 19, 2015	[80 FR 50385]
Revision	Vol. 80	September 18, 2015	[80 FR 56699]
Revision	Vol. 80	October 15, 2015	[80 FR 62389]
Revision	Vol. 80	October 26, 2015	[80 FR 65469]
Revision	Vol. 80	December 1, 2015	[80 FR 75178]
Revision	Vol. 80	December 4, 2015	[80 FR 75817]
Revision	Vol. 81	August 30, 2016	[81 FR 59800]
Revision	Vol. 82	January 18, 2017	[82 FR 5401]
Revision	Vol. 82	October 11, 2017	[82 FR 47328]
Revision	Vol. 82	October 16, 2017	[82 FR 48156]
Revision	Vol. 83	October 15, 2018	[83 FR 51842]
Revision	Vol. 83	November 14, 2018	[83 FR 56713]
Revision	Vol. 83	February 28, 2019	[84 FR 6676]
Revision	Vol. 84	March 4, 2019	[84 FR 7682]
Revision	Vol. 84	March 15, 2019	[84 FR 9590]
Revision	Vol. 85	February 25, 2020	[85 FR 10828]
Revision	Vol. 85	March 9, 2020	[85 FR 13524]
Revision	Vol. 85	March 12, 2020	[85 FR 14526]
Revision	Vol. 85	March 26, 2020	[85 FR 17244]
Revision	Vol. 85	July 2, 2020	[85 FR 39980]
Revision	Vol. 85	July 6, 2020	[85 FR 40386]
Revision	Vol. 85	July 7, 2020	[85 FR 40594]
Revision	Vol. 85	July 7, 2020	[85 FR 40740]
Revision	Vol. 85	July 8,2020	[85 FR 41100]
Revision	Vol. 85	July 9, 2020	[85 FR 41276]
Revision	Vol. 85	July 10, 2020	[85 FR 41411]
Revision	Vol. 85	July 10, 2020	[85 FR 41680]
Revision	Vol. 85	July 13, 2020	[85 FR 42074]
Revision	Vol. 85	July 22, 2020	[85 FR 44216]
Revision	Vol. 85	July 24, 2020	[85 FR 44960]
Revision	Vol. 85	July 28, 2020	[85 FR 45476]
Revision	Vol. 85	August 12, 2020	[85 FR 49084]

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
Revision	Vol. 85	August 13, 2020	[85 FR 49434]
Revision	Vol. 85	August 14, 2020	[85 FR 49724]
Revision	Vol. 85	October 7, 2020	[85 FR 63394]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	March 11, 2021	[86 FR 13819]
Revision	Vol. 86	November 19, 2021	[86 FR 66038]
Revision	Vol. 86	November 19, 2021	[86 FR 66045]
Revision	Vol. 86	November 19, 2021	[86 FR 66096]

Regulation 61-62.63, Subpart YY, shall be revised as follows:

Subpart YY - "National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards"

The provisions of 40 CFR Part 63 Subpart YY, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart YY			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 64	June 29, 1999	[64 FR 34854]
Revision	Vol. 64	November 22, 1999	[64 FR 63695]
Revision	Vol. 64	December 22, 1999	[64 FR 71852]
Revision	Vol. 66	November 2, 2001	[66 FR 55844]
Revision	Vol. 67	June 7, 2002	[67 FR 39301]
Revision	Vol. 67	July 12, 2002	[67 FR 46258, 46289]
Revision	Vol. 68	February 10, 2003	[68 FR 6635]
Revision	Vol. 70	April 13, 2005	[70 FR 19266]
Revision	Vol. 71	April 20, 2006	[71 FR 20446]
Revision	Vol. 72	June 29, 2007	[72 FR 35663]
Revision	Vol. 79	October 8, 2014	[79 FR 60898]
Revision	Vol. 85	July 6, 2020	[85 FR 40386]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 19, 2021	[86 FR 66096]

Regulation 61-62.63, Subpart IIII, shall be revised as follows:

Subpart IIII - "National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks"

The provisions of 40 CFR Part 63 Subpart IIII, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart IIII			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 69	April 26, 2004	[69 FR 22602]
Revision	Vol. 71	April 20, 2006	[71 FR 20446]
Revision	Vol. 71	December 22, 2006	[71 FR 76922]
Revision	Vol. 72	April 24, 2007	[72 FR 20227]
Revision	Vol. 85	July 8, 2020	[85 FR 41100]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 19, 2021	[86 FR 66038]

Regulation 61-62.63, Subpart KKKK, shall be revised as follows:

Subpart KKKK - "National Emission Standards for Hazardous Air Pollutants: Surface Coating of Metal Cans"

The provisions of 40 CFR Part 63 Subpart KKKK, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart KKKK			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 68	November 12, 2003	[68 FR 64432]
Revision	Vol. 71	January 6, 2006	[71 FR 1378]
Revision	Vol. 71	April 20, 2006	[71 FR 20446]
Revision	Vol. 85	February 25, 2020	[85 FR 10828]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 19, 2021	[86 FR 66038]

Regulation 61-62.63, Subpart VVVV, shall be revised as follows:

Subpart VVVV - "National Emission Standards for Hazardous Air Pollutants for Boat Manufacturing"

The provisions of 40 CFR Part 63 Subpart VVVV, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart VVVV			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 66	August 22, 2001	[66 FR 44218]
Revision	Vol. 66	October 3, 2001	[66 FR 50504]
Revision	Vol. 85	March 20, 2020	[85 FR 15960]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 19, 2021	[86 FR 66038]

Regulation 61-62.63, Subpart KKKKK, shall be revised as follows:

Subpart KKKKK - "National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing"

The provisions of 40 CFR Part 63, Subpart KKKKK, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart KKKKK			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 68	May 16, 2003	[67 FR 26690]
Revision	Vol. 68	May 28, 2003	[68 FR 31744]
Revision	Vol. 71	April 20, 2006	[71 FR 20445]
Revision	Vol. 71	June 23, 2006	[71 FR 36014]
Revision	Vol. 80	October 26, 2015	[80 FR 65469]
Revision	Vol. 80	December 4, 2015	[80 FR 75817]
Revision	Vol. 84	November 1, 2019	[84 FR 58601]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 19, 2021	[86 FR 66038]

Regulation 61-62.63, Subpart MMMMM, shall be revised as follows:

Subpart MMMMM - "National Emission Standards for Hazardous Air Pollutants: Flexible Polyurethane Foam Fabrication Operations"

The provisions of 40 CFR Part 63 Subpart MMMMM, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart MMMMM			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 68	April 14, 2003	[68 FR 18062]
Revision	Vol. 71	April 20, 2006	[71 FR 20446]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 18, 2021	[86 FR 64385]

Regulation 61-62.63, Subpart SSSSS, shall be revised as follows:

Subpart SSSSS - "National Emission Standards for Hazardous Air Pollutants for Refractory Products Manufacturing"

The provisions of 40 CFR Part 63 Subpart SSSSS, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart SSSSS			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 68	April 16, 2003	[68 FR 18730]
Revision	Vol. 71	February 13, 2006	[71 FR 7415]

40 CFR Part 63 Subpart SSSSS			
Federal Register Citation	**Volume**	**Date**	**Notice**
Revision	Vol. 71	April 14, 2006	[71 FR 19435]
Revision	Vol. 71	April 20, 2006	[71 FR 20446]
Revision	Vol. 85	November 19, 2020	[85 FR 73854]
Revision	Vol. 86	November 19, 2021	[86 FR 66045]

Regulation 61-62.63, Subpart OOOOOO, shall be revised as follows:

Subpart OOOOOO - "National Emission Standards for Hazardous Air Pollutants for Flexible Polyurethane Foam Production and Fabrication Area Sources"

The provisions of 40 CFR Part 63 Subpart OOOOOO, as originally published in the Federal Register and as subsequently amended upon publication in the Federal Register as listed below, are incorporated by reference as if fully repeated herein.

40 CFR Part 63 Subpart OOOOOO			
Federal Register Citation	**Volume**	**Date**	**Notice**
Original Promulgation	Vol. 72	July 16, 2007	[72 FR 38864]
Revision	Vol. 73	March 26, 2008	[73 FR 15923]
Revision	Vol. 86	November 18, 2021	[86 FR 64385]

61-62.70, Title V Operating Permit Program.

Regulation 61-62.70.5 (c), shall be revised as follows:

(c) Standard application form and required information. Information as described below for each emissions unit at a Part 70 source shall be included in a Department-approved application. Air emissions or air emission units that are insignificant are exempted. However, for these emission units which are exempted, a list of the emission units must be included in the application. "Insignificant Activity" generally means any air emissions or air emissions unit at a plant that has the potential to emit less than five tons per year (5 tpy) of any criteria pollutant or less than ~~1000~~one thousand pounds (1000 lbs) per ~~month~~ year of any compound listed in Regulation 61--62.5, Standard No. 8, Toxic Air Pollutants. The Department may determine that certain types or classes of units may be considered insignificant at higher emission levels, or that, due to the nature of the pollutant(s) emitted, a unit may be considered significant at a lower emission rate. The Department shall maintain a list subject to EPA approval of air emissions or air emission units which are considered to be insignificant. No emission or activity can be excluded from a Title V operating permit to the extent it is needed to determine compliance with an applicable requirement, as defined under Section 70.2(f). An application may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate the fee amount required under the schedule approved pursuant to Section 70.9. The Department-approved forms and attachments shall include the elements specified below:

ATTACHMENT B

STATE ETHICS COMMISSION

CHAPTER 52

Statutory Authority: 1976 Code Sections 8-13-320, 8-13-1110, 8-13-1140, 8-13-1306, and 8-13-1356

Notice of Drafting:

The State Ethics Commission proposes to amend Regulations 52-601 and 52-607 to delete language related to paper filing and to replace outdated filing deadlines with those required by statute. Interested parties may submit comments to Meghan L. Walker, Executive Director, State Ethics Commission, 201 Executive Drive, Suite 150, Columbia, S.C. 29210 by 5 p.m. on July 25, 2022.

Synopsis:

The State Ethics Commission proposes to amend Regulations 52-601 and 52-607 regarding Commission filings, to include updating language to reflect the statutorily mandated electronic filing system and to delete language referring to paper filing.

Legislative review of this amendment is required.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Sections 48-1-10 et seq.

Notice of Drafting:

The Department of Health and Environmental Control (Department) proposes amending R.61-62, Air Pollution Control Regulations and Standards. Interested persons may submit comments on the proposed amendments to Holly Randolph of the Air Regulation and SIP Management Section, Bureau of Air Quality; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; or via email at randolhk@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on July 25, 2022, the close of the Notice of Drafting comment period.

Synopsis:

The United States Environmental Protection Agency (EPA) promulgates amendments to the Code of Federal Regulations (CFR) throughout each calendar year. Recent federal amendments at 40 CFR Parts 60 and 63 include revisions to New Source Performance Standards (NSPS) and Emission Guidelines, and revisions to National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department proposes amending R.61-62.60, South Carolina Designated Facility Plan and New Source Performance Standards, and R.61-62.63, National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories, to incorporate by reference federal amendments promulgated from January 1, 2021, through December 31, 2021.

The Department also proposes amending R.61-62.70, Title V Operating Permit Program, at 70.5(c), to correct an error in an earlier amendment as required by the EPA to maintain compliance with federal law.

The Department may also propose other changes to R.61-62, Air Pollution Control Regulations and Standards, as deemed necessary to maintain compliance with federal law. These changes may include corrections or other changes for internal consistency, clarification, reference, punctuation, codification, formatting, spelling, and overall improvement to the text of R.61-62.

18 DRAFTING NOTICES

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.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-340

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-15, *Certification of Need for Health Facilities and Services*. Interested persons may submit written comments to the Office of Policy and Communications, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Healthcare Quality Public Comment Form at https://forms.office.com/g/9VMEXLWtq0. To be considered, the Department must receive comments no later than 5:00 p.m. on July 25, 2022, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to S.C. Code Sections 44-7-110 through 44-7-340, the Department promulgates substantive and procedural regulations considered necessary by the Department and approved by the S.C. Board of Health and Environmental Control to carry out the Department's Certificate of Need duties. The Department proposes amending R.61-15 for consistency with statutory requirements, to enable an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing, and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. The amendments may also revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review.

The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 48-1-10 et seq.

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-9, Water Pollution Control Permits. Interested persons may submit comment(s) on the proposed amendments to Crystal Rippy of the Bureau of Water; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; rippycd@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on July 25, 2022, the close of the Notice of Drafting comment period.

Synopsis:

(x) ACTION/DECISION
( ) INFORMATION

Date: September 8, 2022

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

From: Bureau of Water

Re: Notice of Proposed Regulation Amending R.61-58, State Primary Drinking Water Regulations.

I. Introduction

The Bureau of Water proposes the attached Notice of Proposed Regulation amending R.61-58, State Primary Drinking Water Regulations, for publication in the September 23, 2022, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-55-10 et seq., known as the State Safe Drinking Water Act, and which directs the Department of Health and Environmental Control ("Department") to promulgate regulations governing the design, construction, operation, and maintenance of public water systems in the 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.

II. Facts

1. R.61-58 through R.61-58.17 are collectively known as the State Primary Drinking Water Regulations. These regulations set design, construction, operation, maintenance, and water quality standards for public water systems in the state. The Department proposes amending R.61-58 to adopt federal regulations commonly referred to as the Lead and Copper Rule Revisions, which were promulgated by the United States Environmental Protection Agency ("EPA") in a final rule published in the *Federal Register* on January 15, 2021 (86 FR 4198). These amendments include new and/or revised requirements for lead service line inventories, public education and outreach, and testing for lead in drinking water at schools and child care facilities.

2. The Department had a Notice of Drafting published in the March 25, 2022, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department did not receive any public comments during the public comment period that closed on April 25, 2022.

3. On March 31, 2022, Department staff sent an email notification to all public water systems subject to these amendments outlining the requirements of the amendments and other pertinent information along with an attached copy of the Notice of Drafting.

4. Appropriate Department staff conducted an internal review of the proposed amendments August 17, 2022.

III. Request for Approval

The Bureau of Water respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 23, 2022, *State Register*.

Jennifer R. Hughes
Bureau Chief, Bureau of Water

Myra C. Reece
Director of Environmental Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the March 25, 2022, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-58, State Primary Drinking Water Regulations

September 8, 2022

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-55-10 et seq.

61-58. State Primary Drinking Water Regulations.

Preamble:

Pursuant to 1976 Code Sections 44-55-10 et seq., the Department of Health and Environmental Control ("Department") proposes to amend R.61-58 to adopt federal regulations commonly referred to as the Lead and Copper Rule Revisions. These amendments were promulgated by the United States Environmental Protection Agency ("EPA") in a final rule published in the *Federal Register* on January 15, 2021 (86 FR 4198). As proposed, the amendments will revise many aspects of the current regulations with respect to requirements for public water systems to monitor for lead and copper in drinking water, including requirements pertaining to sample site selection, monitoring procedures, corrosion control, and public education. In addition, these proposed amendments require public water systems to offer to sample lead in drinking water for schools and child care facilities in their service areas. The Department also proposes other changes to R.61-58 as deemed necessary to maintain compliance with federal law and improve the overall text of R.61-58, including corrections or other changes for internal consistency, clarification, reference, punctuation, codification, formatting, and spelling.

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 March 25, 2022, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
R.61-58.B	Addition, Revision, Reorganization	Adds several definitions and revises others to match federal amendments. Definitions recodified to reflect proposed amendments.
R.61-58.6.B	Addition	Adds requirements for public notification when the lead action level is exceeded.
R.61-58.6.E	Addition	Adds exceeding the lead action level to the list of violations or other situations requiring Tier 1 public notice and requires notice to the EPA Administrator.
Appendix A to R.61-58.6	Revision	Updates citations for lead and copper action level exceedances.

Appendix B to R.61-58.6	Revision	Revises health effects language for lead and revises health effects language related to the Revised Total Coliform Rule to correct errors in previous amendments to make the language consistent with federal regulations.
R.61-58.11.B	Revision	Revises general requirements for lead and copper in drinking water.
R.61-58.11.C	Revision	Revises the applicability of corrosion control treatment steps to small, medium-size, and large water systems.
R.61-58.11.D	Revision	Revises the description of corrosion control treatment requirements.
R.61-58.11.E	Revision	Revises treatment requirements for lead in source water.
R.61-58.11.F	Revision	Revises lead service line inventory and replacement requirements.
R.61-58.11.G	Revision	Revises lead and copper public education and supplemental monitoring and mitigation requirements.
R.61-58.11.H	Revision	Revises monitoring requirements for lead and copper in tap water.
R.61-58.11.I	Revision	Revises monitoring requirements for water quality parameters.
R.61-58.11.J	Revision	Revises monitoring requirements for lead and copper in source water.
R.61-58.11.K	Revision	Revises lead and copper analytical methods requirements.
R.61-58.11.L	Revision	Revises reporting requirements for lead and copper.
R.61-58.11.M	Revision	Revises recordkeeping requirements for lead and copper data.
R.61-58.11.N	Addition	Adds requirements for public water systems to offer to monitor lead in drinking water for schools in their service areas.
R.61-58.11.O	Addition	Adds small water system compliance flexibility for lead in drinking water.
R.61-58.12.C	Addition	Adds requirements to include instructions to access lead service line inventory and lead tap sampling results to a public

		water system's annual Consumer Confidence Report.
R.61-58.12.D	Revision	Revises the public health information language for lead that is to be included in a public water system's annual Consumer Confidence Report.
Appendix D. Consumer Confidence Reports: Regulated Contaminants	Revision	Revise the lead health effects language required in a public water system's annual Consumer Confidence Report
R.61-58.16.D	Revision	Revises the requirement for evaluation of the treatment component during a sanitary survey for ground water systems to include corrosion control treatment and water quality parameters as applicable.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Doug Kinard of the Bureau of Water; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; kinarddb@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 24, 2022, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 8, 2022, 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. 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. Public hearing procedures are subject to change in response to COVID-19 protocols. If applicable, the Department will provide notice of these changes twenty-four (24) hours in advance of the public hearing.

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: R.61-58, State Primary Drinking Water Regulations

Purpose: The Department proposes amending R.61-58 to adopt federal regulations commonly referred to as the Lead and Copper Rule Revisions to maintain compliance with federal regulations and maintain primary enforcement authority for the Safe Drinking Water Act in the state.

NPR_R.61-58 – Draft Board Script

This is a notice of proposed regulation to amend regulation 61-58, State Primary Drinking Water Regulations to adopt the federal regulation commonly referred to as the Lead and Copper Rule Revisions which were promulgated by the United States Environmental Protection Agency ("EPA") in a final rule published in the *Federal Register* on January 15, 2021. These amendments include new and/or revised requirements for lead service line inventories, public education and outreach, and testing for lead in drinking water at schools and child care facilities. The primary goal of this amendment is to enhance public health protection by reducing the public exposure lead in drinking water.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 8, 2022

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

From: Bureau of Water

Re: Notice of Proposed Regulation Amending R.61-9, Water Pollution Control Permits

I. Introduction

The Bureau of Water ("Bureau") proposes the attached Notice of Proposed Regulation amending R.61-9, *Water Pollution Control Permits*, for publication in the September 23, 2022, *South Carolina State Register* ("*State Register*"). Legal authority resides in the South Carolina Pollution Control Act, S.C. Code Ann. 48-1-10 et seq., which authorizes the Department of Health and Environmental Control ("Department") to establish programs to regulate discharges from point sources, including concentrated animal feeding operations. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts this amendment from General Assembly review, as the Department proposes amendment for compliance with federal law.

II. Facts

1. Regulation 61-9.122.23, Concentrated Animal Feeding Operations (CAFOs), provides the definition of a CAFO and provides the National Discharge Pollution Elimination System (NPDES) permitting requirements for CAFOs. The Department proposes amending R.61-9.122.23 to maintain consistency with the current federal regulation in Title 40, Part 122 of the Code of Federal Regulations (40 CFR Part 122), Subpart B, Section 23, *Concentrated animal feeding operations*.

2. The Department had a Notice of Drafting published in the July 22, 2022, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from one group on behalf of several groups by the August 22, 2022, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

3. The Bureau provided notice to interested parties via an email list on July 22, 2022.

4. Appropriate Department staff conducted an internal review of the proposed amendments on August 4, 2022.

III. Request for Approval

The Bureau respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 23, 2022, *State Register*.

Jennifer R. Hughes
Bureau Chief, Bureau of Water

Myra Reece
Director, Environmental Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the July 22, 2022, *State Register*
C. Summary of Public Comments Received and Department Responses
D. Southern Environmental Law Center Comment Letter, August 25, 2022

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-9, WATER POLLUTION CONTROL PERMITS

September 8, 2022

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 48-1-10 et seq.

61-9. Water Pollution Control Permits.

Preamble:

Pursuant to the South Carolina Pollution Control Act, S.C. Code Ann. 48-1-10 et seq., the Department of Health and Environmental Control ("Department") establishes programs to regulate discharges from point sources, including concentrated animal feeding operations. The Department proposes amending R.61-9.122.23, Concentrated Animal Feeding Operations, for conformity with the current federal regulation in Title 40, Part 122 of the Code of Federal Regulations (40 CFR Part 122), Subpart B, Section 23, *Concentrated animal feeding operations*. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts this amendment from General Assembly review, as the Department proposes this amendment for compliance with federal law.

The Department had a Notice of Drafting published in the July 22, 2022, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	**Type of Change**	**Purpose**
(a)	Revision	Amended to clarify references, permitting requirements, and feeding operations.
(b)(1)	Revision Reorganization	Amended for clarity; recodified items.
(b)(2)	Reorganization	Amended to add recodified (a)(1)(ii).
(b)(4)	Technical Correction	Amended to correct punctuation.
(b)(6)	Technical Correction	Amended to correct punctuation.
(b)(6)(ii)	Revision	Amended to clarify U.S. waters.
(b)(8)	Technical Correction	Amended to correct spelling.
(b)(9)	Technical Correction	Amended to correct punctuation and grammar.
(c)(1)	Revision Addition	Amended for clarity.
(c)(2)	Revision	Amended to clarify U.S. waters.
(c)(3)	Revision Technical Correction	Amended to clarify U.S. waters and to correct punctuation.
(d)(1)-(2)	Revision	Amended to comply with federal law.

(e)	Revision	Amended to clarify U.S. waters.
(e)(1)-(2)	Addition	Added to comply with federal law.
(f)-(h)	Deleted	Deleted to replace with current federal law.
New (f)	Addition	Added permit coverage requirement to comply with federal law.
New (g)	Addition	Added as reserved to comply with federal law.
New (h)	Addition	Added procedures for permit coverage to comply with federal law.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendment to Joseph M. Koon of the Bureau of Water; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; koonjm@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 24, 2022, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendment during its December 8, 2022, 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. 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. Public hearing procedures are subject to change in response to COVID-19 protocols. If applicable, the Department will provide notice of these changes twenty-four (24) hours in advance of the public hearing.

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: R.61-9.122.23, Concentrated Animal Feeding Operations

Purpose: The Department proposes amending R.61-9.122.23, Concentrated Animal Feeding Operations, to maintain consistency with the federal regulation at 40 CFR Section 122.23.

Legal Authority: 1976 Code Sections 48-1-10 et seq.

Plan for Implementation: The proposed amendment will take legal effect upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the

amendment. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, 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 Department proposes to amend R.61-9.122.23 to maintain consistency with federal regulations and to improve regulatory clarity.

DETERMINATION OF COSTS AND BENEFITS:

Amending R.61-9.122.23 for consistency with federal regulations will increase the efficiency of processing facility applications, which will be a benefit to the regulated community and the state. There is no anticipated increase in costs to the state or its political subdivisions, or to the regulated community, resulting from these proposed revisions. It is anticipated that these proposed revisions will result in cost savings to the regulated community.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the state or its political subdivisions.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed revisions to R.61-9.122 will provide continued protection of the environment and human health in accordance with updates to federal law.

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

There is no anticipated detrimental effect on the environment and public health if the regulation is not implemented. Adoption of these proposed revisions will ensure consistency with federal requirements and provide continued protection of the environment and human health in accordance with updates to federal law.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-9.122. The National Pollutant Discharge Elimination System.

Statutory Authority: Sections 48-1-10 et seq. and Sections 48-14-10 et seq.

Amend R.61-9.122.23, Concentrated animal feeding operations, to read:

122.23. Concentrated animal feeding operations.

(a) ~~Permit requirement for CAFO~~ Scope. Concentrated animal feeding operations (CAFOs), as defined in paragraph (b) of this section or designated in accordance with paragraph (c) of this section, are point sources ~~that require NPDES permits for discharges or potential discharges~~, subject to NPDES permitting

requirements as provided in this section. Once an animal feeding operation is defined as a CAFO for at least one type of animal, the NPDES requirements for CAFOs apply with respect to all animals in confinement at the operation and all manure, litter, and process wastewater generated by those animals or the production of those animals, regardless of the type of animal.

(b) Definitions applicable to this section:

(1) "Animal feeding operation (AFO)" means a lot or facility (other than an aquatic animal production facility) where the following conditions are met:

~~(i) where the following conditions are met:~~

~~(A)~~(i) Animals (other than aquatic animals) have been, are, or will be stabled or confined and fed or maintained for a total of forty-five (45) days or more in any twelve (12)-month period, and

~~(B)~~(ii) Crops, vegetation, forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility.

~~(ii) Two or more AFO under common ownership are considered to be a single AFO for the purposes of determining the number of animals at an operation if they adjoin each other or if they use a common area or system for the disposal of wastes.~~

(2) "Concentrated animal feeding operation (CAFO)" means an AFO that is defined as a Large CAFO or as a Medium CAFO by the terms of this paragraph, or that is designated as a CAFO in accordance with paragraph (c) of this section. Two or more AFOs under common ownership are considered to be a single AFO for the purposes of determining the number of animals at an operation, if they adjoin each other or if they use a common area or system for the disposal of wastes.

(3) The term "land application area" means land under the control of an AFO owner or operator, whether it is owned, rented, or leased, to which manure, litter, or process wastewater from the production area is or may be applied.

(4) "Large concentrated animal feeding operation (Large CAFO)."~~:~~ An AFO is defined as a Large CAFO if it stables or confines as many as or more than the numbers of animals specified in any of the following categories:

(i) 700 mature dairy cows, whether milked or dry;

(ii) 1,000 veal calves;

(iii) 1,000 cattle other than mature dairy cows or veal calves. The term cattle includes but is not limited to heifers, steers, bulls, and cow/calf pairs;

(iv) 2,500 swine, each weighing ~~55~~fifty-five pounds (55 lbs) or more;

(v) 10,000 swine, each weighing less than ~~55~~fifty-five pounds (55 lbs);

(vi) 500 horses;

(vii) 10,000 sheep or lambs;

(viii) 55,000 turkeys;

(ix) 30,000 laying hens or broilers, if the AFO uses a liquid manure handling system;

(x) 125,000 chickens (other than laying hens), if the AFO uses other than a liquid manure handling system;

(xi) 82,000 laying hens, if the AFO uses other than a liquid manure handling system;

(xii) 30,000 ducks, if the AFO uses other than a liquid manure handling system; or

(xiii) 5,000 ducks, if the AFO uses a liquid manure handling system.

(5) The term "manure" is defined to include manure, bedding, compost, and raw materials or other materials commingled with manure or set aside for disposal.

(6) "Medium concentrated animal feeding operation (Medium CAFO)." The term Medium CAFO includes any AFO with the type and number of animals that fall within any of the ranges listed in paragraph (b)(6)(i) of this section and which has been defined or designated as a CAFO. An AFO is defined as a Medium CAFO if:

(i) The type and number of animals that it stables or confines falls within any of the following ranges:

(A) 200 to 699 mature dairy cows, whether milked or dry;

(B) 300 to 999 veal calves;

(C) 300 to 999 cattle other than mature dairy cows or veal calves. The term cattle includes, but is not limited to, heifers, steers, bulls, and cow/calf pairs;

(D) 750 to 2,499 swine each weighing ~~55~~fifty-five pounds (55 lbs) or more;

(E) 3,000 to 9,999 swine each weighing less than ~~55~~fifty-five pounds (55 lbs);

(F) 150 to 499 horses;

(G) 3,000 to 9,999 sheep or lambs;

(H) 16,500 to 54,999 turkeys;

(I) 9,000 to 29,999 laying hens or broilers, if the AFO uses a liquid manure handling system;

(J) 37,500 to 124,999 chickens (other than laying hens), if the AFO uses other than a liquid manure handling system;

(K) 25,000 to 81,999 laying hens, if the AFO uses other than a liquid manure handling system;

(L) 10,000 to 29,999 ducks, if the AFO uses other than a liquid manure handling system; or

(M) 1,500 to 4,999 ducks, if the AFO uses a liquid manure handling system; and

(ii) Either one of the following conditions is met:

(A) Pollutants are discharged into waters of the United States through a man-made ditch, flushing system, or other similar man-made device; or

(B) Pollutants are discharged directly into waters of the United States which originate outside of ~~the facility~~ and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.

(7) "Process wastewater" means water directly or indirectly used in the operation of the AFO for any or all of the following: spillage or overflow from animal or poultry watering systems; washing, cleaning, or flushing pens, barns, manure pits, or other AFO facilities; direct contact swimming, washing, or spray cooling of animals; or dust control. Process wastewater also includes any water which comes into contact with any raw materials, products, or byproducts including manure, litter, feed, milk, eggs, or bedding.

(8) "Production area" means that part of an AFO that includes the animal confinement area, the manure storage area, the raw materials storage area, and the waste containment areas. The animal confinement area includes but is not limited to open lots, housed lots, feedlots, confinement houses, stall barns, free stall barns, ~~milk rooms~~ milkrooms, milking centers, cowyards, barnyards, medication pens, walkers, animal walkways, and stables. The manure storage area includes but is not limited to lagoons, runoff ponds, storage sheds, stockpiles, under-house or pit storages, liquid impoundments, static piles, and composting piles. The raw materials storage area includes but is not limited to feed silos, silage bunkers, and bedding materials. The waste containment area includes but is not limited to settling basins, and areas within berms and diversions which separate uncontaminated storm water. Also included in the definition of production area is any egg washing or egg processing facility, and any area used in the storage, handling, treatment, or disposal of mortalities.

(9) "Small concentrated animal feeding operation (Small CAFO)." ~~.~~ An AFO that is designated as a CAFO and ~~that~~ is not a Medium CAFO.

(c) How may an AFO be designated as a CAFO? The appropriate authority (i.e., the Department or Regional Administrator, or both, as specified in paragraph (c)(1) of this section) may designate any AFO as a CAFO upon determining that it is a significant contributor of pollutants to waters of the United States.

(1) Who may designate? ~~In South Carolina, CAFO d~~Designations may be made by the Department. The Regional Administrator may also designate CAFOs ~~in South Carolina~~ but only where the Regional Administrator has determined that one or more pollutants in the AFO's discharge contributes to an impairment in a downstream or adjacent state or Indian country water that is impaired for that pollutant.

(2) In making this designation, the Department or the Regional Administrator shall consider the following factors:

(i) The size of the AFO and the amount of wastes reaching waters of the United States;

(ii) The location of the AFO relative to waters of the United States;

(iii) The means of conveyance of animal wastes and process wastewaters into waters of the United States;

(iv) The slope, vegetation, rainfall, and other factors affecting the likelihood or frequency of discharge of animal wastes, manure, and process ~~waste waters~~ wastewaters into waters of the United States; and

(v) Other relevant factors.

(3) No AFO shall be designated under this paragraph unless the Department or the Regional Administrator has conducted an on-site inspection of the operation and determined that the operation should and could be regulated under the permit program. In addition, no AFO with numbers of animals below those established in paragraph (b)(6) of this section may be designated as a CAFO unless:

(i) Pollutants are discharged into waters of the United States through a manmade ditch, flushing system, or other similar man-made device; or

(ii) Pollutants are discharged directly into waters of the United States which originate outside of the facility and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.

(d) ~~Who must seek coverage under an NPDES permit?~~ NPDES permit authorization –

(1) ~~All CAFO owners or operators must apply for a permit. All CAFO owners or operators must seek coverage under an NPDES permit, except as provided in paragraph (d)(2) of this section. Specifically, the CAFO owner or operator must either apply for an individual NPDES permit or submit a notice of intent for coverage under an NPDES general permit. If the Department has not made a general permit available to the CAFO, the CAFO owner or operator must submit an application for an individual permit to the Department.~~ Permit Requirement. A CAFO must not discharge unless the discharge is authorized by an NPDES permit. In order to obtain authorization under an NPDES permit, the CAFO owner or operator must either apply for an individual NPDES permit or submit a notice of intent for coverage under an NPDES general permit.

(2) ~~Exception. An owner or operator of a Large CAFO need not seek coverage under an NPDES permit otherwise required by this section once the owner or operator has received from the Department notification of a determination under paragraph (f) of this section that the CAFO has "no potential to discharge" manure, litter, or process wastewater.~~ Information to submit with permit application or notice of intent. An application for an individual permit must include the information specified in section 122.21. A notice of intent for a general permit must include the information specified in sections 122.21 and 122.28.

(3) Information to submit with permit application. A permit application for an individual permit must include the information specified in section 122.21. A notice of intent for a general permit must include the information specified in sections 122.21 and 122.28.

(e) Land application discharges from a CAFO are subject to NPDES requirements. The discharge of manure, litter, or process wastewater to waters of the United States from a CAFO as a result of the application of that manure, litter, or process wastewater by the CAFO to land areas under its control is a discharge from that CAFO subject to NPDES permit requirements, except where it is an agricultural ~~storm water~~ stormwater discharge as provided in 33 U.S.C. 1362(14). For purposes of this paragraph, where the manure, litter, or process wastewater has been applied in accordance with site-specific nutrient management practices that ensure appropriate agricultural utilization of the nutrients in the manure, litter, or process wastewater, as specified in section 122.42(e)(1)(vi) through (ix), a precipitation-related discharge of manure, litter, or process wastewater from land areas under the control of a CAFO is an agricultural ~~storm water~~ stormwater discharge.

(1) For unpermitted Large CAFOs, a precipitation-related discharge of manure, litter, or process wastewater from land areas under the control of a CAFO shall be considered an agricultural stormwater discharge only where the manure, litter, or process wastewater has been land applied in accordance with site-specific nutrient management practices that ensure appropriate agricultural utilization of the nutrients in the manure, litter, or process wastewater, as specified in section 122.42(e)(1)(vi) through (ix).

(2) Unpermitted Large CAFOs must maintain documentation specified in section 122.42(e)(1)(ix) either on site or at a nearby office, or otherwise make such documentation readily available to the Department or Regional Administrator upon request.

~~(f) "No potential to discharge" determinations for Large CAFO.~~

~~(1) Determination by the Department. The Department, upon request, may make a case-specific determination that a Large CAFO has "no potential to discharge" pollutants to waters of the State. In making this determination, the Department must consider the potential for discharges from both the production area and any land application areas. The Department must also consider any record of prior discharges by the CAFO. In no case may the CAFO be determined to have "no potential to discharge" if it has had a discharge within the 5 years prior to the date of the request submitted under paragraph (f)(2) of this section. For purposes of this section, the term "no potential to discharge" means that there is no potential for any CAFO manure, litter, or process wastewater to be added to waters of the State under any circumstance or climatic condition. A determination that there is "no potential to discharge" for purposes of this section only relates to discharges of manure, litter, and process wastewater covered by this section.~~

~~(2) Information to support a "no potential to discharge" request. In requesting a determination of "no potential to discharge", the CAFO owner or operator must submit any information that would support such a determination, within the time frame provided by the Department and in accordance with paragraphs (g) and (h) of this section. Such information must include all of the information specified in sections 122.21(f) and (i)(1)(i) through (ix). The Department has discretion to require additional information to supplement the request and may also gather additional information through on-site inspection of the CAFO.~~

~~(3) Process for making a "no potential to discharge" determination. Before making a final decision to grant a "no potential to discharge" determination, the Department must issue a notice to the public stating that a "no potential to discharge" request has been received. This notice must be accompanied by a fact sheet which includes, when applicable, a brief description of the type of facility or activity which is the subject of the "no potential to discharge" determination; a brief summary of the factual basis upon which the request is based for granting the "no potential to discharge" determination; and a description of the procedures for reaching a final decision on the "no potential to discharge" determination. The Department must base the decision to grant a "no potential to discharge" determination on the administrative record, which shall include all information submitted in support of a "no potential to discharge" determination and any other supporting data gathered by the permitting authority. The Department must notify any CAFO seeking a "no potential to discharge" determination of its final determination within 90 days of receiving the request.~~

~~(4) What is the deadline for requesting a "no potential to discharge" determination? The owner or operator must request a "no potential to discharge" determination by the applicable permit application date specified in paragraph (g) of this section. If the Department's final decision is to deny the "no potential to discharge" determination, the owner or operator must seek coverage under a permit within 30 days after the denial.~~

~~(5) The "no potential to discharge" determination does not relieve the CAFO from the consequences of an actual discharge. Any unpermitted CAFO that discharges pollutants into the waters of the State is in~~

violation of the Clean Water Act and PCA even if it has received a "no potential to discharge" determination from the Department. Any CAFO that has received a determination of "no potential to discharge", but who anticipates changes in circumstances that could create the potential for a discharge, should contact the Department and apply for and obtain permit authorization prior to the change of circumstances.

(6) The Department retains authority to require a permit. Where the Department has issued a determination of "no potential to discharge", the Department retains the authority to subsequently require NPDES permit coverage if circumstances at the facility change, if new information becomes available, or if there is another reason for the Department to determine that the CAFO has a potential to discharge.

(g) When must a CAFO seek coverage under an NPDES permit?

(1) Operations defined as CAFO prior to the effective date of this regulation. For operations that are defined as CAFO under regulations that are in effect prior to the effective date of this regulation, the owner or operator must have or seek to obtain coverage under an NPDES permit as of the effective date of this regulation and comply with all applicable NPDES requirements, including the duty to maintain permit coverage in accordance with paragraph (h) of this section.

(2) Operations defined as CAFO as of the effective date of this regulation, who were not defined as CAFO prior to that date. For all CAFO, the owner or operator of the CAFO must seek to obtain coverage under an NPDES permit by a date specified by the Department, but no later than February 13, 2006.

(3) Operations that become defined as CAFO after the effective date of this regulation, but which are not new sources. For newly constructed AFO and AFO that make changes to their operations that result in becoming defined as CAFO for the first time, after the effective date of this regulation, but that are not new sources, the owner or operator must seek to obtain coverage under an NPDES permit, as follows:

(i) For newly constructed operations not subject to effluent limitations guidelines, 180 days prior to the time CAFO commences operation or

(ii) For other operations (e.g., resulting from an increase in the number of animals), as soon as possible, but no later than 90 days after becoming defined as a CAFO; except that

(iii) If an operational change that makes the operation a CAFO would not have made it a CAFO prior to the effective date of this regulation, the operation has until April 13, 2006, or 90 days after becoming defined as a CAFO, whichever is later.

(4) New sources. New sources must seek to obtain coverage under a permit at least 180 days prior to the time that the CAFO commences operation.

(5) Operations that are designated as CAFO. For operations designated as a CAFO in accordance with paragraph (c) of this section, the owner or operator must seek to obtain coverage under a permit no later than 90 days after receiving notice of the designation.

(6) No potential to discharge. Notwithstanding any other provision of this section, a CAFO that has received a "no potential to discharge" determination in accordance with paragraph (f) of this section is not required to seek coverage under an NPDES permit that would otherwise be required by this section. If circumstances materially change at a CAFO that has received a NPTD determination, such that the CAFO has a potential for a discharge, the CAFO has a duty to immediately notify the Department and seek coverage under an NPDES permit within 30 days after the change in circumstances.

~~(h) Duty to Maintain Permit Coverage. No later than 180 days before the expiration of the permit, the permittee must submit an application to renew its permit in accordance with section 122.21(g). However, the permittee need not continue to seek continued permit coverage or reapply for a permit if:~~

~~(1) The facility has ceased operation or is no longer a CAFO and~~

~~(2) The permittee has demonstrated to the satisfaction of the Department that there is no remaining potential for a discharge of manure, litter or associated process wastewater that was generated while the operation was a CAFO, other than agricultural storm water from land application areas.~~

(f) By when must the owner or operator of a CAFO have an NPDES permit if it discharges? A CAFO must be covered by a permit at the time that it discharges.

(g) [Reserved]

(h) Procedures for CAFOs seeking coverage under a general permit.

(1) CAFO owners or operators must submit a notice of intent when seeking authorization to discharge under a general permit in accordance with section 122.28(b). The Department must review notices of intent submitted by CAFO owners or operators to ensure that the notice of intent includes the information required by section 122.21(i)(1), including a nutrient management plan that meets the requirements of section 122.42(e) and applicable effluent limitations and standards, including those specified in 40 CFR part 412. When additional information is necessary to complete the notice of intent or clarify, modify, or supplement previously submitted material, the Department may request such information from the owner or operator. If the Department makes a preliminary determination that the notice of intent meets the requirements of sections 122.21(i)(1) and 122.42(e), the Department must notify the public of the Department's proposal to grant coverage under the permit to the CAFO and make available for public review and comment the notice of intent submitted by the CAFO, including the CAFO's nutrient management plan, and the draft terms of the nutrient management plan to be incorporated into the permit. The process for submitting public comments and hearing requests, and the hearing process if a request for a hearing is granted, must follow the procedures applicable to draft permits set forth in 40 CFR 124.11 through 124.13. The Department may establish, either by regulation or in the general permit, an appropriate period of time for the public to comment and request a hearing that differs from the time period specified in 40 CFR 124.10. The Department must respond to significant comments received during the comment period, as provided in 40 CFR 124.17, and, if necessary, require the CAFO owner or operator to revise the nutrient management plan in order to be granted permit coverage. When the Department authorizes coverage for the CAFO owner or operator under the general permit, the terms of the nutrient management plan shall become incorporated as terms and conditions of the permit for the CAFO. The Department shall notify the CAFO owner or operator and inform the public that coverage has been authorized and of the terms of the nutrient management plan incorporated as terms and conditions of the permit applicable to the CAFO.

(2) For EPA-issued permits only. The Regional Administrator shall notify each person who has submitted written comments on the proposal to grant coverage and the draft terms of the nutrient management plan or requested notice of the final permit decision. Such notification shall include notice that coverage has been authorized and of the terms of the nutrient management plan incorporated as terms and conditions of the permit applicable to the CAFO.

(3) Nothing in this paragraph (h) shall affect the authority of the Department to require an individual permit under section 122.28(b)(3).

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 48-1-10 et seq.

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-9, Water Pollution Control Permits. Interested persons may submit comment(s) on the proposed amendments to Ann Clark of the Bureau of Water; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; clarkar@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on August 22, 2022, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to the South Carolina Pollution Control Act, S.C. Code Ann. 48-1-10 et seq., the Department establishes programs to regulate discharges from point sources including concentrated animal feeding operations. The Department proposes to amend R.61-9.122, The National Pollutant Discharge Elimination System. The amendment will remove the existing language of R.61-9.122.23, Concentrated animal feeding operations, and replace it with language that is consistent with current federal regulation 40 CFR Section122.23. The requirement for South Carolina to include regulations in conformance with the federal regulation is stated at 40 CFR Section 123.25(a)(6).

The proposed amendment may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

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

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.(61-9, *Water Pollution Control Permits*)

As of August 22, 2022, close of the Notice of Drafting comment period:

Name	Section
Southern Environmental Law Center	**Notice of Drafting, to Amend R.61-9.122, National Pollution Discharge Permits**
Comment: See attached letter **Department Response:** Department will respond along with other comments received during comment period on the Notice of Proposed Regulation.	
Name	**Section**
Comment: **Department Response:**	
Name	**Section**
Comment: **Department Response:**	

ATTACHMENT D

SOUTHERN ENVIRONMENTAL COMMENT LETTER
AUGUST 22, 2022

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SOUTHERN ENVIRONMENTAL LAW CENTER

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August 22, 2022

Via Email

Ann Clark
SC Department of Health and Environmental Control, Bureau of Water
2600 Bull Street
Columbia, South Carolina 29201
clarkar@dhec.sc.gov

Re: Notice of Drafting, to Amend R.61-9.122, National Pollution Discharge Elimination System

Dear Ms. Clark:

The Southern Environmental Law Center ("SELC"), on behalf of Sierra Club, Congaree Riverkeeper, Winyah Rivers Alliance, Audubon South Carolina, South Carolina Wildlife Federation, South Carolina Environmental Law Project, South Carolina Native Plant Society, and the Coastal Conservation League, submits these comments on the Department of Health and Environmental Control's ("DHEC's") Notice of Drafting to Amend S.C. Reg. 61.9-122 ("Notice"), which regulates discharges from point sources, including concentrated animal feeding operations ("CAFOs"). DHEC claims this regulatory change is exempt from General Assembly review because it is required to maintain compliance with federal law. *See* S.C. Code § 1-23-120(H)(1) ("General Assembly review is not required for regulations promulgated[]. . . to maintain compliance with federal law[.]"). As explained below, DHEC's claim is erroneous and is a transparent attempt to avoid complying with *Blackmon v. SC DHEC* , 436 S.C. 529 (S.C. Ct. App. 2022).

As a preliminary matter, DHEC provides little information in its Notice regarding the nature of the proposed amendments or justification for exempting the changes from General Assembly review. This makes it difficult for the public to consider whether DHEC's claimed exemption is warranted. It is also a violation of the South Carolina Administrative Procedure Act ("SC APA"), which requires notices of drafting to include "a synopsis of what the agency plans to draft." S.C. Code Ann. 1-23-110(A)(1)(b). DHEC must provide enough information in its notices of drafting to provide the public with a meaningful opportunity to comment. Nevertheless, based on the minimal information provided by DHEC, we object to DHEC's claim that these regulatory changes are necessary for compliance with federal law, and in turn exempt from General Assembly review.

South Carolina's CAFO permitting regulations are fully authorized by federal law. DHEC's Notice points to 40 C.F.R. § 123.25(a)(6) as the federal law "requiring" the proposed regulatory change. But section 123.25(a)(6) merely establishes that the federal requirements for

CAFO permitting are a regulatory floor. That is, state regulations must be at least as stringent as federal regulations, but "States are *not* precluded from omitting or modifying any provisions to impose more stringent requirements[.]" 40 C.F.R. § 123.25(a). South Carolina's regulations do just that. As the South Carolina Court of Appeals explained in *Blackmon*, "[t]he South Carolina [CAFO] regulations . . . are based not only on the federal [National Pollutant Discharge Elimination System] regulations but also upon the South Carolina Pollution Control Act, which specifically authorizes the Department to 'prevent pollution[,]'" in turn justifying South Carolina's more stringent regulations. 436 S.C. at 542; *compare Waterkeeper Alliance, Inc v. US EPA*, 399 F.3d 486, 504 (2d Cir. 2005) (concluding that federal law regulates only *actual discharges* of pollutants), *with Blackmon*, 436 S.C. at 542 (explaining that, in addition to regulating actual discharges of pollutants as required by federal law, South Carolina law provides *additional* regulatory authority to *prevent* pollution). Because South Carolina's existing CAFO regulations are fully authorized by federal law, the proposed amendment is not necessary to maintain compliance with federal law, nor is it exempt from review by the General Assembly.

Aside from failing to comply with the SC APA and attempting to circumvent General Assembly review, it is troubling that this is DHEC's response to *Blackmon*. The court in *Blackmon* confirmed that South Carolina's laws and regulations provide a higher level of protection for South Carolina waterways than federal law and found that DHEC was failing to enforce those higher standards—to the detriment of water quality in our State. Apparently DHEC's response to this decision was not to begin enforcing South Carolina law and protecting South Carolina residents and waterways, but to strip South Carolina's CAFO regulations of additional safeguards, making them demonstrably less protective and failing to address the threat that excessive, improper, and poorly regulated land application of animal waste poses to our State's waterways. We urge DHEC to ensure the protection and improvement of water quality in South Carolina by abandoning this unnecessary and harmful amendment process intended to weaken oversight of large CAFOs in the State.

Sincerely,

/s/ Emily Wyche
Southern Environmental Law Center
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Charleston, South Carolina 29403

Cc (via email only):
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Trip King, Audubon South Carolina and South Carolina Wildlife Federation
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