SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

December 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 October 1, 2022, through October 31, 2022.

III. **FACTS:** For the period of October 1, 2022, through October 31, 2022, Healthcare Quality reports 2 Administrative Orders and 3 Consent Orders totaling $11,500 in assessed monetary penalties.

Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Assessed Penalties	Required Payment
Community Care	Community Residential Care Facility (CRCF)	0	1	$5,000	$3,000
Healthcare Systems and Services	Emergency Medical Services (EMS) Agency	1	1	$5,900	$5,900
	Paramedic	1	1	$600	$600
TOTAL		**2**	**3**	**$11,500**	**$9,500**

Submitted By:

Gwendolyn C. Thompson
Gwen C. Thompson
Deputy Director
Healthcare Quality

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

December 8, 2022

Bureau of Community Care

Facility Type	Total Number of Licensed Facilities	Total Number of Licensed Beds
Community Residential Treatment Facility (CRCF)	471	8,134

1. Sherman Residential Care (16 Licensed Beds) – Greenville

Investigation and Violations: The Department was notified by the Department of Labor, Licensing and Regulation (LLR) in March 2022 that the facility administrator's license had expired. The facility was issued citations-by-mail in March 2022, April 2022, and June 2022, for violating Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, for failing to have a licensed administrator. In March 2022, the facility was also issued a citation-by-mail for violating the regulation by failing to notify the Department within 72 hours of a change in administrator status.

Enforcement Action: The Department requested the facility attend an enforcement conference and after the parties met, they agreed to resolve the matter with a consent order. Considering the severity level of the violations at the facility, the Department determined imposition of a civil monetary penalty was warranted. The facility agreed to the imposition of a $5,000 monetary penalty and to pay $3,000 within 30 days of executing the Consent Order. The remaining $2,000 is held in abeyance upon a three-month period of substantial compliance with Regulation 61-84 and the Consent Order.

Remedial Action: As of November 28, 2022, the Department is processing the facility's required payment of $3,000. In addition, the facility had a licensed administrator during the Department's most recent onsite visit during November 2022.

Prior Orders: None in the past 5 years.

Bureau of Healthcare Systems and Services

Provider Type	Total Number of Licensed EMS Agencies
Emergency Medical Services (EMS) Agency	268

2. Secure Transportation Services Corporation (Advanced Life Support) – Rock Hill

Investigation and Violations: The Department was notified by the EMS agency that a non-credentialed driver provided patient care for 11 patient encounters over a two-day period. It is a violation of the Emergency Medical Services Act of South Carolina and Regulation 61-7, *Emergency Medical Services*, for an EMS agency to allow uncertified personnel to perform patient care.

Enforcement Action: Based on the foregoing, the Department and the EMS agency met for an enforcement conference and agreed to resolve this matter with a consent order. The EMS agency agreed to the imposition of a $650 monetary penalty and was required to pay the full amount.

Remedial Action: The EMS agency has paid the required $650.

Prior Orders: None in the past 5 years.

3. Carolina Emergency Medical Services, LLC (Basic Life Support) – Anderson

Investigation and Violations: The Department conducted an investigation and found that the EMS agency did not have a medical control physician for 6 days in which 27 patients were provided care. The EMS agency repeatedly refused to provide records and documentation requested by the Department during the investigation.

As a result, the Department determined the EMS agency violated the Emergency Medical Services Act of South Carolina and Regulation 61-7, *Emergency Medical Services*, by failing to maintain a medical control physician. The Department also found the EMS agency in violation of the abovementioned state law and regulation by failing to maintain records that include approved patient care report forms, employee or member rosters or both, and training records and/or failing to make these records available for inspection by the Department at any reasonable time or upon request.

Enforcement Action: Based on the foregoing, the Department and the EMS agency met for an enforcement conference and the parties discussed the allegations and tried to reach an agreement. Because the parties could not agree on terms, the Department issued an Administrative Order requiring the EMS agency to pay $5,250 within 30 days of issuance of the Administrative Order.

Remedial Action: As of November 28, 2022, the EMS agency has not paid the required $5,250. The Department is pursuing additional action against the EMS agency.

Prior Orders: None in the past 5 years.

Emergency Medical Technician (EMT) Certification Level	Total Number of Certified Paramedics
Paramedic	4,207

4. Charles McDaniel – Paramedic

Investigation and Violations: The Department conducted an investigation into a complaint alleging that a patient's valium prescription was seized by two emergency medical technicians (EMTs) who arrived during a call for service. The Department further found that the seizure of valium was not noted on the electronic

patient care record (ePCR) created for the call and the valium was not properly disposed of following its seizure.

The Department determined that Mr. McDaniel committed misconduct as defined by the Emergency Medical Services Act of South Carolina and Regulation 61-7, *Emergency Medical Services*, by removing a controlled substance from a patient's home and not documenting the incident in an official document required by the Department. The Department determined this was misconduct because of the use of a false, fraudulent, or forged statement or document or practice of a fraudulent, deceitful, or dishonest act in connection with the certification requirements or official documents required by the Department.

Enforcement Action: As a result of the foregoing, the Department invited Mr. McDaniel to attend an enforcement conference and informed that failure to attend the enforcement conference may result in an enforcement action by issuance of an Administrative Order without his consent. Mr. McDaniel did not attend the enforcement conference nor did he notify the Department with a reasonable excuse for why he could not attend. Therefore, the Department issued an Administrative Order to Mr. McDaniel requiring him to pay $300 within 30 days from the issuance of the Administrative Order. Failure to make payment within 30 days will result in the suspension of Mr. McDaniel's Paramedic certification.

Remedial Action: As of November 28, 2022, Mr. McDaniel has not made the required $300 payment. However, the Department extended the payment deadline to December 2, 2022.

Prior Orders: None in the past 5 years.

5. Brad E. Howard – Paramedic

Investigation and Violations: The Department conducted an investigation and found that valium was seized by two emergency medical technicians (EMTs) who had arrived during a call for service. The Department further found that that the seizure of valium was not noted on the electronic patient care record (ePCR) created for the call and the valium was not properly disposed of following its seizure. Finally, the Department found that Mr. Howard did not properly document the call.

As a result, the Department determined that Mr. Howard committed misconduct as prescribed by the Emergency Medical Services Act of South Carolina and Regulation 61-7, *Emergency Medical Services*, by removing a controlled substance from a patient's home and not documenting the incident in an official document required by the Department. The Department determined this was misconduct because of the use of a false, fraudulent, or forged statement or document or practice of a fraudulent, deceitful, or dishonest act in connection with the certification requirements or official documents required by the Department.

Enforcement Action: Based on the foregoing, the Department and Mr. Howard met for an enforcement conference and the parties agreed to resolve the matter with a Consent Order. Mr. Howard agreed to the imposition of $300 monetary penalty and the requirement to pay two monthly installments of $150 each within 30 days and 60 days, respectively, of execution of the Consent Order. Mr. Howard also agreed to complete a Professional Ethics and Personal Leadership (PEPL) class within 12 months of execution of the Consent Order.

Remedial Action: Mr. Howard has made the first required payment of $150. Mr. Howard is required to pay the remaining $150 by December 5, 2022. Mr. Howard's completion of the PEPL class is still pending.

Prior Orders: The Department and Mr. Howard previously executed a Consent Order in 2018, in which Mr. Howard agreed to a 90-day suspension of his paramedic certificate and to successfully complete the

PEPL class. The Consent Order resulted from the Department's findings that Mr. Howard committed misconduct as defined by state law and regulation by disregarding an appropriate order by a physician concerning emergency medical treatment. More specifically, the Department found that Mr. Howard failed to provide emergency medical treatment of a quality deemed acceptable by the Department. Mr. Howard self-medicated using non-prescribed medications from the EMS agency's stock.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
December 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 October 1, 2022, through October 31, 2022.

3. **FACTS:** For the reporting period of October 1, 2022, through October 31, 2022, the Office of Environmental Affairs issued one hundred two (102) Consent Orders with total assessed civil penalties in the amount of one hundred sixty-three thousand, three hundred fifty dollars ($163,350.00). Also, five (5) Administrative Orders with total assessed civil penalties in the amount of fifty-nine thousand, nine hundred fifty-one dollars ($59,951.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	1	$28,600.00	3	$5,320.00
Aboveground Tanks	1	$10,651.00	0	0
Solid Waste	1	$15,300.00	0	0
Hazardous Waste	0	0	4	$48,500.00
SUBTOTAL	**3**	**$54,551.00**	**7**	**$53,820.00**
Water				
Recreational Water	0	0	52	$46,680.00
Drinking Water	0	0	0	0
Water Pollution	0	0	3	$14,700.00
SUBTOTAL	**0**	**0**	**55**	**$61,380.00**
Air Quality				
SUBTOTAL	**0**	**0**	**0**	**0**
Environmental Health Services				
Food Safety	1	$400.00	37	$44,150.00
Onsite Wastewater	1	$5,000.00	3	$4,000.00
SUBTOTAL	**2**	**$5,400.00**	**40**	**$48,150.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**5**	**$59,951.00**	**102**	**$163,350.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

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

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 22-0135-UST
Order Date: October 12, 2022
Individual/Entity: **Coosawhatchie CStore, LLC**
Facility: Coosawhatchie General Store
Location: 6282 West Frontage Road
Coosawhatchie, SC 29936
Mailing Address: Same
County: Jasper
Previous Orders: None
Permit/ID Number: 10422
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. 2022).

Summary: Coosawhatchie CStore, LLC (Individual/Entity) owns underground storage tanks (USTs) in Jasper County, South Carolina. On March 7, 2022, the Department conducted a file review 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 underground storage tank 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 and evidence of financial assurance by December 13, 2022. The Department has assessed a total civil penalty in the amount of twenty-eight thousand, six hundred dollars ($28,600.00). The Individual/Entity shall pay a civil penalty in the amount of twenty-eight thousand, six hundred dollars **($28,600.00)** by December 13, 2022.

Update: The Individual/Entity did not file a Request for Review; therefore the Order became effective October 29, 2022.

2) Order Type and Number: Consent Order 22-0286-UST
Order Date: October 3, 2022
Individual/Entity: **Northeast Real Property**
Facility: Dana Transportation

Location: 7117 Cross Country Road
Charleston, SC 29418
Mailing Address: P.O. Box 129
Demopolis, Al 36732
County: Charleston
Previous Orders: None
Permit/ID Number: 16846
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 & Supp 2022).

Summary: Northeast Real Property (Individual/Entity) owns underground storage tanks (USTs) in Charleston County, South Carolina. On July 6, 2022, the Department conducted a file review 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 demonstrate financial responsibility for an UST system and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity shall submit a completed Certificate of Financial Responsibility and evidence of financial assurance by November 17, 2022. The Department has assessed a total civil penalty in the amount of twenty-five thousand, seven hundred twenty dollars ($25,720.00). The Individual/Entity shall pay a civil penalty in the seven hundred twenty dollars **($720.00)** by November 17, 2022, and pay a suspended penalty in the amount of twenty-five thousand dollars ($25,000.00) should any requirement of the Order not be met.

Update: All compliance documentation and the civil penalty have been received. This Order has been closed.

3) Order Type and Number: Consent Order 22-0133-UST
Order Date: October 6, 2022
Individual/Entity: **Cliff Canty**
Facility: Cliff's Food Store 6
Location: 326 West Hampton Highway
Olanta, SC 29114
Mailing Address: 589 Cooktown Road
Lake City, SC 29560
County: Florence
Previous Orders: None
Permit/ID Number: 15180
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.31(b)(1), 280.70(a) and 280.70(c) (2012 & Supp 2022).

Summary: Cliff Canty (Individual/Entity) owns an underground storage tank (UST) in Florence County, South Carolina. The Department conducted an inspection and issued a Notice of Alleged Violation on March 18, 2022. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation,

as follows: failed to have a corrosion protection system inspected by a qualified tester every three years; failed to maintain corrosion protection or appropriate release detection on a temporarily closed UST; and failed to properly abandon a temporarily closed UST system after twelve (12) months.

Action: The Individual/Entity is required to: submit a Tank & Sludge Disposal form for the permanent closure of the UST at the Facility by November 21, 2022; within thirty (30) days of the Department's approval of the form, permanently close the UST; and within sixty (60) days of permanent closure, submit an UST Closure and Assessment Report. The Department has assessed a total civil penalty in the amount of sixteen thousand dollars ($16,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)** by October 21, 2022 and pay a suspended penalty in the amount of fifteen thousand dollars ($15,000.00) should any requirement of the Order not be met.

Update: The Individual/Entity has paid the civil penalty. The UST has been permanently closed. The UST Closure and Assessment Report is due January 20, 2023.

4) Order Type and Number: Consent Order 22-0266-UST
Order Date: October 14, 2022
Individual/Entity: **Upstate Venture Group, LLC**
Facility: BP on 85
Location: 901 North Mountain Street
Blacksburg, SC 29702
Mailing Address: Same
County: Cherokee
Previous Orders: None
Permit/ID Number: 10818
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, 280.41(b)(2)(i) (2012 & Supp 2022).

Summary: Upstate Venture Group, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Cherokee County, South Carolina. On June 8, 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 equip a pressurized line with an automatic line leak detector.

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 three thousand, six hundred dollars ($3,600.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, six hundred dollars **($3,600.00)** by November 28**,** 2022.

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

Aboveground Storage Tank Enforcement

5) Order Type and Number: Administrative Order 21-01-AST

Order Date: October 6, 2022
Individual/Entity: **Audi's Holdings, LLC**
Facility: Sarah's Tobacco #3
Location: 1307 Dudley Road
Marion, SC 29571
Mailing Address: 4703 Briarfield Road
Columbia, SC 29206
County: Marion
Previous Orders: None
Permit/ID Number: 18716
Violations Cited: The South Carolina Pollution Control Act (PCA), S.C. Code Ann. § 48-1-10 et seq. (2008 and Supp. 2021).

Summary: Audi's Holdings, LLC (Individual/Entity) owns aboveground storage tanks (ASTs) in Marion County, South Carolina. On January 18, 2019, the Department conducted a file review and issued a Notice of Alleged Violation. The Individual/Entity has violated the South Carolina Pollution Control Act, as follows: failed to investigate and sample discharges based on the procedures, methods, intervals and locations prescribed by the Department; failed to develop and provide control and prevention information and other such information as the Department may reasonable require; and failed to ensure that discharges into the environment of the State do not occur, without a permit issued by the Department.

Action: The Individual/Entity is required to submit a Tier I Assessment Report. The Department has assessed a total civil penalty in the amount of nineteen thousand, six hundred fifty-one dollars ($19,651.00). The Individual/Entity shall pay a civil penalty in the amount of nineteen thousand, six hundred fifty-one dollars **($19,651.00)** by December 6, 2022.

Update: The Individual/Entity did not submit a Request for Review; therefore, the Order became effective October 22, 2022.

Solid Waste Enforcement

6) Order Type and Number: Administrative Order 22-18-SW
Order Date: September 29, 2022
Individual/Entity: **Heyward Swift**
Facility: N/A
Location: 151 Royster Road
Townville, SC
Mailing Address: 214 Bowen Drive
Anderson, SC 29621
County: Anderson
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 (2018 & Supp. 2019) (Act) and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation (2015) (Regulation), R.61-107.19, Part I.A.8., Part III.B.6., and Part IV.A.3.

Summary: Heyward Swift (Individual/Entity), owns property located in Anderson County, South Carolina. The Department conducted inspections on November 17, 2021, March 7, 2022, and April 12, 2022. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation as follows: operated a Class One and Class Two landfill prior to obtaining a permit from the Department.

Action: The Individual/Entity is required to: immediately cease receipt and/or transport of solid waste debris onto the site; remove and properly dispose of all solid waste debris from the site at a permitted solid waste management facility and provide disposal receipts to the Department by November 28, 2022. The Department assessed a total civil penalty in the amount of fifteen thousand, three hundred dollars ($15,300.00). The Individual/Entity shall pay a civil penalty in the amount of fifteen thousand, three hundred dollars **($15,300.00)** by November 28, 2022.

Update: The Individual/Entity did not file a Request for Review; therefore, the Order became effective October 14, 2022.

Hazardous Waste Enforcement

7)

Order Type and Number:	Consent Order 22-16-HW
Order Date:	October 14, 2022
Individual/Entity:	**Lexington Health, Inc. d/b/a Lexington Medical Center**
Facility:	Lexington Health, Inc. d/b/a Lexington Medical Center
Location:	2720 Sunset Boulevard West Columbia, SC 29169
Mailing Address:	Same
County:	Lexington
Previous Orders:	None
Permit/ID Number:	SCR 000 000 430
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: Lexington Health, Inc. d/b/a Lexington Medical Center (Individual/Entity) is a hospital located in Lexington County, South Carolina. The Department conducted an inspection at the facility on June 6, 2022. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to accumulate hazardous waste under the control of the operator of the process where the waste was generated; failed to mark or label containers with the words “Hazardous Waste,” accumulation start dates, and an indication of the hazards of the contents; failed to keep containers closed except when adding or removing waste; failed to maintain written job descriptions and job titles for each position related to hazardous waste management and the name of the employee filling that position; failed to maintain the type and amount of both introductory and continuing training; failed to describe the arrangements made with local emergency responders in the Contingency Plan; failed to submit a copy of the Contingency Plan and

the Quick Reference Guide to the local emergency responders; failed to record the time weekly hazardous waste inspections were conducted; failed to have containers of non-creditable hazardous waste pharmaceuticals closed and labeled with the phrase "Hazardous Waste Pharmaceuticals"; failed to demonstrate the length of time non-creditable hazardous waste pharmaceuticals had been accumulated from the date it became a waste; failed to determine whether potentially creditable pharmaceuticals were potentially creditable hazardous waste pharmaceuticals; and 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.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of seventeen thousand, five hundred dollars ($17,500.00). The Individual/Entity is required to pay a civil penalty in the amount of seventeen thousand, five hundred dollars **($17,500.00)** by November 15, 2022.

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

8) Order Type and Number: Consent Order 22-19-HW
Order Date: October 19, 2022
Individual/Entity: **Cogsdill Tool Products, Inc.**
Facility: Cogsdill Tool Products, Inc.
Location: 1001 Guion Drive
Lugoff, SC 29020
Mailing Address: Same
County: Kershaw
Previous Orders: None
Permit/ID Number: SCD 005 320 544
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021).

Summary: Cogsdill Tool Products, Inc. (Individual/Entity) is a manufacturer of roller burnishing, deburring and CNC controlled boring, facing, and contouring precision tools at its facility located in Kershaw County, South Carolina. The Department conducted an inspection at the facility on May 20, 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 the words "Hazardous Waste," accumulation start dates, and an indication of the hazards of the contents; failed to perform weekly hazardous waste inspections; failed to ensure personnel take part in a hazardous waste training program and an annual review; failed to maintain a written description of the type and amount of both introductory and continuing training given to personnel; failed to include in the Contingency Plan, a list of all emergency equipment at the facility along with its capabilities; and failed to submit a copy of the Contingency Plan and the Quick Reference Guide to local emergency responders.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of fourteen thousand five hundred dollars ($14,500.00). The Individual/Entity is required to pay a civil penalty

in the amount of fourteen thousand five hundred dollars **($14,500.00)** by December 19, 2022.

Update: None at the time of the report.

9) Order Type and Number: Consent Order 22-17-HW
Order Date: October 21, 2022
Individual/Entity: **Maaco Collision Repair and Auto Painting**
Facility: Maaco Collision Repair and Auto Painting
Location: 5786 Dorchester Road
North Charleston, SC 29418
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: SCR 000 002 030
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: Maaco Collision Repair and Auto Painting (Individual/Entity), specializes in auto repair and painting at its facility located in Charleston County, South Carolina. The Department conducted an inspection on May 12, 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 the words "Hazardous Waste," an indication of the hazards of the contents, and accumulation start dates; failed to keep containers closed except when adding or removing waste; failed to, at least weekly, inspect central accumulation areas; failed to attempt to make arrangements and maintain records documenting arrangements made with local emergency responders; failed to ensure an emergency coordinator be on the premises or on call; failed to post the name and number of the emergency coordinator, the location of fire extinguishers, spill control materials, and the telephone number of the fire department next to the phone; and failed to declare its generator status.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of four thousand, five hundred dollars ($4,500.00). The Individual/Entity shall pay a civil penalty in in the amount of four thousand, five hundred dollars **($4,500.00)** in accordance with the terms of a promissory note beginning November 1, 2022.

Update: The Individual/Entity is making payments in accordance with the promissory note.

10) Order Type and Number: Consent Order 22-18-HW
Order Date: October 27, 2022
Individual/Entity: **Clarios, LLC**
Facility: Clarios, LLC
Location: 1204 Old Walhalla Highway
West Union, SC 29696
Mailing Address: Same

County: Oconee
Previous Orders: None
Permit/ID Number: SCD 981 922 404
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021), the South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 et seq. (2018 and Supp. 2021), and the South Carolina Solid Waste Management: Used Oil Regulations, 8 S.C. Code Ann. Regs. 61-107.279 (2012 and Supp. 2021).

Summary: Clarios, LLC (Individual/Entity) is a manufacturer of car battery components specializing in lead strip casting at its facility located in Oconee County, South Carolina. The Department conducted an inspection at the facility on July 7, 2022. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act, the Hazardous Waste Management Regulations, the South Carolina Solid Waste Policy and Management Act, and the Used Oil Regulations as follows: failed to determine if a solid waste was a hazardous waste; failed to keep containers closed except when adding or removing waste; failed to mark or label containers with the words "Hazardous Waste," accumulation start dates, and an indication of the hazards of the contents; failed to maintain written job descriptions that included the requisite skills, education, qualifications, and duties for personnel assigned to each position; failed to label universal waste lamps with the words "Universal Waste – Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)"; failed to amend the Contingency Plan whenever the list of emergency coordinators changed; and failed to label containers of used oil with the words "Used Oil."

Action: The Individual/Entity is required to: submit analytical results and a waste profile for the lead dust waste, documentation demonstrating the list of emergency coordinators listed in the Contingency Plan and Quick Reference Guide are accurate; and written job descriptions that included the requisite skills, education, qualifications, and duties for personnel assigned to each position by November 28, 2022. The Department assessed a total civil penalty in the amount of twelve thousand dollars ($12,000.00). The Individual/Entity is required to pay a civil penalty in the amount of twelve thousand dollars **($12,000.00)** by November 28, 2022.

Update: None at the time of the report.

BUREAU OF WATER

Recreational Waters Enforcement

11) Order Type and Number: Consent Order 22-134-RW
Order Date: October 3, 2022
Individual/Entity: **Hilton Head Lakes North Owners Association**
Facility: Hilton Head Lakes North
Location: 2000 Club Way
Hardeeville, SC 29927

Mailing Address:	1040 William Hilton Parkway Hilton Head Island, SC 29928
County:	Jasper
Previous Orders:	None
Permit/ID Number:	27-1020D
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Hilton Head Lakes North Owners Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Jasper County, South Carolina. The Department conducted inspections on June 29, 2022, and August 9, 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 chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; and the thermometer that monitors the spa temperature was not working 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 October 17, 2022.

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

12)

Order Type and Number:	Consent Order 22-136-RW
Order Date:	October 3, 2022
Individual/Entity:	**Scion Columbia Apartments, LLC**
Facility:	Redpoint Columbia
Location:	1050 Southern Drive Columbia, SC 29201
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1107B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Scion Columbia Apartments, 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 29, 2022, and July 29, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; there was pool furniture in the pool; the pool floor was dirty; the deck was uneven with sharp edges; there was debris in the skimmer baskets; the water level was too high on the first inspection and too low on the second inspection; the drinking water fountain was not operating; the chlorine and pH levels were not within the acceptable range of water quality standards; the shepherd's crook was missing a bolt; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded weekly in the bound and numbered log book; a depth marker tile was broken; the waterline tiles were dirty; and the bound and numbered log book was not maintained a minimum of three times per week by the pool 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 October 11, 2022.

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

13) Order Type and Number: Consent Order 22-137-RW
Order Date: October 3, 2022
Individual/Entity: **Gregg Park Homeowners Association**
Facility: Gregg Park
Location: 71 Gregg Parkway
Columbia, SC 29206
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-309-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Gregg Park Homeowners Association (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 20, 2022, and July 21, 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 furniture was not at least four feet from the pool edge; there was debris in the skimmer baskets; the chlorine level was not within the acceptable range of water quality standards; the main drain grate was loose; and the pool rules sign was not legible.

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 October 12, 2022.

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

14) Order Type and Number: Consent Order 22-138-RW
Order Date: October 3, 2022
Individual/Entity: **Charleston Foundry Owner, LLC**
Facility: Foundry Point Apartments
Location: 20 Romney Street
Charleston, SC 29403
Mailing Address: 2108 Monrovia Street, Suite 100
Charleston, SC 29405
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1375B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Charleston Foundry Owner, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 5, 2022, and August 3, 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

chlorine level was not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

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 October 16, 2022.

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

15)

Order Type and Number:	Consent Order 22-139-RW
Order Date:	October 3, 2022
Individual/Entity:	**35 Folly, LLC**
Facility:	35 Folly Apartments
Location:	35 Folly Road Charleston, SC 29425
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1253B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: 35 Folly, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 5, 2022, and August 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 drinking water fountain and foot rinse shower were not operating properly; the gate did not self-close and latch; the pH level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by October 20, 2022**.**

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

16)

Order Type and Number:	Consent Order 22-140-RW
Order Date:	October 3, 2022
Individual/Entity:	**MCG Charlotte Mill House, DST**
Facility:	Mill House Apartments
Location:	820 Clawson Place Fort Mill, SC 29715
Mailing Address:	Same
County:	York
Previous Orders:	None
Permit/ID Number:	46-1224B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: MCG Charlotte Mill House, DST (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 27, 2022, and August 9, 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 chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the bound and numbered log book was not available for review on the first inspection; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection; and the foot rinse shower 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 October 16, 2022.

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

17)

Order Type and Number:	Consent Order 22-141-RW
Order Date:	October 4, 2022
Individual/Entity:	**Adlerian Child Care Center and Kindergarten, Inc.**
Facility:	Adlerian Child Care Center
Location:	7817 Broad River Road Irmo, SC 29063
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-310-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Adlerian Child Care Center and Kindergarten, Inc. (Individual/Entity) leases and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 28, 2022, and August 3, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the pool equipment room was not locked; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; only one "Shallow Water – No Diving Allowed" sign was posted and the sign posted did not have the correct wording; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; there were chlorine tablets in the skimmer baskets; the pool walls and floor were not visible due to cloudy water; the water level was too low; and the main drain grates were not visible due to cloudy water.

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 October 14, 2022.

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

18) Order Type and Number: Consent Order 22-142-RW
Order Date: October 4, 2022
Individual/Entity: **Timber Creek 2019, LLC**
Facility: Timber Creek Apartments
Location: 501 Camelot Drive
Spartanburg, SC 29301
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 42-045-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Timber Creek 2019, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Spartanburg County, South Carolina. The Department conducted inspections on June 16, 2022, and August 5, 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 lifeline did not have enough floats and the existing floats were damaged; a ladder was missing non-slip tread inserts; the water level was too low; skimmers were missing weirs; a bathroom did not have paper towels or soap; the foot rinse shower was not operating properly; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; there was algae present on the pool floor and walls; and there were chlorine tablets in the skimmer baskets.

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 October 18, 2022.

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

19) Order Type and Number: Consent Order 22-143-RW
Order Date: October 4, 2022
Individual/Entity: **Ft. Jackson Hotel Partners, LLC**
Facility: Home 2 Suites
Location: 7340 Garners Ferry Road
Columbia, SC 29209
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-1187B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Ft. Jackson Hotel Partners, 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 July 7, 2022, and August 10, 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 dirty; there was debris in the skimmer baskets; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the bound and numbered log book was not available for review on the first inspection; the bound and numbered log book was not maintained on a daily basis on the second inspection; the cyanuric acid level was not recorded weekly in the bound and numbered log book on the second inspection; there were chlorine pucks in the skimmer baskets; skimmers were missing weirs; and a light in the pool wall was out of its niche.

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 October 18, 2022.

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

20)

Order Type and Number:	Consent Order 22-144-RW
Order Date:	October 5, 2022
Individual/Entity:	**Beach Canalside Lofts, LLC**
Facility:	Canalside Lofts
Location:	383 Taylor Steet Columbia, SC 29201
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1094B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Beach Canalside Lofts, 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 May 24, 2022, July 20, 2022, and August 5, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmer baskets were floating; a light in the pool wall was out of its niche; the life ring did not have a permanently attached rope; the shepherd's crook was obstructed; there were no "Shallow Water – No Diving Allowed" signs posted; there were no "No Lifeguard On Duty - Swim At Your Own Risk" signs posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; the coping was deteriorated; the pool walls, floor, and waterline tiles were dirty; skimmers were missing weirs; the bathrooms were dirty; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded weekly in the bound and numbered log book; the deck was uneven with sharp edges; the water level was too low; and the chlorine level was not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand, forty dollars ($2,040.00).

The Individual/Entity shall pay a civil penalty in the amount of two thousand, forty dollars **($2,040.00)** by October 24, 2022**.**

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

21) Order Type and Number: Consent Order 22-145-RW
Order Date: October 6, 2022
Individual/Entity: **Blockade Runner Motor Inn, Inc.**
Facility: Blockade Runner
Location: 1910 North Ocean Boulevard
North Myrtle Beach, SC 29597
Mailing Address: Same
County: Horry
Previous Orders: 19-025-RW ($680.00)
20-005-RW ($1,600.00)
Permit/ID Number: 26-G61-1 & 26-G63-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Blockade Runner Motor Inn, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Horry County, South Carolina. The Department conducted inspections on July 6, 2022, and August 11, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a gate did not self-close and latch; the cyanuric acid level was above the water quality standards acceptable limit; only one "Shallow Water – No Diving Allowed" sign was posted; the chlorine level was not within the acceptable range of water quality standards; the waterline tiles were dirty; the bound and numbered log book was not available for review; and the water level was too high.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars **($4,000.00)** by October 19, 2022.

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

22) Order Type and Number: Consent Order 22-146-RW
Order Date: October 6, 2022
Individual/Entity: **Boiling Springs Apts., LLC**
Facility: Promenade at Boiling Springs
Location: 901 Dornoch Drive
Boiling Springs, SC 29316
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 42-1028B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Boiling Springs Apts., LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Spartanburg County, South Carolina. The Department conducted inspections on May 27, 2022, and

July 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: ladders were not tight and secure; there was algae on the pool wall; a skimmer was missing a weir; the flow meter was not operating during the first inspection and was not operating properly during the second inspection; the chlorine level was not within the acceptable range of water quality standards; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review on the first inspection and was not maintained on a daily basis on the second inspection; the disinfection equipment was not operating properly; the bathroom did not have paper towels or a hand dryer; and the drinking water fountain 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 October 20, 2022.

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

23)

Order Type and Number:	Consent Order 22-147-RW
Order Date:	October 6, 2022
Individual/Entity:	**21 National Guard, LLC**
Facility:	21 Oaks Apartments
Location:	21 National Guard Road Columbia, SC 29223
Mailing Address:	4100 East Mississippi Avenue, Suite 700 Denver, CO 80246
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1025B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: 21 National Guard, 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 24, 2022, and July 29, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: some of the depth marker tiles were broken and some of the tiles were missing; the pool wall and floor were dirty; the deck was uneven with sharp edges; there was no foot rinse shower; the pool equipment room was not locked; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational and partially obstructed; the bound and numbered log book was not available for review; and there was air in the recirculation system.

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 October 20, 2022.

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

24) Order Type and Number: Consent Order 22-148-RW
Order Date: October 6, 2022
Individual/Entity: **Lighthouse Tennis Club Owners Assn., Inc.**
Facility: Lighthouse Tennis Club
Location: Lighthouse Road & Plant Drive
Hilton Head Island, SC 29928
Mailing Address: 1040 William Hilton Parkway
Hilton Head Island, SC 29928
County: Jasper
Previous Orders: None
Permit/ID Number: 07-114-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Lighthouse Tennis Club Owners Assn., Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Jasper County, South Carolina. The Department conducted inspections on July 12, 2022, and August 12, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was not tight and secure; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out and was not legible; the current pool operator of record information was not posted to the public; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by October 19, 2022.

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

25) Order Type and Number: Consent Order 22-149-RW
Order Date: October 10, 2022
Individual/Entity: **Columbia Ft. Jackson, LLC**
Facility: Candlewood Suites
Location: 921 Atlas Road
Columbia, SC 29209
Mailing Address: 8632 Wilkinson Boulevard
Charlotte, NC 28214
County: Richland
Previous Orders: None
Permit/ID Number: 40-1086B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Columbia Ft. Jackson, 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 July 8, 2022, and August 10, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder had a damaged rung and was missing non-slip tread inserts; a ladder rung was upside down; a handrail was not tight and secure; there was algae on the pool floor; the waterline tiles were dirty; the deck was uneven with sharp edges; the water level was too

low; a skimmer was missing a weir; the drinking water fountain was not operating properly; the pool vacuum was in the pool; the chlorine level was not within the acceptable range of water quality standards; only one "Shallow Water – No Diving Allowed" sign was posted and the letters on the sign posted were not the appropriate size; the letters on the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted were not the appropriate size; the current pool operator of record information was not posted to the public on the first inspection; the facility could not produce current valid documentation of pool operator certification on the second inspection; and the log book was not properly bound or numbered.

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 October 20, 2022.

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

26)	Order Type and Number:	Consent Order 22-150-RW
	Order Date:	October 10, 2022
	Individual/Entity:	**Ayrshire Homeowners Association, Inc.**
	Facility:	Ayrshire
	Location:	1091 Archibald Avenue Fort Mill, SC 29708
	Mailing Address:	130 Ben Casey Drive, Suite 100 Fort Mill, SC 29708
	County:	York
	Previous Orders:	CO 20-114-RW ($680.00)
	Permit/ID Number:	46-1169G
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Ayrshire Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 27, 2022, and August 9, 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 drinking water fountain was not operating properly; 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 posted were not the appropriate size; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)** by October 16, 2022.

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

27)	Order Type and Number:	Consent Order 22-151-RW
	Order Date:	October 10, 2022
	Individual/Entity:	**Brushy Meadows Homeowners Association, Inc.**

Facility:	Brushy Meadows
Location:	107 Brushy Meadows Drive Greer, SC 29650
Mailing Address:	219 Meadow Lake Trail Greer, SC 29650
County:	Greenville
Previous Orders:	None
Permit/ID Number:	23-457-1 & 23-1075C
Violations Cited:	S.C. Code Ann. Regs. 61-51(K)(1)(c)

Summary: Brushy Meadows Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Greenville County, South Carolina. On July 19, 2022, the pool and kiddie pool were inspected, and violations were issued for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool and kiddie pool were re-opened 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 seven hundred dollars ($700.00). The Individual/Entity shall pay a civil penalty in the amount of seven hundred dollars **($700.00)** by October 24, 2022.

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

28)

Order Type and Number:	Consent Order 22-152-RW
Order Date:	October 10, 2022
Individual/Entity:	**Bay Pointe Owner, LLC**
Facility:	Bay Pointe at Summerville Apartments
Location:	260 Pidgeon Bay Road Summerville, SC 29483
Mailing Address:	Same
County:	Dorchester
Previous Orders:	None
Permit/ID Number:	18-1088B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Bay Pointe Owner, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. The Department conducted inspections on June 23, 2022, and August 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 furniture was not at least four feet from the edge of the pool; the chlorine level was not within the acceptable range of water quality standards; and the cyanuric acid level was above the water quality standards acceptable limit.

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 October 26, 2022**.**

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

29) Order Type and Number: Consent Order 22-156-RW
Order Date: October 11, 2022
Individual/Entity: **The Rock Hill Nest, LLC**
Facility: Rock Hill Nest
Location: 412 Technology Center Way
Rock Hill, SC 29730
Mailing Address: 39 West Montgomery Avenue
Rockville, MD 20850
County: York
Previous Orders: None
Permit/ID Number: 46-1223B & 46-1222D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Rock Hill Nest, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a spa located in York County, South Carolina. The Department conducted inspections on July 6, 2022, and July 28, 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 chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the log book was not properly bound or numbered; the log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; and the cyanuric acid level was not recorded on a weekly basis in the log book.

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 October 27, 2022.

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

30) Order Type and Number: Consent Order 22-153-RW
Order Date: October 12, 2022
Individual/Entity: **BLX Parkside Owner, LLC**
Facility: Palmilla Apartments
Location: 1385 Ashley River Road
Charleston, SC 29407
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1269B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: BLX Parkside Owner, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 6, 2022, and August 9, 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 drinking water fountain was not operating properly; non-pool related items were stored in the pool equipment room; the chlorine level was not within the acceptable range of water

quality standards; the pool rules sign was not completely filled out; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by November 1, 2022**.**

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

31) Order Type and Number: Consent Order 22-154-RW
Order Date: October 12, 2022
Individual/Entity: **TD North Charleston Hotel, LLC**
Facility: Marriott North Charleston
Location: 4770 Goer Drive
Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1283B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: TD North Charleston Hotel, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 15, 2022, and August 9, 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 drinking water fountain and foot rinse shower were not operating properly; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the pool rules sign did not have all the required rules; the current pool operator of record information was not posted to the public; the log book was not properly bound and numbered on the first inspection; and the bound and numbered log book was not maintained on a daily basis and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection.

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 November 1, 2022**.**

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

32) Order Type and Number: Consent Order 22-155-RW
Order Date: October 12, 2022
Individual/Entity: **Pelican Apts., LLC**
Facility: Pelican Motel
Location: 2310 North Ocean Boulevard
North Myrtle Beach, SC 29582
Mailing Address: Same
County: Horry

Previous Orders:	None
Permit/ID Number:	26-008-1 & 26-008-2
Violations Cited:	S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Pelican Apts., LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Horry County, South Carolina. On August 8, 2022, and August 11, 2022, the pool and kiddie pool were inspected, and violations were issued for failure to properly operate and maintain; and on August 8, 2022, violations were issued for re-opening the pool and kiddie pool prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine level was not within the acceptable range of water quality standards; the life ring was deteriorated; the emergency notification device was not accessible; the pool deck was not clear of hazards; the current pool operator of record information was not posted to the public; and the pool and kiddie pool were 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 two thousand forty dollars ($2,040.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand forty dollars **($2,040.00)** by October 17, 2022.

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

33)

Order Type and Number:	Consent Order 22-157-RW
Order Date:	October 12, 2022
Individual/Entity:	**The Montessori Early Learning Center, Inc.**
Facility:	Montessori Early Learning Center
Location:	1101 Balsam Road Columbia, SC 29210
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-367-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: The Montessori Early Learning Center, Inc. (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 7, 2022, and August 1, 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; the pool deck was not clean and clear of hazards in that there was a strip of raised caulk around the pool edge; there was debris in the skimmer baskets; a skimmer was missing a weir; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; only one “No Lifeguard On Duty - Swim At Your Own Risk” sign was posted; the log book was not properly bound or numbered on the first inspection; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection.

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 October 26, 2022.

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

34) Order Type and Number: Consent Order 22-158-RW
Order Date: October 12, 2022
Individual/Entity: **Corey Gardens Homeowners' Association, Inc.**
Facility: Corey Gardens
Location: 101 Amberwood Drive, Summerville, SC 29483
Mailing Address: 4754 Franchise Street, Charleston, SC 29418
County: Dorchester
Previous Orders: None
Permit/ID Number: 18-069-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Corey Gardens Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. The Department conducted inspections on June 24, 2022, and August 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: there were no universal "no diving" tiles; the bathroom did not have paper towels or soap; the drinking water fountain was not operating properly; the fill spout was not stainless steel or equivalent; the facility address was not posted at the emergency notification device; the log book was not properly bound or numbered on the first inspection; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection.

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 October 18, 2022.

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

35) Order Type and Number: Consent Order 22-159-RW
Order Date: October 12, 2022
Individual/Entity: **Strata Sage, LLC**
Facility: Sage at 1240
Location: 1242 Winnowing Way, Mount Pleasant, SC 29464
Mailing Address: 4370 La Jolla Village Drive, Suite 960, San Diego, CA 92122
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1200B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Strata Sage, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 3, 2022, July 19, 2022, and August 16, 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; there was algae on the pool wall and floor; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; the log book was not properly bound or numbered on the first inspection; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection; and the bound and numbered log book was not maintained on a daily basis on the second and third inspections.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand, forty dollars ($2,040.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, forty dollars **($2,040.00)** by October 16, 2022.

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

36)

Order Type and Number:	Consent Order 22-160-RW
Order Date:	October 12, 2022
Individual/Entity:	**Ashton Woods Apartments, LLC**
Facility:	Ashton Woods Apartments
Location:	9525 Hwy 78 Ladson, SC 29456
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1148B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Ashton Woods Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 31, 2022, and August 9, 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 depth marker tiles on the pool deck were broken; skimmers were missing weirs; the bathrooms did not have toilet paper; the foot rinse shower was not operating properly; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

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 October 24, 2022**.**

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

37) Order Type and Number: Consent Order 22-161-RW
Order Date: October 14, 2022
Individual/Entity: **Silver Creek Valley, LLC**
Facility: Savannah Oaks Apartments
Location: 1402 Groves Boulevard
North Augusta, SC 29841
Mailing Address: Same
County: Aiken
Previous Orders: None
Permit/ID Number: 02-042-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Silver Creek Valley, LLC (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 July 19, 2022, and August 16, 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 lifeline floats were not properly spaced; a ladder was missing bumpers; the waterline tiles were dirty; the chlorine and pH levels were not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; 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 sign posted did not have the correct wording; the current pool operator of record information was not posted to the public; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by October 31, 2022**.**

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

38) Order Type and Number: Consent Order 22-162-RW
Order Date: October 14, 2022
Individual/Entity: **Cainhoy Pointe Apartments, LLC**
Facility: Palmetto Place Condominiums
Location: 1030 Jack Primus Road
Charleston, SC 29492
Mailing Address: Same
County: Berkeley
Previous Orders: None
Permit/ID Number: 08-1050B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Cainhoy Pointe Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on June 23, 2022, and August 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: a ladder was missing bumpers; the pool equipment room was not accessible; a gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of

water quality standards; and the bound and numbered log book was not available for review.

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 October 27, 2022.

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

39)

Order Type and Number:	Consent Order 22-163-RW
Order Date:	October 17, 2022
Individual/Entity:	**Ballards Pointe I Association**
Facility:	Ballards Pointe I
Location:	287 Ballard Lane Santee, SC 29142
Mailing Address:	P.O. Box 23081 Columbia, SC 29224
County:	Orangeburg
Previous Orders:	None
Permit/ID Number:	38-1006B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Ballards Pointe I Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Orangeburg County, South Carolina. The Department conducted inspections on June 27, 2022, and July 27, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was not tight and secure; there was algae on the pool wall and floor; the plaster on the pool floor was deteriorated; tiles on the pool wall were missing; the water level was too low; a skimmer was missing a weir; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; the pool rules sign was not completely filled out; the "Shallow Water – No Diving Allowed" signs did not have the correct wording; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the current pool operator of record information was not posted to the public; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

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 October 24, 2022.

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

40)

Order Type and Number:	Consent Order 22-164-RW
Order Date:	October 17, 2022
Individual/Entity:	**Ermine Road MHC, LLC**
Facility:	Lexington Village
Location:	600 Ermine Road West Columbia, SC 29170

Mailing Address:	P.O. Box 10851 Raleigh, NC 27605
County:	Lexington
Previous Orders:	None
Permit/ID Number:	32-053-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Ermine Road MHC, 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 June 30, 2022, and July 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: the lifeline floats were not properly spaced; a depth marker tile was cracked; the pool floor and wall were dirty; the grout was missing between the waterline tiles; the pool deck was uneven with sharp edges; a skimmer was missing a weir; there was debris in the skimmer baskets; a skimmer basket was floating; the water level was too high; the bathrooms did not have soap; the fill spout was not stainless steel or equivalent and was not co-located with a ladder or diving board; the chlorine level was not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; the life ring did not have a permanently attached rope and was not properly hung in its designated location; the bound and numbered log book was not maintained on a daily basis; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

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 October 30, 2022.

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

41)

Order Type and Number:	Consent Order 22-165-RW
Order Date:	October 17, 2022
Individual/Entity:	**Hammett Crossing Homeowners Association**
Facility:	Hammett Crossing
Location:	8A Ager Court Greer, SC 29650
Mailing Address:	10 Patewood Drive, Suite 270 Greenville, SC 29615
County:	Greenville
Previous Orders:	None
Permit/ID Number:	23-491-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Hammett Crossing Homeowners Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Greenville County, South Carolina. The Department conducted inspections on July 15, 2022, and August 12, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; the bathrooms did not have soap; the drinking

water fountain was not operating properly; the flow meter was not operating properly; and the chlorine level was not within the acceptable range of water quality standards.

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 November 1, 2022.

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

42)

Order Type and Number:	Consent Order 22-166-RW
Order Date:	October 18, 2022
Individual/Entity:	**Prince Homeowners Association, Inc.**
Facility:	Prince Resort at Cherry Grove Pier
Location:	3601 N Ocean Boulevard North Myrtle Beach, SC 29582
Mailing Address:	7400 North Kings Hwy Myrtle Beach, SC 29572
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1447B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)(10)

Summary: Prince Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department issued a Notice of Alleged Violation on October 11, 2022, as a result of a review of Department records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to report to the Department in writing, on a Department approved form, any death, injury, or accident requiring an EMS response, emergency room visit, or hospitalization within seventy-two hours of the occurrence.

Action: The Individual/Entity is required to submit an incident report to the Department by October 28, 2022. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**$400.00**) by November 7, 2022.

Update: The Individual/Entity submitted the required incident report to the Department. The civil penalty has been paid and the Consent Order is closed.

43)

Order Type and Number:	Consent Order 22-169-RW
Order Date:	October 20, 2022
Individual/Entity:	**BF Landings West Ashley, LLC**
Facility:	Ashford Riverview
Location:	1476 Orange Grove Road Charleston, SC 29407
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-066-1

Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: BF Landings West Ashley, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 3, 2022, and July 28, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a lifeline with floats was not attached to the pool wall; a transition line was not present; the chlorine level was not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; there was only one "No Lifeguard On Duty – Swim At Your Own Risk" sign posted; the recirculation and filtration system was leaking; depth marker tiles were broken; a gate did not self-close and latch; and the facility address was not posted at the emergency notification device.

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 November 9,2022.

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

44)

Order Type and Number:	Consent Order 22-170-RW
Order Date:	October 21, 2022
Individual/Entity:	**KNP Hospitality, Inc.**
Facility:	Rodeway Inn
Location:	2311 Ashley Phosphate Road Charleston, SC 29418
Mailing Address:	Same
County:	Charleston
Previous Orders:	21-097-RW ($680.00)
Permit/ID Number:	10-265-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: KNP Hospitality, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 6, 2022, and August 15, 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 drinking water fountain and foot rinse shower were not operating properly; the fill spout was not stainless steel or equivalent; the pH level was not within the acceptable range of water quality standards; the life ring was deteriorated; the pool rules sign was not completely filled out; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; and the lifeline floats were not properly spaced.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)** by November 6, 2022.

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

45) Order Type and Number: Consent Order 22-171-RW
Order Date: October 21, 2022
Individual/Entity: **Carriage Hill Horizontal Property Regime**
Facility: Carriage Hill Apartments
Location: 5225 Clemson Avenue
Columbia, SC 29206
Mailing Address: 1905 Sunset Boulevard, Suite E
West Columbia, SC 29169
County: Richland
Previous Orders: None
Permit/ID Number: 40-009-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Carriage Hill Horizontal Property Regime (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 21, 2022, and July 26, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a depth marker tile was cracked; the bolt cover on the handrail was broken with a sharp edge; a ladder was bent; there was a water hose was on the pool deck and the hose did not have a backflow prevention device, the deck as uneven with sharp edges; there was grout missing between the deck and coping; a skimmer was missing a weir; a gate did not self-close and latch, the entry gate was propped open; a section of the perimeter had openings greater than four inches; the chlorine level was not within the acceptable range of water quality standards; both of the "Shallow Water – No Diving Allowed" signs posted were obstructed; and both main drain grates only had one screw.

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 November 4, 2022.

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

46) Order Type and Number: Consent Order 22-172-RW
Order Date: October 21, 2022
Individual/Entity: **Forest Acres Gym, LLC**
Facility: MUV Fitness Forest Acres
Location: 4114 Forest Drive
Columbia, SC 29201
Mailing Address: 800 Columbiana Drive, Suite 201
Irmo, SC 29063
County: Richland
Previous Orders: None
Permit/ID Number: 40-1113D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Forest Acres Gym, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Richland County, South Carolina. The Department conducted inspections on June 21, 2022, and July 26, 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 spa floor was dirty; there was mold on the deck; the water level was too low; there was debris in the skimmer baskets; skimmers were missing weirs; the bathrooms were dirty; the sauna had mold on the walls and floor; the chlorine level was not within the acceptable range of water quality standards; the main drain grates did not have screws; the facility address was not posted at the emergency notification device; and the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted were obstructed.

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 November 7, 2022.

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

47)

Order Type and Number:	Consent Order 22-167-RW
Order Date:	October 24, 2022
Individual/Entity:	**Belfair Homeowners' Association, Inc.**
Facility:	Belfair
Location:	100 Belfair Way Irmo, SC 29063
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-408-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Belfair Homeowners' Association, Inc. (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, July 25, 2022, and August 8, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; there was standing water on the deck; skimmers were missing weirs; the pool equipment room was not accessible; the emergency notification device was not operating properly; the pool rules sign was not completely filled out and did not have all of the required rules; the current pool operator of record information was not posted to the public; the chlorine and pH levels were not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; there were chlorine sticks in the skimmer baskets; there was algae on the pool floor and walls; the pool furniture was not at least four feet from the pool edge; the water level was too high; and skimmer baskets were floating.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand, forty dollars ($2,040.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, forty dollars **($2,040.00)** by November 2, 2022**.**

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

48) Order Type and Number: Consent Order 22-168-RW
Order Date: October 24, 2022
Individual/Entity: **AVR MSP Columbia, LLC**
Facility: Atlantic at Park Ridge Apartments
Location: 356 Lake Murray Boulevard
Irmo, SC 29063
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-1158B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: AVR MSP Columbia, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on July 11, 2022, and August 15, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was standing water on the deck; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; a ladder was not tight and secure; the water line tiles were dirty; and the water level was too high.

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 November 2, 2022.

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

49) Order Type and Number: Consent Order 22-173-RW
Order Date: October 24, 2022
Individual/Entity: **Honey Ridge Villas Homeowners Association, Inc.**
Facility: Honey Ridge Villas
Location: 204 Oakmont Avenue
Ladson, SC 29456
Mailing Address: Same
County: Dorchester
Previous Orders: None
Permit/ID Number: 18-014-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Honey Ridge Villas Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. The Department conducted inspections on June 3, 2022, and August 16, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: depth marker tiles were broken; there was a hose on the pool deck causing a trip hazard; the bathroom did not have toilet paper during the first inspection and was not accessible during the second inspection; the chlorine level was not within the acceptable

range of water quality standards; and the life ring did not have a permanently attached rope.

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 November 2, 2022.

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

50)

Order Type and Number:	Consent Order 22-174-RW
Order Date:	October 24, 2022
Individual/Entity:	**Maniben, LLC**
Facility:	Quality Inn and Suites
Location:	7251 Garners Ferry Road Columbia, SC 29209
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-356-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Maniben, 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 July 7, 2022, and August 10, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a depth marker tile was cracked; the pool floor was dirty, the plaster on the pool floor was deteriorated; the wall tiles were dirty; the step edge tiles were deteriorated; the foot rinse shower was not operating properly; the pool equipment room was not locked; the life ring was not United States Coast Guard approved; the facility address was not posted at the emergency notification device; the pool rules sign did not have all of the required rules; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; and the bound and numbered log book was not maintained a minimum of three times per week by the pool 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 November 7, 2022.

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

51)

Order Type and Number:	Consent Order 22-175-RW
Order Date:	October 24, 2022
Individual/Entity:	**Quail Valley Swim and Racquet Club of Irmo**
Facility:	Quail Valley Swim and Racquet Club of Irmo

Location:	1361 Country Squire Road Columbia, SC 29212
Mailing Address:	Same
County:	Lexington
Previous Orders:	None
Permit/ID Number:	32-075-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Quail Valley Swim and Racquet Club of Irmo (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 June 30, 2022, and August 3, 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 plaster on the pool floor was deteriorated; the frost proof tiles were missing on the pool wall; tiles were missing on the pool floor; the pool deck was not clear of hazards; skimmers were missing weirs; the pool equipment room was not locked; a light in the pool wall was out of its niche; the life ring was deteriorated; the emergency notification device was not approvable; and one of the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted did not have the correct wording.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of sixty-eight dollars ($68.00). The Individual/Entity shall pay a civil penalty in the amount of sixty-eight dollars **($68.00)** by November 5, 2022.

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

52)

Order Type and Number:	Consent Order 22-176-RW
Order Date:	October 24, 2022
Individual/Entity:	**Hudson Myrtle Beach, LLC**
Facility:	Inspire Coastal Grand
Location:	1749 Sea Pine Boulevard Myrtle Beach, SC 29577
Mailing Address:	102 Autumn Hall Drive, Suite 210 Wilmington NC 28403
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-2069B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Hudson Myrtle Beach, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 30, 2022, and September 6, 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 gate was open; the pH level was not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis on the first inspection; and the bound and numbered log book was not available for review on the second inspection.

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 November 3, 2022.

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

53) Order Type and Number: Consent Order 22-177-RW
Order Date: October 25, 2022
Individual/Entity: **Coopers Ridge Apartments, LLC**
Facility: Coopers Ridge Apartments
Location: 111 Coopers Ridge Boulevard
Ladson, SC 29456
Mailing Address: Same
County: Dorchester
Previous Orders: 20-108-RW ($680.00)
Permit/ID Number: 08-1037B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Coopers Ridge Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. The Department conducted inspections on June 1, 2022, and August 16, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; skimmer baskets were floating; the bathrooms did not have toilet paper; the chlorine level was not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; and the emergency notification device was not operational.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)** by November 6, 2022.

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

54) Order Type and Number: Consent Order 22-178-RW
Order Date: October 27, 2022
Individual/Entity: **SC 5000F 42M, LLC**
Facility: 42 Magnolia Apartments
Location: 5150 Forest Drive
Columbia, SC 29206
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-335-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: SC 5000F 42M, 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 15, 2022, and July 21, 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; the fill spout was not stainless steel or equivalent; the chlorine and pH levels were not within the acceptable range of water quality standards; gates did not self-close and latch; and the bound and numbered log book was not available for review.

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 November 13, 2022.

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

55)

Order Type and Number:	Consent Order 22-180-RW
Order Date:	October 27, 2022
Individual/Entity:	**Andaman Limited, Inc.**
Facility:	Rodeway Inn
Location:	1725 Kings Highway North Surfside Beach, SC 29575
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1862B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Andaman Limited, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 13, 2022, and July 11, 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 drinking water fountain was not operating properly; the chlorine level was not within the acceptable range of water quality standards; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by November 8, 2022.

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

56)

Order Type and Number:	Consent Order 22-181-RW
Order Date:	October 27, 2022
Individual/Entity:	**New Murrells, LLC**
Facility:	Country Inn & Suites
Location:	1303A Tadlock Drive Murrells Inlet, SC 29576
Mailing Address:	Same
County:	Horry
Previous Orders:	None

Permit/ID Number: 26-M93-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: New Murrells, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 9, 2022, and August 11, 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 pH level was not within the acceptable range of water quality standards; the pool furniture was not at least four feet from the edge of the pool; a light in the pool wall was out of its niche; a gate did not self-close and latch; and the log book was not properly bound and numbered.

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 November 13, 2022.

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

57) Order Type and Number: Consent Order 22-182-RW
Order Date: October 27, 2022
Individual/Entity: **Neely Farm Homeowners Association, Inc.**
Facility: Neely Farm
Location: 1200 Neely Farm Road
Simpsonville, SC 29681
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 23-403-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Neely Farm Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on July 12, 2022, and August 9, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight and secure; skimmers were missing weirs; a light in the pool wall was out of its niche; the emergency notification device was not operational; there was no pool rules sign; the current pool operator of record information was not posted to the public; and a gate did not self-close and latch.

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 November 9, 2022.

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

58) Order Type and Number: Consent Order 22-179-RW
Order Date: October 28, 2022

Individual/Entity: **West Shore Mill, LLC**
Facility: The Reserve at Mill Landing
Location: 809 East Main Street
Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-192-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: West Shore Mill, 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 June 20, 2022, and July 19, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; a tree had fallen across the fence; a gate did not self-close and latch; skimmers were missing weirs; there was no drinking water fountain; there was no foot rinse shower; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not accessible; there was only one "Shallow Water – No Diving Allowed" sign posted; the plaster on the pool floor was deteriorated; the water level was too high; and the bound and numbered log book was not available for review.

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 November 14, 2022.

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

59) Order Type and Number: Consent Order 22-183-RW
Order Date: October 31, 2022
Individual/Entity: **West Shore Lake Carolina, LLC**
Facility: Town Center at Lake Carolina
Location: 20 Helton Drive
Columbia, SC 29229
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-1140B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: West Shore Lake Carolina, 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 1, 2022, and August 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: there was algae on the pool walls and floor; there was debris in the skimmer baskets; skimmers were missing weirs; skimmer baskets were broken; the bathrooms were dirty; the drinking water fountain was not operating properly; the foot rinse shower was not operating properly; the chlorine level was not within the acceptable range of water quality standards; a main drain grate was broken; the emergency notification device was

not operational; the pool rules sign was not completely filled out and did not have all of the required rules; one of the "Shallow Water – No Diving Allowed" signs posted did not have the correct wording and the letters were not the correct size; the letters on one of the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted were not the correct size; the facility could not produce current valid documentation of pool operator certification; the bound and numbered log book was not available for review on the first inspection; the bound and numbered log book was not maintained on a daily basis and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection; the disinfection equipment was not operating properly; a handrail was not tight and secure; and the life ring did not have a permanently attached rope.

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 November 14, 2022.

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

60)

Order Type and Number:	Consent Order 22-184-RW
Order Date:	October 31, 2022
Individual/Entity:	**Milen Enterprises, Inc.**
Facility:	Holiday Inn Express
Location:	2435 Elms Center Road North Charleston, SC 29406
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1135B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Milen Enterprises, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 6, 2022, and August 5, 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 chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by November 21, 2022**.**

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

61)

Order Type and Number:	Consent Order 22-185-RW
Order Date:	October 31, 2022

Individual/Entity:	**The Catalina Homeowners' Association, Inc.**
Facility:	Catalina Manor
Location:	206 1st Ave N N Myrtle Beach, SC 29582
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1588B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: The Catalina Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on July 6, 2022, and August 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: a ladder was missing bumpers; the plaster on the pool floor was deteriorated; a skimmer basket was floating; the gate did not self-close and latch; the bound and numbered log book was not available for review; the pool floor was dirty; a skimmer was missing a weir; and the chlorine level was not within the acceptable range of water quality standards.

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 November 17, 2022.

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

62)

Order Type and Number:	Consent Order 22-186-RW
Order Date:	October 31, 2022
Individual/Entity:	**RLJ C Charleston HD Lessee, LLC**
Facility:	Courtyard Marriott Charleston
Location:	125 Calhoun Street Charleston, SC 29440
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-577-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: RLJ C Charleston HD Lessee, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 7, 2022, and August 10, 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 chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; and the cyanuric acid level was not recorded weekly in the bound and numbered log book.

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 November 7, 2022.

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

Water Pollution Enforcement

63) Order Type and Number: Consent Order 22-061-W
Order Date: October 26, 2022
Individual/Entity: **J L Anderson**
Facility: J L Anderson CO. Inc.
Location: Widow Johnson Road, Chesterfield, SC, 29550
Mailing Address: P.O. Box 430 Cheraw SC 29520
County: Chesterfield
Previous Orders: None
Permit/ID Number: SCG730388
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110 (d) and Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(a), and SCG730388

Summary: JL Anderson (Individual/Entity) owns and is responsible for the proper operation and maintenance of its mine in Chesterfield County, South Carolina. On June 23, 2022, a Notice of Violation was issued as a result of pH violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to comply with limitations of Permit SCG730388 for pH.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by November 26, 2022; conduct a six (6) monitoring 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 four thousand five hundred dollars ($4,500.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand five hundred dollars **($4,500.00)** by November 26, 2022.

Update: The civil penalty has been paid in full. The Individual/Entity is in communication with Department staff regarding submittal of its written notification of corrective action completion date.

64) Order Type and Number: Consent Order 22-062-W
Order Date: October 26, 2022
Individual/Entity: **Berkeley County Water & Sewer Authority**
Facility: BCW&SA, Lower Berkeley WWTF
Location: 2111 Red Bank Road

Goose Creek, SC 29445
Mailing Address: 212 Oakley Plantation Drive
Moncks Corner, SC 29461-5036
County: Berkeley
Previous Orders: 21-064-W ($5,250.00)
Permit/ID Number: SC0046060
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: Berkeley County Water & Sewer Authority (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Berkeley County, South Carolina. On July 18, 2022, a Notice of Violation was issued as a result of violations of the permitted discharge limits for Ammonia-nitrogen (Ammonia) 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 Ammonia.

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 November 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 total civil penalty in the amount of three thousand ($3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars **($3,000.00)** by November 26, 2022.

Update: The Individual/Entity paid the civil penalty and has submitted its notification of the completion date for all necessary corrective actions.

65) Order Type and Number: Consent Order 22-063-W
Order Date: October 26, 2022
Individual/Entity: **Blackstream Development, LLC**
Facility: Lake Stone Development Project
Location: Highway 101 and McElrath Road
Woodruff, SC 29388
Mailing Address: 5 Century Drive, Suite 210
Greenville, SC 29607
County: Spartanburg
Previous Orders: None
Permit/ID Number: SCR10Z7FY
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-90(a), and Water Pollution Control Permits and S.C. Code Ann Regs. 61-9.122.41(a) and (e)

Summary: Blackstream Development, LLC (Individual/Entity) is responsible for land disturbing activity at a development project in Spartanburg County, South Carolina. The Department conducted inspections on January 27, 2022, and March 2, 2022, and observed unsatisfactory conditions at the land disturbance site. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: discharged sediment into the environment, including into waters of the State, in

a manner other than in compliance with a permit issued by the Department, and failed to install and properly operate and maintain all erosion and sediment controls as specified in the approved SWPPP as required by the Permit.

Action: The Individual/Entity is required to: prevent sediment from leaving the Site, repair or replace faulty BMPs; clear waste and debris, perform and record weekly inspections; properly stabilize the Site by November 26, 2022; and submit a Notice of Termination (NOT) within thirty days of achieving permanent stabilization of the Site. The Department has assessed a total civil penalty in the amount of seven thousand two hundred dollars ($7,200.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand two hundred dollars **($7,200.00)** by November 26, 2022.

Update: The Individual/Entity has paid the civil penalty and has submitted documentation reporting that deficiencies have been corrected at the Site.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

66)

Order Type and Number:	Administrative Order 22-116-FOOD
Order Date:	October 5, 2022
Individual/Entity:	**Jason Criscillis**
Facility:	313 Cafe
Location:	807 Bypass 123, Suite C Seneca, SC 29678
Mailing Address:	P. O. Box 311 Six Mile, SC 29682
County:	Oconee
Previous Orders:	None
Permit Number:	37-206-01287
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: 313 Cafe (Individual/Entity) operates a retail food establishment in Oconee County, South Carolina. The Department conducted inspections on April 7, 2022, June 29, 2022, July 7, 2022, and July 14, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be smooth, durable, and easily cleanable for areas where retail food establishment operations are conducted; and failed to ensure that wall and ceiling covering materials are attached so that they are easily cleanable.

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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

Update: On November 21, 2022, the Department mailed via First Class and Certified Mail a Notice of Intent to Suspend Permit.

67) Order Type and Number: Consent Order 22-164-FOOD
Order Date: October 5, 2022
Individual/Entity: **Zorba's of St. Andrews**
Facility: Zorba's of St. Andrews
Location: 6169 St. Andrews Road
Columbia, SC 29210
Mailing Address: Same
County: Lexington
Previous Orders: 2018-206-03-111 ($800.00);
2018-206-03-134 ($800.00);
2020-206-03-009 ($1,500.00); and
21-26-FOOD ($1,000.00)
Permit Number: 32-206-00882
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Zorba's of St. Andrews (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on October 6, 2021, July 25, 2022, August 4, 2022, August 12, 2022, and August 23, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure employees wash hands after engaging in activities that contaminate their hands; failed to obtain food from sources that comply with law; failed to ensure that time/temperature control for safety foods 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; failed to ensure that physical facilities were maintained in good repair; and 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 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)**.

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

68) Order Type and Number: Consent Order 22-165-FOOD
Order Date: October 6, 2022
Individual/Entity: **Araceli Ochoa Bello and**
Andrea Ochoa Bello
Facility: Araceli Ochoa Bello and
Andrea Ochoa Bello
Location: 115 Batson Drive, Lot 202
Greenville, SC 29617
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit Number: None

Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Araceli Ochoa Bello and Andrea Ochoa Bello (Individual/Entity) operate a mobile retail food establishment in Greenville County, South Carolina. The Department conducted investigations on July 24, 2022, and August 3, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: provided food to the public without a valid permit issued 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 two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2,000.00)** in installments with the final payment being by January 7, 2023.

Update: The Individual/Entity is current on the agreed upon payment plan.

69) Order Type and Number: Consent Order 22-174-FOOD
Order Date: October 6, 2022
Individual/Entity: **Quagliata Brothers Italian Deli**
Facility: Quagliata Brothers Italian Deli
Location: 4999 Carolina Forest Boulevard, #5
Myrtle Beach, SC 29579
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-14310
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Quagliata Brothers Italian Deli (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 14, 2021, March 4, 2022, and July 26, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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.

70) Order Type and Number: Consent Order 22-175-FOOD
Order Date: October 6, 2022
Individual/Entity: **Soho Steak & Seafood**
Facility: Soho Steak & Seafood
Location: 407 21st Avenue North

		Myrtle Beach, SC 29577
	Mailing Address:	Same
	County:	Horry
	Previous Orders:	None
	Permit Number:	26-206-13723
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Soho Steak & Seafood (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on October 5, 2021, August 12, 2022, and August 22, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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.

71)	Order Type and Number:	Consent Order 22-177-FOOD
	Order Date:	October 6, 2022
	Individual/Entity:	**Piggly Wiggly #158**
	Facility:	Piggly Wiggly #158
	Location:	208 East McIntyre Street Mullins, SC 29574
	Mailing Address:	724 Attwood Circle Mt. Pleasant, SC 29464
	County:	Marion
	Previous Orders:	None
	Permit Number:	33-206-01263
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Piggly Wiggly #158 (Individual/Entity) operates a restaurant located in Florence County, South Carolina. The Department conducted inspections on October 5, 2021, October 14, 2021, and March 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 foods 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.

72) Order Type and Number: Consent Order 22-180-FOOD
Order Date: October 6, 2022
Individual/Entity: **Wendy's #8119**
Facility: Wendy's #8119
Location: 2462 Highway 501
Conway, SC 29526
Mailing Address: 3105 Glenwood Avenue, Suite 103
Raleigh, NC 27612
County: Horry
Previous Orders: None
Permit Number: 26-206-06793
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Wendy's #8119 (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on November 18, 2021, April 13, 2022, and August 9, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

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.

73) Order Type and Number: Consent Order 22-181-FOOD
Order Date: October 6, 2022
Individual/Entity: **Michael's Pizza, Pasta & Grill**
Facility: Michael's Pizza, Pasta & Grill
Location: 1701 North Kings Highway
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: 2018-206-06-033 ($2,000.00)
Permit Number: 26-206-07160
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Michael's Pizza, Pasta & Grill (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on December 2, 2021, December 9, 2021, August 15, 2022, and August 25, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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 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.

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 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.

74)

Order Type and Number:	Consent Order 22-182-FOOD
Order Date:	October 11, 2022
Individual/Entity:	**Little Caesar's Pizza #8**
Facility:	Little Caesar's Pizza #8
Location:	610 Highway 1 South Lugoff, SC 29078
Mailing Address:	P. O. Box 290743 Columbia, SC 29229
County:	Kershaw
Previous Orders:	None
Permit Number:	28-206-00570
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Little Caesar's Pizza #8 (Individual/Entity) operates a restaurant located in Kershaw County, South Carolina. The Department conducted inspections on August 8, 2022, August 18, 2022, and August 25, 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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

75)

Order Type and Number:	Consent Order 22-185-FOOD
Order Date:	October 11, 2022
Individual/Entity:	**Cook Out**
Facility:	Cook Out
Location:	205 Highway 17 North North Myrtle Beach, SC 29582
Mailing Address:	15 Laura Lane, Suite 300 Thomasville, NC 27260
County:	Horry
Previous Orders:	None

Permit Number: 26-206-13549
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Cook Out (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on December 14, 2021, May 20, 2022, May 27, 2022, and August 26, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable.

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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

76) Order Type and Number: Consent Order 22-173-FOOD
Order Date: October 12, 2022
Individual/Entity: **KJ's Market #36**
Facility: KJ's Market #36
Location: 543 St. Andrews Road
Columbia, SC 29210
Mailing Address: P. O. Box 1629
Lake City, SC 29560
County: Lexington
Previous Orders: 2020-206-03-009 ($1,500.00); and
21-26-FOOD ($1,000.00)
Permit Number: 32-211-06210
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: KJ's Market #36 (Individual/Entity) operates a retail market located in Lexington County, South Carolina. The Department conducted an inspection on August 29, 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: The Individual/Entity has met all requirements of the Order. This Order has been closed.

77) Order Type and Number: Consent Order 22-178-FOOD
Order Date: October 13, 2022
Individual/Entity: **IGA Deli/Bakery #51**

Facility: IGA Deli/Bakery #51
Location: 325 West Wesmark Boulevard
Sumter, SC 29150
Mailing Address: P. O. Box 1629
Lake City, SC 29560
County: Sumter
Previous Orders: None
Permit Number: 43-206-00991
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: IGA Deli/Bakery #51 (Individual/Entity) operates a restaurant located in Sumter County, South Carolina. The Department conducted inspections on August 9, 2022, August 18, 2022, and August 25, 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 ensure that an air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment was at least twice the diameter of the water supply inlet and not be less than one (1) inch.

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)** by November 13, 2022.

Update: If payment is not received by December 1, 2022, the Department will issue a payment Demand Letter.

78) Order Type and Number: Consent Order 22-197-FOOD
Order Date: October 13, 2022
Individual/Entity: **Menkoi Ramen House**
Facility: Menkoi Ramen House
Location: 493-1 Town Center Place
Columbia, SC 29229
Mailing Address: 801 East Springs Road
Columbia, SC 29223
County: Richland
Previous Orders: None
Permit Number: 40-206-09050
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Menkoi Ramen House (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on August 25, 2022, August 31, 2022, and September 7, 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.

79) Order Type and Number: Consent Order 22-200-FOOD
Order Date: October 14, 2022
Individual/Entity: **Cook Out – Anderson, Inc.**
Facility: Cook Out – Anderson, Inc.
Location: 3432 Clemson Boulevard
Anderson, SC 29625
Mailing Address: 15 Laura Lane, Suite 300
Thomasville, NC 27360
County: Anderson
Previous Orders: None
Permit Number: 04-206-03897
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Cook Out – Anderson, Inc. (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on June 7, 2022, August 18, 2022, August 26, 2022, and September 1, 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.

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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

80) Order Type and Number: Consent Order 22-99-FOOD
Order Date: October 17, 2022
Individual/Entity: **Domino's**
Facility: Domino's
Location: 509 Highway 17 North
North Myrtle Beach, SC 29582
Mailing Address: Same
County: Horry
Previous Orders: 2018-206-06-149 ($1,600.00)
Permit Number: 26-206-13368
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Domino's (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on November 2, 2021, June 15, 2022, June 23, 2022, June 30, 2022, and July 8, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to comply with the Hazard Analysis and Critical Control Point (HACCP) plan and procedures that are submitted and approved as a basis for a modification or waiver; and failed to maintain and provide to the Department, upon request, records that demonstrate the HACCP plan is being employed.

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 three thousand dollars ($3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars **($3,000.00)**.

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

81)

Order Type and Number:	Consent Order 22-100-FOOD
Order Date:	October 17, 2022
Individual/Entity:	**Pearls**
Facility:	Pearls
Location:	3106 Highway 17 South Atlantic Beach, SC 29582
Mailing Address:	P. O. Box 1091 North Myrtle Beach, SC 29586
County:	Horry
Previous Orders:	None
Permit Number:	26-206-13339
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Pearls (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on October 13, 2021, June 14, 2022, and June 23, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure a sink with at least three (3) compartments was provided for manually washing, rinsing, and sanitizing equipment and utensils.

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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

82)

Order Type and Number:	Consent Order 22-169-FOOD
Order Date:	October 17, 2022
Individual/Entity:	**Fat Daddy's BBQ, LLC**
Facility:	Fat Daddy's BBQ, LLC

Location:	115 H. Hampton Avenue Greenwood, SC 29646
Mailing Address:	Same
County:	Greenwood
Previous Orders:	None
Permit Number:	24-206-03117
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Fat Daddy's BBQ, LLC (Individual/Entity) operates a restaurant located in Greenwood County, South Carolina. The Department conducted inspections on February 9, 2022, May 11, 2022, and August 11, 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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

83)

Order Type and Number:	Consent Order 22-171-FOOD
Order Date:	October 17, 2022
Individual/Entity:	**Applebee's #85029**
Facility:	Applebee's #85029
Location:	3441 Clemson Boulevard Anderson, SC 29621
Mailing Address:	450 North Brand Boulevard Glendale, CA 91203
County:	Anderson
Previous Orders:	None
Permit Number:	04-206-04521
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Applebee's #85029 (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on July 12, 2022, July 21, 2022, and July 27, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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.

84) Order Type and Number: Consent Order 22-191-FOOD
Order Date: October 17, 2022
Individual/Entity: **Food Lion #2209 Market**
Facility: Food Lion #2209 Market
Location: 1085 Old Clemson Highway
Seneca, SC 29672
Mailing Address: P. O. Box 1330
Salisbury, NC 28145
County: Oconee
Previous Orders: None
Permit Number: 37-211-00891
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Food Lion #2209 Market (Individual/Entity) operates a retail market located in Oconee County, South Carolina. The Department conducted inspections on August 16, 2022, August 25, 2022, and September 1, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide water at a temperature of at least 100 degrees F through a mixing valve or combination faucet at the handwashing sink(s) and failed to ensure that the temperature of the wash solution in manual warewashing equipment was maintained at not less than 110 degrees F (43 degrees C), or the temperature as specified on the cleaning agent manufacturer's label instructions.

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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

85) Order Type and Number: Consent Order 22-208-FOOD
Order Date: October 17, 2022
Individual/Entity: **Burger King #9035**
Facility: Burger King #9035
Location: 1381 Bells Highway
Walterboro, SC 29488
Mailing Address: P. O. Box 1517
Walterboro, SC 29488
County: Colleton
Previous Orders: None
Permit Number: 15-206-00320
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Burger King #9035 (Individual/Entity) operates a restaurant located in Colleton County, South Carolina. The Department conducted inspections on June 16, 2022, August 8, 2022, and September 8, 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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

86)

Order Type and Number:	Consent Order 22-210-FOOD
Order Date:	October 17, 2022
Individual/Entity:	**Margarita's Mexican Restaurant**
Facility:	Margarita's Mexican Restaurant
Location:	9906 North Kings Highway Myrtle Beach, SC 29572
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit Number:	26-206-09305
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Margarita's Mexican Restaurant (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on April 19, 2022, August 24, 2022, and September 1, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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.

87)

Order Type and Number:	Consent Order 22-214-FOOD
Order Date:	October 17, 2022
Individual/Entity:	**Four Points**
Facility:	Four Points
Location:	101 Fantasy Harbour Boulevard Myrtle Beach, SC 29579
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit Number:	26-206-14207
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Four Points (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 9, 2021, March 16, 2022, and September 1, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: 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.

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.

88)

Order Type and Number:	Consent Order 22-95-FOOD
Order Date:	October 20, 2022
Individual/Entity:	**Agave Mexican Grill**
Facility:	Agave Mexican Grill
Location:	1430 Ribaut Road Port Royal, SC 29935
Mailing Address:	Same
County:	Beaufort
Previous Orders:	2017-206-08-010 ($1,600.00)
Permit Number:	07-206-02515
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Agave Mexican Grill (Individual/Entity) operates a restaurant located in Beaufort County, South Carolina. The Department conducted inspections on October 8, 2021, October 18, 2021, June 14, 2022, and June 17, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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 provide equipment sufficient in number and capacity to maintain food temperatures for cooling and heating food and holding cold and hot food.

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)** by November 20, 2022.

Update: If payment is not received by December 1, 2022, the Department will issue a payment Demand Letter.

89)

Order Type and Number:	Consent Order 22-190-FOOD
Order Date:	October 21, 2022
Individual/Entity:	**Maria Antonia Maza-Lopez**
Facility:	Dona Tona Mexican Restaurant

Location: 3221 Highway 701 North
Conway, SC 29526
Mailing Address: 1207 Pink Lane
Conway, SC 29527
County: Horry
Previous Orders: None
Permit Number: 26-206-13969
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Dona Tona Mexican Restaurant (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on March 3, 2022, July 26, 2022, August 5, 2022, August 11, 2022, August 18, 2022, August 26, 2022, and September 15, 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; 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. 61-25The Department has assessed a total civil penalty in the amount of three thousand four hundred dollars ($3,400.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand four hundred dollars **($3,400.00)** in installments.

Update: The Individual/Entity is current on the agreed upon payment plan.

90) Order Type and Number: Consent Order 22-193-FOOD
Order Date: October 20, 2022
Individual/Entity: **T W Boon's**
Facility: T W Boon's
Location: 405 Main Street
Greenwood, SC 29646
Mailing Address: Same
County: Greenwood
Previous Orders: None
Permit Number: 24-206-01680
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: T W Boon's (Individual/Entity) operates a restaurant located in Greenwood County, South Carolina. The Department conducted inspections on July 27, 2022, July 28, 2022, August 3, 2022, and August 11, 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)** in installments.

Update: The Individual/Entity is current on the agreed upon payment plan.

91)

Order Type and Number:	Consent Order 22-206-FOOD
Order Date:	October 20, 2022
Individual/Entity:	**ACM Fatz, VII, LLCV d/b/a Fatz**
Facility:	ACM Fatz, VII, LLCV d/b/a Fatz
Location:	1361 West Wade Hampton Blvd, Suite A Greer, SC 29650
Mailing Address:	1361 West Wade Hampton Blvd, Suite F, #6 Greer, SC 29650
County:	Greenville
Previous Orders:	None
Permit Number:	23-206-12155
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: ACM Fatz, VII, LLCV d/b/a Fatz (Individual/Entity) operates a mobile retail food establishment located in Greenville County, South Carolina. The Department conducted inspections on July 27, 2022, August 3, 2022, and September 12, 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)** by November 20, 2022.

Update: The Department called the Individual/Entity on November 28, 2022, requesting the payment to be paid.

92)

Order Type and Number:	Consent Order 22-83-FOOD
Order Date:	October 25, 2022
Individual/Entity:	**Tokyo Express**
Facility:	Tokyo Express
Location:	250 Highway 17 North North Myrtle Beach, SC 29582
Mailing Address:	Same
County:	Horry
Previous Orders:	21-24-FOOD ($500.00)
Permit Number:	26-206-13707
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Tokyo Express (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on October 26, 2021, March 29, 2022, and May 26, 2022. The Individual/Entity has violated the South

Carolina Retail Food Establishment Regulation as follows: 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.

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)** in installments.

Update: The Individual/Entity is current on the agreed upon payment plan.

93)

Order Type and Number:	Consent Order 22-168-FOOD
Order Date:	October 25, 2022
Individual/Entity:	**John's Country Cooking ©**
Facility:	John's Country Cooking ©
Location:	5923 Highway 28 North Iva, SC 29639
Mailing Address:	607 George Alewine Road Due West, SC 29639
County:	Abbeville
Previous Orders:	None
Permit Number:	01-206-00937
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: John's Country Cooking © (Individual/Entity) operates a restaurant located in Abbeville County, South Carolina. The Department conducted inspections on July 14, 2022, July 21, 2022, and July 28, 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 four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

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

94)

Order Type and Number:	Consent Order 22-194-FOOD
Order Date:	October 25, 2022
Individual/Entity:	**Subway**
Facility:	Subway
Location:	302 Pearman Dairy Road Anderson, SC 29625
Mailing Address:	Same
County:	Anderson
Previous Orders:	None
Permit Number:	04-206-04035

Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Subway (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on August 26, 2022, September 1, 2022, and September 8, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

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.

95) Order Type and Number: Consent Order 22-204-FOOD
Order Date: October 25, 2022
Individual/Entity: **El Mariachi**
Facility: El Mariachi
Location: 1078 Sunset Boulevard
West Columbia, SC 29169
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit Number: 32-211-05825
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: El Mariachi (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on May 3, 2022, June 29, 2022, July 8, 2022, and August 25, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods; failed to ensure that time/temperature control for safety foods 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 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 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 November 25, 2022.

Update: The Department received a check on November 15, 2022, but the check was not written out to SC DHEC. The Department called the Individual/Entity on November 15, 2022, requesting a check payable to SC DHEC.

96) Order Type and Number: Consent Order 22-205-FOOD

Order Date: October 25, 2022
Individual/Entity: **Tacos Locos & Grill**
Facility: Tacos Locos & Grill
Location: 103 N. 12th Street, Suite D
West Columbia, SC 29169
Mailing Address: Same
County: Lexington
Previous Orders: 2019-206-03-111 ($4,800.00);
2020-206-03-005 ($2,000.00); and
22-114-FOOD ($500.00)
Permit Number: 32-206-06745
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Tacos Locos & Grill (Individual/Entity) operates a retail food establishment located in Lexington County, South Carolina. The Department conducted inspections on June 27, 2022, July 6, 2022, and August 25, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods; 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 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)** by November 27, 2022.

Update: If payment is not received by December 1, 2022, the Department will issue a payment Demand Letter.

97) Order Type and Number: Consent Order 22-207-FOOD
Order Date: October 25, 2022
Individual/Entity: **El Mercadito Chiapanelo**
Facility: El Mercadito Chiapanelo
Location: 1801 Park View Road
Conway, SC 29526
Mailing Address: Same
County: Horry
Previous Orders: 21-126-FOOD ($500.00)
Permit Number: 26-206-14500
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: El Mercadito Chiapanelo (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on January 10, 2022, June 27, 2022, July 7, 2022, August 26, 2022, and September 2, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods; failed to use effective methods to cool cooked time/temperature control for safety foods; and 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.

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 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.

98) Order Type and Number: Consent Order 22-211-FOOD
Order Date: October 25, 2022
Individual/Entity: **Crabby George's Seafood Buffet**
Facility: Crabby George's Seafood Buffet
Location: 7904 North Kings Highway
Myrtle Beach, SC 29572
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-12625
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Crabby George's Seafood Buffet (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 2, 2022, June 10, 2022, June 15, 2022, September 2, 2022, and September 12, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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 two thousand four hundred dollars ($2,400.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand four hundred dollars **($2,400.00)**.

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

99) Order Type and Number: Consent Order 22-160-FOOD
Order Date: October 26, 2022
Individual/Entity: **ACM Fatz VII, LLC**
Facility: ACM Fatz VII, LLC
Location: 212 Wall Street
Camden, SC 29020
Mailing Address: 4324 Wade Hampton Blvd.
Taylors, SC 29687
County: Kershaw
Previous Orders: 21-13-FOOD
Permit Number: 28-206-00814
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: ACM Fatz VII, LLC (Individual/Entity) operates a restaurant located in Kershaw County, South Carolina. The Department conducted inspections on September 16, 2021, July 21, 2022, July 29, 2022, and August 15, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements; failed to ensure that physical facilities were maintained in good repair; and 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 five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)** by November 26, 2022.

Update: If payment is not received by December 1, 2022, the Department will issue a payment Demand Letter.

100)

Order Type and Number:	Consent Order 22-201-FOOD
Order Date:	October 26, 2022
Individual/Entity:	**San Jose Mexican Restaurant**
Facility:	San Jose Mexican Restaurant
Location:	115 North Point Drive Lexington, SC 29073
Mailing Address:	107 Maple Road Lexington, SC 29073
County:	Lexington
Previous Orders:	None
Permit Number:	32-206-07138
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: San Jose Mexican Restaurant (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on December 16, 2021, September 1, 2022, September 2, 2022, September 8, 2022, and September 14, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure employees wash hands after engaging in activities that contaminate their hands; failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control; 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 ensure that the plumbing system was installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the retail food establishment; and 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 two thousand nine hundred dollars ($2,900.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand nine hundred dollars **($2,900.00)**.

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

101) Order Type and Number: Consent Order 22-212-FOOD
Order Date: October 26, 2022
Individual/Entity: **The Wicked Tuna Rooftop Bar and Grill**
Facility: The Wicked Tuna Rooftop Bar and Grill
Location: 110 North Ocean Boulevard
Myrtle Beach, SC 29575
Mailing Address: 1503 Brookgreen Drive
Myrtle Beach, SC 29577
County: Horry
Previous Orders: None
Permit Number: 26-206-13970
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: The Wicked Tuna Rooftop Bar and Grill (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on March 22, 2022, August 23, 2022, and August 31, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

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.

102) Order Type and Number: Consent Order 22-209-FOOD
Order Date: October 28, 2022
Individual/Entity: **Callibaker's Firehouse**
Facility: Callibaker's Firehouse
Location: 910 Lake Arrowhead Road
Myrtle Beach, SC 29572
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-13377
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Callibaker's Firehouse (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on March 2, 2022, August 31, 2022, and September 9, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods 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.

103)

Order Type and Number:	Consent Order 22-236-FOOD
Order Date:	October 28, 2022
Individual/Entity:	**Express China**
Facility:	Express China
Location:	2005 Harden Street Columbia, SC 29204
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit Number:	40-206-07919
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Express China (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on July 13, 2022, July 22, 2022, and September 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 foods 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)** by November 28, 2022.

Update: None at the time of this report.

On-Site Wastewater Enforcement

104)

Order Type and Number:	Administrative Order 22-057-OSWW
Order Date:	September 23, 2022
Individual/Entity:	**Sharon Knight**
Facility:	Sharon Knight
Location:	1815 Williams Circle Lancaster, SC 29720
Mailing Address:	1881 Edgeport Drive Lancaster, SC 29720
County:	Lancaster
Previous Orders:	None

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

Summary: Sharon Knight (Individual/Entity) owns property located in Lancaster County, South Carolina. The Department conducted an investigation on April 26, 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: Department staff continue to monitor the site as there have been some challenges making confirmation of any repairs and/or the current status.

105) Order Type and Number: Consent Order 22-058-OSWW
Order Date: October 14, 2022
Individual/Entity: **Charles Porter, III, DBA Trae's Clearing & Grading, LLC**
Facility: Charles Porter, III, DBA Trae's Clearing & Grading, LLC
Location: Gateway Outpost, Sitton Mill Road
Seneca, SC 29676
Mailing Address: 256 Cedar Hill Road
Six Mile, SC 29682
County: Oconee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Charles Porter, III, DBA Trae's Clearing & Grading, LLC (Individual/Entity), installed a large OSWW system on property located in Oconee County, South Carolina. The Department conducted a review of submitted documents on August 25, 2022, and determined that sub-systems of the large OSWW system were installed outside the parameters of the permit to construct and Reg. 61-56. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: constructing an OSWW system outside the parameters of the permit to construct, using pipes of a schedule lower than specified in the regulation, and not installing infiltration trenches perpendicular to the direction of the slope and parallel to the contour of the land per the regulation.

Action: The Individual/Entity is required to cease and desist installing OSWW system outside the parameters of the permit to construct and outside the requirements of Reg. 61-56. 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: The Individual/Entity has met all requirements of the Order. This Order has been closed.

106) Order Type and Number: Consent Order 22-059-OSWW
Order Date: October 17, 2022
Individual/Entity: **Jay E. Floyd, Professional Engineer for Ragan Smith**
Facility: Jay E. Floyd, Professional Engineer for Ragan Smith
Location: Gateway Outpost, Sitton Mill Road Seneca, SC 29676
Mailing Address: 1410 Cowart Street, Suite 200 Chattanooga, TN 37408
County: Oconee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Jay E. Floyd, Professional Engineer for Ragan Smith (Individual/Entity) was the professional engineer for a large OSWW system installed on property located in Oconee County, South Carolina. The Department conducted a review of submitted documents on August 25, 2022, and determined that sub-systems of the large OSWW system were installed outside of the parameters of the permit to construct and Reg. 61-56. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: constructing an OSWW system outside the parameters of the permit to construct, using pipes of a schedule lower than specified in the regulation, and not installing infiltration trenches perpendicular to the direction of the slope and parallel to the contour of the land per the regulation.

Action: The Individual/Entity is required to cease and desist installing OSWW systems outside the parameters of the permit to construct and outside the requirements of Reg. 61-56. 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: The Individual/Entity has met all requirements of the Order. This Order has been closed.

107) Order Type and Number: Consent Order 22-054-OSWW
Order Date: October 19, 2022
Individual/Entity: **Ivan Rusev, DBA Rock Solid Excavation Services, LLC**
Facility: Ivan Rusev, DBA Rock Solid Excavation Services, LLC
Location: 2933 Pacolet Highway Gaffney, SC 29340
Mailing Address: 140 Wilkins Road Campobello, SC 29322

County:	Cherokee
Previous Orders:	22-033-OSWW
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Ivan Rusev, DBA Rock Solid Excavation Services, LLC (Individual/Entity), installed an OSWW system at a property located in Cherokee County, South Carolina. Department personnel conducted a review of records and documents that were submitted to the Department during late June through July 2022. Department personnel determined that the OSWW system was installed outside the permitted location and that the documentation was submitted to the Department later than the required two business days. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: they constructed an OSWW system not in accordance with the permit and did not supervise their employees in the construction of the OSWW system for which they were responsible.

Action: The Individual/Entity is required to cease and desist installing OSWW systems outside the parameters of the permit. 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.

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

Date: December 8, 2022

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

From: Bureau of Planning and Construction

Re: Public Hearing for Notice of Final Regulation Amending R. 61-15, *Certification of Need for Health Facilities and Services*, Document No. 5136

I. Introduction

The Bureau of Planning and Construction ("Bureau") proposes the attached Notice of Final Regulation amending R. 61-15, *Certification of Need for Health Facilities and Services* be filed with the Legislative Council to be forwarded to the Speaker of the House and President of Senate with a request for General Assembly review. Legal authority resides in 1976 Code Sections 44-7-110 through 44-7-340, which requires the Department of Health and Environmental Control ("Department") to establish standards to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), requires General Assembly review of these amendments. The amendments will take legal effect as of the date of publication in the *State Register*.

II. Facts

1. The Bureau proposes amending R. 61-15 to update provisions in accordance with stakeholder input and recommendations from the Legislative Audit Council.

2. The Department had a Notice of Drafting published in the June 24, 2022, *State Register*. The Department received 96 public comments by July 25, 2022, the close of public comment period.

3. The Department held a stakeholder meeting to discuss the Notice of Drafting on July 20, 2022, with 67 participants.

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

5. Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received 17 public comments by October 24, 2022, the close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

6. The Department held a stakeholder meeting to discuss the Notice of Proposed Regulation on October 4, 2022, with 25 participants.

7. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

The Bureau of Planning and Construction respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-15, *Certification of Need for Health Facilities and Services*, for filing with the Legislative Council for review by the General Assembly.

Gwen Thompson
Director
Healthcare Quality

Dr. Trenessa Jones, DSL
Director
Bureau of Planning and Construction

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

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

December 8, 2022

Document No. 5136
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 44-7-110 through 44-7-340

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

Synopsis:

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 amends 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's amendments also include adding, removing, and modifying definitions contained within the regulation. The Department updated 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 amendments revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The amendments also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

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

Instructions:

Replace R. 61-15 in its entirety with this amendment.

Section-by-Section Discussion of 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.

Section	Type of Change	Purpose
101. Purpose.	Revision	Amended to add the word "care" to make the terminology 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 errors.
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.

Section	Type of Change	Purpose
Ambulatory Surgical Facility 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	Deletion	Deleted these definitions because they are otherwise 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

Section	Type of Change	Purpose
		with the LAC recommendation 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 will be provided on the web-based 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 will be provided on the web-based 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.

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

SECTION 101. Purpose.

The purpose of ~~these~~this ~~R~~regulations ~~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 costs, 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~~or 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 this 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 twelveeighteen (1218) months from the date of issuance. If the proposalexempted project is not implemented within this twelveeighteen-month period, the exemption becomes void and another exemption must be requested in order for the applicant to undertake the proposalproject. 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 butand 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 102103.1.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 thousandtwo million dollars ($600,0002,000,000) or adjusted, as in Section 102103.1.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 thousandtwo million dollars ($600,0002,000,000) 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 thesethis regulations; 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~~ are 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 cCertificate of nNeed review, as defined inpursuant to Section 102103 of thesethis regulations, 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 Carolinathe 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~~

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 amends 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 amendments also include adding, removing, and modifying definitions contained within the regulation. The Department updated 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 amendments revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The amendments 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 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 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 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 18 criteria. Overall, the Department's amendments aim to increase flexibility and minimize the undue burden to the regulated community.

DETERMINATION OF COSTS AND BENEFITS:

The Department anticipates the 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 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 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 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 establishment 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 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 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 has not been substantively revised since 2003 and needs to be updated to reflect current technology and industry standards. These amendments aim to decrease the undue burden on the regulated community and include allowing for a modernized Certificate of Need application format and process, increasing the timeframes for determinations (exemption and non-applicability) from 12 months to 18 months, and streamlining, modernizing, and consolidating the project review criteria from 33 criteria to 18 criteria, which includes the addition of a quality of care criterion.

The Department is also addressing the Legislative Audit Council (LAC) recommendations published in their February 2022 report, including 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 anticipates decreased costs and increased benefits to the regulated community by improving the application process and increasing the monetary thresholds that trigger Certificate of Need review. Without the amendments, the Department will be obligated to continue enforcing the regulatory requirement to receive two copies of a Certificate of Need application on 8 ½ x 11-inch paper, one side only, and 3-hole punched on the left side.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 5136
R. 61-15, *Certification of Need for Health Facilities and Services*

As of the October 24, 2022, close of the Notice of Proposed Regulation comment period:

NAME	SECTION
Ed Bender, SC Hospital Association	General

COMMENT:
On behalf of SCHA and the ninety-three (93) hospitals that comprise its membership, please accept this letter commending the South Carolina Department of Health and Environmental Control's ("DHEC" or the "Department") work on this proposed regulation.

As stated in your "determination of need and reasonableness" for the regulation, the last substantive revision to this document was in 2003. And even longer in the case of the medical equipment and capital expenditure thresholds, whose figures date back to 1993. SCHA believes South Carolina's certificate of need ("CON") laws, including these regulations, need modernization, but as the healthcare providers for millions of South Carolinians, SCHA knows the vital role CON plays in protecting quality and containing the cost of healthcare in this state. These proposed revisions are the first step in modernizing South Carolina's CON program.

Many comments to the existing regulation called for the repeal of CON or to make changes prohibited by law. SCHA appreciates the Department's adherence to the rules governing agency rulemaking and its unwillingness to act beyond the scope of its authority when drafting these revisions. SCHA strongly believes each of the changes proposed to 61-15 are firmly within the grant of authority given to DHEC by the General Assembly. For example, in the CON statutes, the General Assembly plainly states DHEC has the authority via regulation to prescribe amounts for medical equipment and capital expenditures. S.C. Code Ann. § 44-7-160 (3) & (6). In doing so, the Department is merely following that legislative directive. For opponents of CON to claim DHEC is usurping legislative authority by raising these thresholds is purely false.

Furthermore, SCHA supports the Department's decision to revise the regulation right now. As previously mentioned, it has been nearly two decades since the last revision. Additionally, the Legislative Audit Council ("LAC") outlined several DHEC-specific areas where the Department could improve CON, all of which are addressed in this proposal. Given the outdated nature of the text and the legislative request for improvement, DHEC's choice to revise the regulation now is welcomed and appropriate.

In closing, SCHA thanks the Department for its work revising the CON regulations and we support the proposals as drafted. We look forward to continuing our organizations' strong partnership working to better the health of all South Carolinians.

DEPARTMENT RESPONSE: Acknowledged.

NAME	SECTION
James Chin	General

COMMENT:
General Impression: Overall feel the amendments are fair and does bring certain economic Thresholds current.

DEPARTMENT RESPONSE: Acknowledged.

NAME	SECTION
Holly Pisarik, SC Medical Association	General

COMMENT:
1. Certificate of Need laws in South Carolina have failed to achieve their intended purpose and updates to the Certificate of Need regulation cannot change that.

Pursuant to S.C. Code 44-7-120, South Carolina's purpose in first enacting CON sixty years ago was to promote cost containment, prevent unnecessary duplication of health care facilities, and guide the establishment of health facilities and services to best serve public needs. However, numerous research studies have shown that CON laws have failed to achieve their intended goals.[1] CON has instead become a way to claim territory and to restrict the entry of new competitors. This weakens the market's ability to contain health care costs, undercuts consumer choice, stifles innovation, and leads to reduced quality and access.[2]

- The Mercatus Center of George Mason University, a not-for-profit university-based research center, has studied the effects of CON in South Carolina. Mercatus finds that the state's CON laws are associated with per capita healthcare spending that is higher than it would be without CON. [3]

- The Mercatus Center also has considered whether CON impacts health care quality. It does; and not for the better. Mercatus reports that the most recent research "suggests that deaths from treatable complications following surgery and mortality rates from heart failure, pneumonia, and heart attacks are all statistically significantly higher among hospitals in CON states than hospitals in non-CON states.

- One national study found that "[O]btaining CONs for new technology may take upward of 18 months, delaying facilities from offering the most-advanced equipment to patients and staff. Such issues also reportedly affect providers' ability in some states to recruit top-tier specialist physicians."[4]

- The Mercatus Center has concluded that CON programs are associated not just with fewer hospitals overall, but also with fewer rural hospitals, fewer rural ASCs, and fewer rural hospice care facilities.[5] Moreover, without CON, South Carolina would have 43 percent more rural hospitals than currently.[6]

- The Federal Trade Commission and the U.S. Department of Justice have reviewed CON laws, including South Carolina's, and found them to be anticompetitive.7. Accordingly, the two antitrust enforcement agencies urged South Carolina to repeal its CON laws.[8]

DEPARTMENT RESPONSE: Acknowledged. Repeal of CON laws requires action by the General Assembly.

NAME	SECTION

Holly Pisarik, SC Medical Association	General

COMMENT:

2. Updates to the Certificate of Need regulation cannot implement some of the Legislative Audit Counsel's most important recommendations.

Our understanding is that the agency is moving forward with this process, in large part, to respond to the Legislative Audit Council's review of the agency's Certificate of Need Program dated February 2022 (Review). This Review contains thirteen recommendations, five of which can only be accomplished by the SC General Assembly. Two of the recommendations that could have the most impact on increasing access and lowering costs fall within those that must be accomplished by the SC General Assembly –

- The S.C. General Assembly should reform or repeal the State Certification of Need and Planning Act to exclude any review of low-cost facilities and equipment such as MRI machines and ambulatory surgical centers.

- The S.C. General Assembly should consider restricting or regulating other anti-competitive practices in the healthcare industry, such as non-compete agreements.

CON programs are a significant barrier to the market entry of freestanding outpatient facilities, including ambulatory surgical centers (ASCs). ASCs have been found in numerous studies of quality to have complication rates that are low and patient satisfaction that is high.[9] For example, a study published in Health Affairs concluded that ASCs "provide a lower-cost alternative to hospitals as venues for outpatient surgeries."[10]

The efficiencies of ASCs and their added benefit of raising the performance of competing community hospitals also have been acknowledged by the FTC and DOJ:

Ambulatory surgery centers offered patients more convenient locations, shorter wait times, and lower coinsurance than hospital departments. Technological innovations, such as endoscopic surgery and advanced anesthetic agents, were a central factor in this success. Many traditional acute care hospitals have responded to these market innovations by improving the quality, variety, and value of their own surgical services, often developing on-or off-site ambulatory surgery centers of their own.[11]

Notwithstanding the potential of an outpatient facility to offer new, lower cost, more convenient or higher quality services, the facility faces the added time, cost and uncertainty of the CON approval process. To win approval, applicants must have the deep pockets to spend exorbitant amounts on lawyers and consultants to prepare CON applications. The process for obtaining a CON can take years and can cost tens or even hundreds of thousands of dollars in preparation costs. Ultimately the process could prohibit entry or expansion outright if the CON is denied. Consequently, the onerous cost and process of undergoing CON review and the uncertain outcome has a distinct chilling effect on seeking to enter markets in competition with incumbent providers. Thus, states such as South Carolina that require CONs for ambulatory surgical centers have, on average, 14 percent fewer such centers.[12]

Because the agency cannot implement some of the most important of the LAC's recommendation to repeal CON for low-cost equipment, ASCs, and other anti-competitive measures, any changes will have little impact on increasing access and lowering cost.

[9] *See* Casalino L *et al. Focused factories? Physician-owned Specialty Facilities,* Health Affairs (Millwood) 2003; 22 (6) 56-67 ("Casalino").
[10] *See* Munnich and Parente, *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up,* Health Affairs, 33 no. 5 (2014): 764-769.
[11] Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform (September 15, 2008).
[12] Mercatus, Lessons from Research at 5.

DEPARTMENT RESPONSE: The Department identified the CON regulation as needing amending independent of and prior to receiving the LAC audit.

NAME	SECTION
Holly Pisarik, SC Medical Association	General

COMMENT:

3. Although Certificate of Need should be repealed, not updated through regulation, to the extent they are updated, those updates should be substantial.

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 proposes amendments to the Regulation, we comment on the following:

A. Proposed Increase in Threshold for Acquisition of Medical Equipment for Diagnosis and Treatment is Too Low

In the amendments, the Department proposes an increase in the threshold for the total project cost for the acquisition of medical equipment which is to be used for diagnosis or treatment from six-hundred thousand to two million dollars.

First, the Department is ostensibly proposing amendments to comply with the recommendations of the LAC. The LAC recommended elimination of CON for low-cost equipment such as MRI machines. Although the Department does not have the authority to eliminate such a requirement, if it were truly trying to comply with the LAC recommendation, it would not set such a conservative threshold. **Under the proposed increased threshold, out of all of the MRI machines for which an applicant has applied for a CON since 2021, only 1 of the 7 would have fallen under the proposed threshold.** ($1,226,862, $2,484,316, $2,611,159, $2,672,282, $3,038,620, $2,654,407, $4,702,000). **All other applicants would still have had to apply for a CON.**

In fact, of the 40 CON applications filed since 2021 for the acquisition of medical equipment for diagnosis and treatment, 32 of the 40 applicants would still have had to apply for a CON under the proposed increased threshold. Two of the 8 that would have been exempt are very close to the threshold, so the slightest increase in construction and/or equipment costs, and they would have had to apply for a CON as well.

Second, although the bill to repeal or significantly reform CON did not pass, what was passed in the Senate and introduced in the House gives a clear indication that the proposed $2 million threshold is too low and does not comport with legislative will. The Senate passed S.290 this past legislative session which would have totally eliminated the need for a CON for the acquisition of medical equipment for diagnosis and treatment. The Chair of the CON Ad Hoc Committee introduced an amendment to S.290

which set an increased threshold to **$3.5 million for the equipment cost, not even the total project cost.**

Accordingly, the SCMA recommends the threshold be increased to at least five million dollars if the standard is still to remain the total project cost, rather than cost of equipment.

B. Proposed Increase in Threshold for Capital Expenditures is Too Low

In the amendments, the Department proposes an increase in the threshold for capital expenditures by or on behalf of a healthcare facility from two-million dollars to five-million dollars.

Again, although the bill to repeal or significantly reform CON did not pass, what was passed in the Senate and introduced in the House gives a clear indication that the proposed $5 million threshold is too low and does not comport with legislative will. The Senate passed S.290 this past legislative session which would have totally eliminated the need for a CON for capital expenditures by or on behalf of a healthcare facility.

The Chair of the CON Ad Hoc Committee introduced an amendment to S.290 which set an increased threshold to **$7.5 million for capital expenditures.**

The SCMA recommends increasing the threshold to $10 million.

C. Eliminate Certain Services in the State Health Plan to Which CON Applies

The SCMA believes that 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.

D. Implement Additional 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 promote cost containment as required by the statute, 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, quality data, CEO and other executive salary, bond ratings, among other things considered relevant by the department).

DEPARTMENT RESPONSE: Not adopted.
3a. The amendments proposed by the Department address the four purposes of the CON program. They are to promote cost containment, prevent unnecessary duplication of healthcare facilities and services, guide the establishment of healthcare facilities and services which will best serve public need, and ensure that high-quality services are provided in the State.
3b. After researching CON program thresholds in neighboring states, the Department determined these thresholds were in line with US inflation calculator. Using the calculator, with 1993 figures as a base, the equipment threshold would have calculated to $1.5M. The proposed amendment lists the threshold at $2M for equipment.

3c. CONs are required for ASFs because the CON Act defines healthcare facility to include ASFs and requires a CON for construction/establishment of an ASF. Thus, to the extent SCMA is seeking ASFs to be exempt from CON review, legislative action by the General Assembly would be required.
3d. Currently, the applicant is required to submit cost and charity care (indigent care) as part of the application process.

NAME	SECTION
James Chin	102.1

COMMENT:
State of TN recently added a limitation based on distance to limit the number of opposition filing arbitrary suits.

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. **Furthermore, persons filing as an affected party whose facility address is greater than 30 miles from the proposed CON application's facility site are ineligilbe** [sic] **to qualify as an affected party.** ~~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.~~

DEPARTMENT RESPONSE: Not adopted. The Department is bound by statutory definitions.

NAME	SECTION
Elizabeth Fletcher, Spartanburg Regional Healthcare System	102.10

COMMENT:
Section 102. Definitions
10. Like Equipment with Similar Capabilities (Page 16)
The definition as written states that the "functional and technological capabilities are identical to the equipment to be replaced;". SRHS recommends the word "identical" be removed since it would be impossible to replace a piece of equipment with an identical match. Given that most pieces of equipment that are being replaced are between fifteen and twenty years old, the equipment has been modernized and therefore it is not identical. To remain consistent with the definition, SRHS suggests the definition be revised to "functional and technological capabilities are consistent with the equipment to be replaced;"

DEPARTMENT RESPONSE: Not adopted. The Department is bound by statutory definitions.

NAME	SECTION
Shelley Pifer, Lexington Medical Center	102.10

COMMENT:
10. Like equipment with similar capabilities. - Lexington Medical Center recommends deleting the word "identical" in this definition.

DEPARTMENT RESPONSE: Not adopted. The Department is bound by statutory definitions.

NAME	SECTION
James Chin	102.17

COMMENT:

Need to be specific in cases that involve a mix of non-medical area and medical area and/or if the equipment is used part of the time as in mobile MRIs.

Purchase price can be debated, suggest you use the market appraisal of the county. You should also include language to allow the department to request for 3rd party appraisal if needed.

~~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 costs, 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~~ or** buildings will be calculated based on the total value **or prorated value as in the building specific to the medical sq footage or equipment if the equipment is used part time such as mobile MRI** (**~~purchase price~~ Market appraisal as defined by the county**) of the equipment or building being leased.

DEPARTMENT RESPONSE: Not adopted. The Department will look at the total project cost on a case-by-case basis and apply GAAP when applicable.

NAME	SECTION
Elizabeth Fletcher, Spartanburg Regional Healthcare System	103

COMMENT:

Section 103. Applicability

1(c) and 1(f): Thresholds for Equipment and Capital Expenditures (Pages 17 - 18)

Spartanburg Regional Healthcare System supports and appreciates the Department increasing the capital expenditure threshold to $5,000,000; the equipment threshold to $2,000,000; and indexing both for inflation. Since the current thresholds have been in place for decades, they are severely outdated.

DEPARTMENT RESPONSE: Acknowledged.

NAME	SECTION
Shelley Pifer, Lexington Medical Center	103

COMMENT:

Overall, Lexington Medical Center is in favor of all changes made to Section 103, especially raising the capital expenditure threshold from $2,000,000 to $5,000,000 and the medical equipment threshold from $600,000 to $2,000,000.

DEPARTMENT RESPONSE: Acknowledged.

NAME	SECTION
Sara Sears, Self Regional Healthcare	103.1

COMMENT:

Self Regional supports the increased threshold of $5,000,000.

Self Regional supports the increased threshold of $2,000,000. Remove the requirement of total project cost.

DEPARTMENT RESPONSE: Acknowledged and not adopted. The Department cannot remove the total project cost from the equipment threshold CON requirement. This would require legislative change by the General Assembly.

NAME	SECTION
Sara Sears, Self Regional Healthcare	104.1

COMMENT:
Eliminate exemption determination requirement for replacement of equipment for which a CON was already acquired.

DEPARTMENT RESPONSE: Not adopted. The Department is required to follow statutory requirements.

NAME	SECTION
Sara Sears, Self Regional Healthcare	105.1

COMMENT:
Elimination of non-applicability determination for replacement of like equipment with similar capabilities.

DEPARTMENT RESPONSE: Not adopted. The Department is required to follow statutory requirements.

NAME	SECTION
Shelley Pifer, Lexington Medical Center	301

COMMENT:
Lexington Medical Center is in support of a web-based application.

DEPARTMENT RESPONSE: Acknowledged.

NAME	SECTION
Elizabeth Fletcher, Spartanburg Regional Healthcare System	301

COMMENT:
Section 301. Submission of Application
1: Web-based application (Page 27)
Spartanburg Regional Healthcare System supports and appreciates the Department's efforts to implement an electronic application to modernize the CON application and review process. As part of the design and development of the electronic application, Spartanburg Regional Healthcare System would encourage the capability of making the electronic application available to others to streamline the Freedom of Information request process if possible.

DEPARTMENT RESPONSE: Acknowledged.

NAME	SECTION
M. Elizabeth Crum, Burr & Forman LLP	604

COMMENT:
SECTION 604. 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 results 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 results in the transfer and the subsequent voidance of the Certificate of Need.

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.

4. This section 604 is not applicable when an entity holding an unfulfilled Certificate of Need is subject to a purchase transaction involving one or more affiliated entities that own at least two licensed health care facilities, where the unfulfilled CON is a part of and not the object of the purchase transaction.

DEPARTMENT RESPONSE: Not adopted. The Department is bound by statutory requirements. The suggested changes would extend or modify statute.

Date: December 8, 2022

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

From: Bureau of Radiological Health

Re: Public Hearing for Notice of Final Regulation Amending R.61-64, *X-Rays (Title B)*, Document No. 5138

I. Introduction

The Bureau of Radiological Health proposes the attached Notice of Final Regulation amending R.61-64, *X-Rays (Title B)*. Legal authority resides in S.C. Code Section 13-7-40 et seq., which directs the Department of Health and Environmental Control ("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. The amendments will take legal effect as of the date of publication in the *State Register*.

II. Facts

1. The Bureau proposes amending R. 61-64 to update provision in accordance with stakeholder input and recommendations from collaborative bodies including the Conference of Radiation Control Program (CRCPD), Food and Drug Administration (FDA), National Council on Radiation Protection and Measurements (NCRP), American College of Radiology (ACR), and the American National Standards Institute (ANSI).

2. The Department had a Notice of Drafting published in the February 25, 2022, *State Register*. The Department received over 70 comments during the public comment period that ended March 28, 2022.

3. Appropriate Department staff conducted regular scheduled internal reviews of the proposed amendments from February until October.

4. The Department held a stakeholder meeting to discuss the Notice of Drafting on March 16, 2022.

5. Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received public comments from 67 comments from 17 individuals by the October 24, 2022, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

6. The Department held a stakeholder meeting to discuss the Notice of Proposed Regulation on October 11, 2022.

7. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board during the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

The Bureau of Radiological Health respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R. 61-64, *X-Rays (Title B)* for filing with the Legislative Council for review by the General Assembly.

Gwen Thompson
Director
Healthcare Quality

Susan E. Jenkins
Director
Bureau of Radiological Health

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-64, *X-Rays (Title B)*

December 8, 2022

Document No. 5138
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 13-7-40 et seq.

61-64. X-Rays (Title B).

Synopsis:

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 amends R.61-64, X-Rays (Title B) to include, but 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 also amends requirements regarding registration, inspections, violations, enforcement, equipment, and mammography. The 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 also included changes such as corrections for readability, grammar, punctuation, codification, and other such regulatory text improvements.

The Department had a Notice of Drafting published in the February 25, 2022, *South Carolina State Register*.

Instructions:

Replace R.61-64 in its entirety with this amendment.

Section-by-Section Discussion of 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. 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. Revised language in regulation to enable the Department to make a determination on a case-by-case basis regarding Radiation Safety Committees.
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/Revision	Deleted retrofit allowance because it is no longer relevant. Revised proposed NPR strike-through of RHB 3.9.4 and amended regulation to include a date threshold.
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. Revised RHB 3.12.3.1.3 to require calculated dose for lost or damaged personnel badges only for individuals that meet RHB 4.12.4. Added language to RHB 3.12.5.1 to allow the use of a one-badge calculated effective dose equivalent. Removed language from RHB 3.12.5.2.1 that required the use of an effective dose equivalent at 25% of the maximum permissible dose. Revised RHB 3.12.5.2.2 to replace quarterly requirements to no less than twice per year.
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.
4.1 – Scope	Addition	Amended Scope to include the establishment of the requirements for shielding for all Parts of this regulation.
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. Revised 4.2.13 to clarify exposure at skin entrance limits based on anatomical size.
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. Amended to add scope for shielding. Revised proposed NPR language to require a shielding plan for a period of five (5) or more consecutive days. Revised proposed NPR language to require the completion of the area survey within thirty (30) days of the installation of the x-ray

		equipment. The survey must be provided to the facility at the time of completion or within 30 days of the completion of the survey. The survey must be provided to the Department within thirty (30) days of the completions of the survey.
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. Revised proposed NPR language to require a shielding plan for a period of five (5) or more consecutive days.
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. Revised 4.11.2 to allow for the use of exposure switches located inside CT rooms to align with industry standard design and practices.
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. Revised proposed NPR language to clarify exposure at skin entrance limits based on anatomical size
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. Revised NPR language to ensure compliance is demonstrated through the evaluation of common exams at each facility. Revised NPR language regarding Radiation Output for Brain Perfusions has been removed to align with industry practices.

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. Revised proposed NPR definition of Licensed Practitioner to replace with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The formula image in 10.39 was deleted and replaced with text.
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.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-64. X-Rays (Title B).

Statutory Authority: S.C. Code Sections 13-7-40 et seq.

Table of Contents

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 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 thesethis regulations 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 maila 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 mustshall not include the patient's name or other information that could lead to identification of the patient. The written report mustshall 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:			
-	Major	Moderate	Minor

Potential for Harm:	(11-30)	(4-10)	(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 fFacility 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:

2.6.6.6.12.7.8.5.1 The applicant must pPossess a current radioactive materials license if instrument calibration is done utilizing radioactive materials or registration authorizing radiation instrument calibration;

2.6.6.6.22.7.8.5.2 Training in principles of radiation protection;

2.6.6.6.32.7.8.5.3 Training in operation and calibration of radiation detection and measurement instrumentation;

2.6.6.6.42.7.8.5.4 One (1) year experience in an instrument calibration laboratory; and

2.6.6.6.52.7.8.5.5 Shall submit a description of the procedures that will be utilized in performing instrument calibrations.

2.6.6.72.7.8.6 Class VII - Therapeutic facility and shielding design, area radiation survey, orand calibration:

2.6.6.7.12.7.8.6.1 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

2.6.6.7.22.7.8.6.2 Having the following minimum training and experience:

2.6.6.7.2.12.7.8.6.2.1 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

2.6.6.7.2.22.7.8.6.2.2 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;.

2.6.6.7.32.7.8.6.3 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.

2.6.6.7.42.7.8.6.4 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).

2.6.6.82.7.8.7 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 officerRadiation 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; or2.7.8.7.2 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.~~On a case-by-case basis, and 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~~January 1, 1994, 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 provide a replacement device. If the individual requires monitoring per RHB 3.12.4, the Radiation Safety Officer shall calculate the exposure for the time period from issuance to loss or damage of the 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, except as provided in 3.12.5.2.1.1.

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, 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~~ Semi-annual 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.

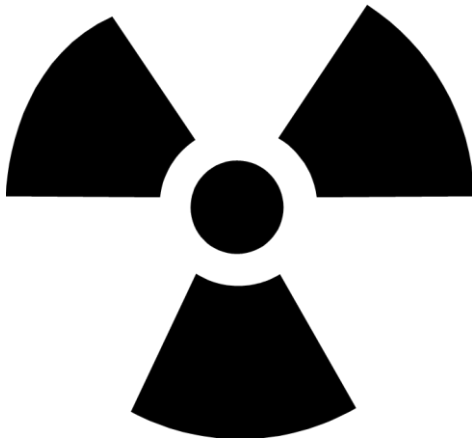
3.13.4 The registrant shall establish the controls required by RHB 3.13.1 and 3.13.3 in a way that does not prevent individuals from leaving a high radiation area.

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. This Part also establishes requirements for shielding for all Parts of this regulation.

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 for the specified anatomical thicknesses 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~~

X-Ray Tube Voltage (kilovolt peak)				
Designed Operating Range	**Measured Operating Potential**	**Minimum HVL (mm in Aluminum)**		
		Specified Dental Systems [1]	**Other X-Ray Systems [2]**	**Other X-Ray Systems [3]**
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.
[3] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

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.

The following requirements for shielding apply to all Parts of this regulation.

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) or more 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 The survey shall be completed within thirty (30) calendar days of installation of the x-ray equipment. 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 completion of the survey. 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.~~2~~1.2 A written request shall be made by a Class ~~V~~III, 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.~~3~~1.3 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 4.3~~this 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 ~~7~~seven 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 ~~5~~five centimeters by ~~5~~five centimeters (5 cm x 5 cm).

RHB 4.8. Mobile and Portable Radiographic ~~Equipment~~Systems.

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-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.

4.8.5 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-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.

4.8.7 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~~ five (5) or more 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: $\overline{T} \geq 5(Tmax - Tmin)$.

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): $\overline{E} \geq 5(Emax - Emin)$.

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, except when performing procedures requiring the use of exposure switches located on or near the CT gantry and designed to provide a delay before initiating x-rays and provided all requirements of RHB 4.2.9 are met.

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 ~~Spot 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 for the anatomical thicknesses 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~~Exemptions ~~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 clinically performed at the facility to include the source-to-image receptor distance (SID) used. If at least one of these exams is not represented in Appendix D, an exam type listed in Appendix D clinically performed at the facility shall also be evaluated. (Techniques clinically used by the facility must be used to evaluate patient exposure at skin entrance) (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)*~~Xray 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.)~~

DENTAL

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 used to evaluate patient exposure at skin entrance) (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. Inspections 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~~ddose" 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~~ssurface" 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), 1 Gy=100 rad. In air, 1 Gy 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 (1) 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).

~~9.59~~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~~5.9.1 and 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 licensed practitioner as defined in the Medical Radiation Health and Safety Act, Chapter 74, Title 44 of the South Carolina Code of Laws.

~~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 doseexcept when that individual is receiving an occupational dose.

9.15510.146 “Minor” means an individual lessyounger 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 20twenty 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 10ten percent (10%).

9.156.5) When the calculated weekly treatment dose exceeds the weekly prescribed dose by 30thirty 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 “NormalNominal 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 (1) 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 assembly" 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; ~~shall~~ 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; ~~shall~~ 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.~~

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: R.61-64, X-Rays (Title B)

Purpose: The Department amends R.61-64, X-Rays (Title B) to include, but 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 amends requirements regarding registration, inspections, violations, enforcement, equipment, patient shielding, and mammography. The 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 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 amendments. The revisions related to the new NCRP recommendations are a substantial change to the longstanding, 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 REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments are necessary to update provisions with current practices and standards and to improve the overall effectiveness of the regulation.

The 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 amended 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 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 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 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 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. 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 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(A)(3)(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 revise R.61-64.

The following statements and reports were relied upon in developing the 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.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 5138
R.61-64, *X-Rays (Title B)*

As of the October 24, 2022, close of the Notice of Proposed Regulation comment period:

NAME	SECTION
Kelly Bouthillet, SC Nurses Association	General

COMMENT:
It has come to our attention that you all are proposing a DHEC regulation change that would essentially prohibit APRNs (Nurse Practitioners in particular) from conducting ionized fluoroscopy, even with the approved DHEC training. The regulation currently defines (9-13710-132) a "Licensed Practitioner as an individual with professional specialization who has met the criteria as outlined by the SC Department of Labor, Licensing, and Regulation". Our understanding is that DHEC is proposing to delete that language and insert new language to read "Licensed practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state."

The South Carolina Nurses Association strongly opposes the proposed language. Currently, Nurse Practitioners in SC engage in fluoroscopy in their offices, or the office owned by their employers. Furthermore, Nurse Practitioners are reading X-rays (chest X-ray for example) within the office setting. Nurse Practitioners receive graduate training and education on reading X-rays and under DHEC guidance, Nurse Practitioners complete the necessary training to engage in ionized fluoroscopy. Changing the language to restrict this activity to physicians, dentists, podiatrists, chiropractors, and osteopaths will prohibit Nurse Practitioners from engaging in fluoroscopy and impede access to health care, especially in rural or to underserved areas or populations.

We support provider licensing by SC Department of Labor, Licensing, and Regulation. Moreover, we support Nurse Practitioners continue the practice of ionized fluoroscopy as part of their collaborative agreement with their physician(s) who are available for consultation and advice.

DEPARTMENT RESPONSE:
Not Adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
The Coalition for Access to Healthcare Executive Board	General

COMMENT:
It has come to our attention that you all are proposing a DHEC regulation change (R.61-64, X-rays Title B) that would essentially prohibit APRNs (Nurse Practitioners in particular) from conducting ionized fluoroscopy, even with the approved DHEC training. The regulation currently defines (9-13710-132) a "Licensed Practitioner as an individual with professional specialization who has met the criteria as outlined by the SC Department of Labor, Licensing, and Regulation". Our understanding is that DHEC is proposing to delete that language and insert new language to read "Licensed practitioner

means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state."

We strongly oppose the proposed language. Currently, Nurse Practitioners in SC engage in fluoroscopy in their offices, or the office owned by their employers (hospital institution outpatient office, rural health clinic, federally qualified health center for example). Furthermore, Nurse Practitioners are reading X-rays (chest X-ray for example) within the office setting. Nurse Practitioners receive graduate training and education on reading X-rays and under DHEC guidance, Nurse Practitioners complete the necessary training to engage in ionized fluoroscopy.

We support provider licensing by SC Department of Labor, Licensing, and Regulation. Moreover, we support Nurse Practitioners continue the practice of ionized fluoroscopy as part of their collaborative agreement with their physician(s) who are available for consultation and advice. Fluoroscopy is critical to practices who care for underserved and vulnerable populations who cannot access traditional hospital based fluoroscopy due to travel constraints or costs.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute. There is currently no written DHEC guidance or formally approved training for Nurse Practitioners with regard to X-Rays.

NAME	SECTION
Marcia Iszard, SC Association of Nurse Anesthetists	General

COMMENT:
As written, the proposed regulation would prohibit APRNs, specifically Certified Registered Nurse Anesthetists, from utilizing ionized fluoroscopy. The regulation currently defines (9-13710-132) a "Licensed Practitioner as an individual with professional specialization who has met the criteria as outlined by the SC Department of Labor, Licensing, and Regulation," which includes CRNAs. DHEC's proposal has deleted that language and inserted the following: "Licensed practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state."

S.C.A.N.A. strongly opposes the proposed language. Currently, CRNAs utilize fluoroscopy (a form of ionized radiation) according to their national scope of practice provided by their national professional organization[1] and as defined in the SC Nurse Practice Act, Chapter 33, Title 40. CRNAs utilize fluoroscopy in all settings, including office settings, hospitals, outpatient offices, surgery centers, and rural healthcare centers. CRNAs are educated in radiation safety and proper techniques of safe fluoroscopic equipment use.[2]

As drafted, the language will restrict this activity to only physicians, dentists, podiatrists, chiropractors, and osteopaths and will prohibit APRNs (including CRNAs) from utilizing fluoroscopy. We believe this language was unintentional in drafting, which ultimately prohibits APRNs from using this imaging modality. We respectfully request that APRNs, including CRNAs, be included within this language.

The South Carolina Board of Nursing at the SC Department of Labor, Licensing and Regulation is the licensing agency for CRNAs. Within the CRNA practice act, they are required to work within a scope of practice and are opposed to any limitations and restrictions imposed on their scope of practice.

40-33-34 (B) An APRN is subject, at all times, to the scope and standards of practice established by the board-approved credentialing organization representing the specialty area of practice and shall function within the scope of practice of this chapter and must not be in violation of Chapter 47.
ln conclusion, ionized fluoroscopy is critical for practice sites that care for underserved and vulnerable patients. These patients do not have access to traditional hospital services due to travel distances and financial constraints preventing them from traveling far distances to receive healthcare services.

[1] The "Scope of Nurse Anesthesia Practice" (available at aana.com) includes using and supervising the use of ultrasound, fluoroscopy, and other technologies.
[2] See the "Standards for Accreditation of Nurse Anesthesia Programs" (available at coacrna.org).

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Daniel Bozarth, Upstate Carolina Radiology	General

COMMENT:
I am writing this letter over concern about a proposed position statement. The issue involves usage of fluoroscopy and X-ray by advanced practice providers, specifically Physician Assistants and Nurse Practitioners.

I am the Director of Interventional Radiology at Upstate Carolina Interventional Services of Upstate Carolina Radiology. We cover multiple facilities in the upstate including Spartanburg Regional Health Services and Bon Secours Mercy St. Francis in Greenville. We have over thirty partner physicians. We also employ two Physician Assistants and two Nurse Practitioners. They are integral to our IR service and our patient care. Part of their procedural component of their work includes the use of fluoroscopy. Part of their training in interventional radiology includes education of radiation safety and its use. The course is provided by and signed off by our radiation safety officers. The provider then continues to be under direct physician supervision while providing care. All interventional radiologists have been trained and certified in radiation safety and continue to supervise in such manner.

If our advanced practice providers are restricted in their use of fluoroscopy and x-ray there would be drastic and detrimental effects on our ability to provide patient care. We would be unable to provide the level and amount of care we currently provide the upstate. As the South Carolina population continues to grow and age, their assistance in these procedures is vital to our ability to continue with and grow with the community. Any restriction in their usage of imaging guidance will be a detriment to the health of the population of the upstate. We have well trained very experienced providers who continue to be supervised by physicians who are specifically trained and certified in radiation safety.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner"

in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Jason Locke, Upstate Carolina Radiology	General

COMMENT:
I'm an attending interventional radiologist at Upstate Carolina Radiology. I agree with Dr. Daniel Bozarth's letter/comments regarding the need for APP to continue utilizing fluoroscopy services. A loss of APP ability to utilize fluoroscopy will without doubt decrease access for patients in Upstate South Carolina to obtain timely interventional procedures and will eventually lead to worsening healthcare outcomes. Please support the use of fluoroscopy in APP in South Carolina.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Joshua McCain, Lexington Radiology Association	General

COMMENT:
I sent an attached letter to the regulation comment website which fully details our position on the change in language for a "Licensed practitioner". Any change in regulation that prohibits PAs or NPs from using Fluoro [sic] would have serious negative implications for patient access to care and departmental operations for the largest hospital systems in the state (Lexington, Prisma, McCleod, Grand Strand, etc). LLR has been licensing PAs and NPs to perform Fluoro [sic] exams under alleviate supervision as part of their scope of practice for approx [sic] 15 plus years. We should focus on updating the SC Radiation Safety Act to reflect current practice in Radiology. We should not make any regulation changes that would set us back 20 plus years.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Heather Nemeth, Roper St. Francis Healthcare	General

COMMENT:
I fully support the comments submitted by the SCRS on October 5, 2022. Here is an abbreviated version of those comments:

"SCRS Proposes the Following Definition

The 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)] states in section 13 7 40(F): "The

department in connection with the control and regulation of radiation sources, in addition to its other duties as imposed by law shall:"…"(10) promulgate and repeal regulations pertaining to the qualifications of operators applying ionizing or nonionizing radiation to humans.". DHEC has laudably done so through R.61-64, X-rays (Title B). Pursuant this authority, the SCRS proposes DHEC adopt the following definition of Licensed Practitioner, instead of the currently proposed one.

SCRS Proposed Definition:
"Licensed practitioner" means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state; a person licensed as a Radiology Physician Assistant and granted scope of practice inclusive of fluoroscopy by the South Carolina Board of Medical Examiners and included in an Approved Written Scope of Practice Guideline with a radiologist; a person licensed as a Nurse Practitioner by the Board of Nursing when in a Practice Agreement with a Radiologist inclusive of fluoroscopy and with commensurate radiation safety training.

The Use of Fluoroscopy by Licensed Practitioners in the Presence of SCRQSA Certified Radiologic Technologists is a Best Practice

Nothing about these comments negates SCRS's belief that it is best practice for Licensed Practitioners of all advanced degree backgrounds, including MDs, to utilize fluoroscopy with a SCRQSA certified Radiologic Technologist present alongside us as we care for patients. Radiologic Technologists are our colleagues and friends and we have great regard for their specialized training. As a matter of course, in our radiology departments and facilities where fluoroscopy is utilized, it is uniformly done so with a certified Radiologic Technologist present.

SCBME licensed PAs who do not have radiation safety training and who do not have a Radiology PA SOP inclusive of fluoroscopy should be prohibited from performing fluoroscopy in South Carolina and any delegation to such a PA would be in violation of the prohibition found in the Medical Practice Act at 40-47-30(C)."

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Richard Harp, Upstate Carolina Radiology	General

COMMENT:
This letter is in response to the recent motion to exclude APPs from the list of healthcare providers that may utilize limited fluoroscopy. I am the Interventional Chair in Spartanburg for Upstate Carolina Radiology. We employ two NPs and two PAs who are integral to our busy practice. The proposal to revoke these privileges is concerning and will have adverse consequences.

First and foremost patient care delivery will be negatively impacted. Our APPs perform numerous therapeutic and diagnostic procedures that require limited fluoroscopic guidance. Were their privileges to be revoked, it would require that these procedures revert back to the Interventional or Diagnostic radiologist. Our healthcare system continues to be overburdened with increased demand for services coupled with increased staffing retention issues. This is particularly true in more rural settings where recruitment is historically difficult. Preventing qualified APPs from delivery of these services will

exponentially increase wait times for said services, increase healthcare costs, prevent physician providers from focusing on more advanced care delivery and increase physician burnout.

Secondly, under radiologist supervision, our APPs have been proven to deliver safe and effective patient care when utilizing fluoroscopy. One of our NPs was the first APP to be employed in a radiology setting in the state of South Carolina having started her career twenty years ago. Over the past two decades we have expanded our use of APPs. Their safety and proficiency has been demonstrated during that time. The basis for the revised position statement focuses, as it should, on patient safety. There have been no documented incidents of patient injury caused by an APPs fluoroscopy utilization. The sudden exclusion from fluoroscopic use will be detrimental for both the practices that employ the APPs and the patients who depend upon them.

Lastly, the number of APPS employed in Radiology has increased substantially. Although the exact number is unclear, to our knowledge every radiology practice in South Carolina employs multiple mid-level providers. The economic impact for these skilled providers cannot be ignored. Many may lose their jobs due to dramatic volume decreases that will result from the inability to perform fluoroscopic guided procedures. With the need for skilled providers increasing now is not the time to further restrict available resources.

We respect the committees [sic] stance for measures that promote patient safety. However, this blanket statement is unwarranted and it's [sic] basis not supported by actual data. The ramifications will be far reaching and have a substantial impact on an already stressed healthcare system. For these reasons, we respectfully ask that you reconsider and re-write this position statement that will allow for continued APP fluoroscopy privileges.

Respectfully,
Richard Harp, MD, MBA
Chief of Interventional Radiology, Spartanburg Medical Center
Medical Executive Committee Chair

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

Name	Section
Karen Behrns, GE	General

COMMENT:
Amend vendor training. FDA already has requirements for techs and training. Allow omission for 2A and 2B vendors for OEM service providers. Installation can take weeks. Use FDA 2579 instead.

DEPARTMENT RESPONSE:
Not Adopted. Training records must be submitted to the Department to verify compliance with training and education requirements. FDA Form 2579 is not required, making the established monthly notification to the Department necessary.

NAME	SECTION

Paula Jeter, Spartanburg Regional Healthcare System	Appendix F

COMMENT:
Item 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)" - The first part of this requirement specifies most common exams but the term in paranthesis [sic] could be construed as all techniques used clinically. Recommend clarifying this to perform the test for the most common exams.

DEPARTMENT RESPONSE:
Adopted. Clarified exposure at skin entrance limits based on anatomical size.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	Appendix F

COMMENT:
Appendix F Radiographic units
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)

The above would imply that all common exams the site performs requires an ESEE calculation. This needs to be clarified. This should be "Patient exposure at skin entrance, for most common exams (in appendix D) performed at the …".

Appendix F CT units
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)

Please note that for a Brain Perfusion exam most of the dose comes from continuous monitoring of anatomy for contrast. This is patient dependent and cannot be easily measured. In practicality this is monitored by looking at doses from patient images and not from a direct measurement of dose. This needs to be removed from the regulation or a methodology to measure this should be suggested. Please clarify what you are actually wanting for this requirement. We recommend that this should be a protocol review and calculated dose rather than a direct measurement of CTDI.

DEPARTMENT RESPONSE:
Partially Adopted. Clarified to ensure compliance is demonstrated through the evaluation of common exams at each facility. Radiation Output for Brain Perfusions has been removed to align with industry practices.

NAME	SECTION
Prisma	Appendix F

COMMENT:
Appendix F, Computed Tomography (CT), Item 11, requires radiation output for multiple medical protocols. If a specified protocol is not performed at the registrant's facility (e.g., don't scan pediatric patients), are these measurements still required to be documented in the CT performance testing? In addition, brain perfusion output measurements are not typically performed by Class IX vendors; per American College of Radiology (ACR) CT accreditation program, vendors review the protocol for appropriateness only. We recommend removing the requirement to determine radiation output measurements for Brain Perfusion, but incorporating a protocol review if used.

DEPARTMENT RESPONSE:
Adopted. Radiation Output for Brain Perfusions has been removed to align with industry practices.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	1.2.9,4.2.2, and 10.132

COMMENT:
We appreciate BRH's attempt to address the accelerating trend of non-radiologists (both doctors and extenders) performing fluoro-using procedures. I'm a member of SCRS, and I applaud the concepts put forth in the SCRS letter on this topic. The terms "NPs", "PAs", or "licensed practitioners" themselves convey no proof of adequate fluoroscopic training. For that reason, by title alone, these individuals are not qualified. However, if physician extenders 1) work under supervision of radiologists, and 2) receive adequate, documented training, then they can safely and effectively perform fluoroscopy-using procedures. Supervision by radiologists is important because non-radiologist physicians in general do not have sufficient formalized and updated training in radiation safety and dose management. The need for extenders to have documented, and not just ad-hoc, training is self-evident. There are courses available, such as these:

1) AAPA/ASRT Fluoroscopy Online Test Preparatory Course. https://assets-us-01.kc-usercontent.com/406ac8c6-58e8-00b3-e3c1-0c312965deb2/fc83f405-5e22-43eb-ae39-56da51d08718/Fluoroscopy%20Examination%20Content%20Specifications%202018.pdf

2) Fluorosafety's "Advanced Training Program on the Safe Use of Fluoroscopy". https://fluorosafety.com/advanced-training-program/

So, we have acceptable didactic training pathways available. We also have some precedent in SC, through the work done years ago to define a "Radiology Physician Assistant" (RPA) via the Board of Medical Examiners. I'm told this involves a training component as well as a Scope of Practice. However, it only applies to RPAs not NPs, and we have several NPs practicing in identical ways, with similar training, in SC. They must not be disenfranchised by any new regulations; patient care availability would definitely suffer. The most proper way to handle these "pathway issues" would be to have SCRQSA vet and manage training adequacy and documentation, but that may prove unlikely in the short run. If that would happen, a definition of "licensed practitioner" would become more simplified, but for now, we could consider this definition for "licensed practitioner" in 10.132:

"For the purpose of this regulation, Licensed Practitioner means:
1) a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state, or
2) a person who is licensed in this state as a Physician Assistant (PA) or Nurse Practitioner (NP), who additionally meets the requirements of a Radiology PA as defined by the SC Board of Medical Examiners, and who is supervised by a radiologist, or
3) NPs and PAs practicing under supervision of radiologists and in good standing with the state prior to the adoption of these regulations."

(Precedence for this may be found in RHB 2.7 re: vendor grandfathering).

Could also insert some language that allow the Nursing Board to define a pathway for an "RNP" in the future. SCBOME can also handle Continuing Ed requirements if needed. Whatever happens, don't disenfranchise current PAs and NPs working under radiologists currently. Any final version should also be tested against these other potential scenarios: PAs/NPs fluoroing and setting breaks for orthopedic surgeons, speech language pathologists doing their own flouro, PAs/NPs doing fluoro for urologists,

PAs/NPs performing hysterosalpingograms for OB/GYNs. None of these scenarios would be acceptable due to a lack of training and supervision in radiation safety and dose management.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition has been edited to reference the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	1.2.9

COMMENT:
At a minimum, physician assistants (PA) and advanced registerd [sic] nurse practitioners (ARNP) who are already performing such procedures per the South Carolina Medical Board approval should be grandfathered in to continue to practice and to avoid gaps in the ability to provide needed patient care and services.

The new definition affects the ability of physician extenders, such as physician assistants (PA) and advanced registerd [sic] nurse practicioners [sic](ARNP), to continue to perform minor interventional procedures. Since Radiology PA's scope of practice issued by the State Board of Medical Examiners (SBME) includes minor fluoroscopic interventional (FGI) procedures, the regulations should not be limited to exclude them. In addition, before the regulation is changed to exclude licensed practicioners [sic] such as PA's and ARNP's from performing minor FGI procedurs [sic], the regulations should provide a pathway for these medical professionals to meet a similar scope of practice guidelines or specify minimum education & experience requirements. Colorado's regulations are provide [sic] an example for licensure of physician extenders and ongoing continuing education an [sic] training.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition has been edited to reference the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Laura Srebnik, Medical Imaging & Technology Alliance	2.5.1.3

COMMENT:
In our previous comment letter, MITA underscored that currently, Class I/II Vendors are required by 2.5.1.3 to confirm that a registration sticker is present on a control. MITA recommends that 2.5.1.3 is revised to strike ‘as required to be confirmed by RHB 2.8.2’ from the regulation. This should be the sole responsibility of the Facility/Registrant as Class I/II Vendors do not have ownership/control of Facility/Registrant related items.

DEPARTMENT RESPONSE:
Not Adopted. Allows vendor 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

David Vassy, Spartanburg Regional Healthcare	2.7

COMMENT:
Applaud raising the qualifications for those who do dose measurements, and the appropriate use of "grandfathering". However, see 4.4.1ff. When shielding, the distinction between Class VIII (non-medical) and Class IX (Medical) has been dropped. That decreases experience requirement to do medical shielding.

DEPARTMENT RESPONSE:
Acknowledged. Class VIII is specific to non-healing arts. Class IX is specific to healing arts.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	2.7

COMMENT:
Class VIII Vendors (non-healing arts) should not be permitted to perform shielding designs for Healing Arts facilities unless they have experience in Healing Arts shielding. They should be removed from relevant regulations.

DEPARTMENT RESPONSE:
Acknowledged. Class VIII is specific to non-healing arts. Class IX is specific to healing arts.

NAME	SECTION
Laura Srebnik, Medical Imaging & Technology Alliance	2.7.8.2

COMMENT:
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/or servicing of devices.

With respect to 2.7.8.2, Class II A, B and C Vendors: MITA recommends an exception be made for Original Equipment Manufacturers (OEMs) that produce X-ray medical devices as the draft requirement is duplicative and causes an undue burden. OEMs that design X-ray medical devices are bound by FDA Medical Device Regulation 21 CFR Part 820.25, Personnel. As such, Quality Management Systems are already in place to ensure that the necessary education, background, training, and experience for personnel to perform their assigned responsibilities have been established and are documented. These records can be provided upon request. An exception may also facilitate the use of National Service Teams to support demand.

Additionally, for non-OEMs, MITA recommends clarification and consistency with CRCPD Appendix E. The current draft regulation (issued February 2009) does not allow flexibility for types of services provided (General vs Specialized). As qualification levels and service activities vary widely in complexity, the regulation as drafted does not allow service providers to leverage a service model that aligns to such complexities.

DEPARTMENT RESPONSE:
Not Adopted. Training records must be submitted to the Department to verify compliance with training and education requirements. These training requirements are consistent with CRCPD SSR Part B Appendix E.

NAME	SECTION
Laura Srebnik, Medical Imaging & Technology Alliance	2.8.1.4

COMMENT:

Currently, Class I/II Vendors are required by 2.8.1.4 to submit DHEC Form D-0823 Report of Sale or Installation of X-ray Equipment monthly. MITA recommends removal of this requirement as it represents another redundancy and an undue burden. The information required is already contained within FDA Form 2579, is accepted by all other states, and is also the recommendation of CRCPD within Sec. B.15 Assembler and/or Transfer Obligation (which directly aligns to 21CFR Part 1002 Subchapter J- Radiological Health, Subpart E Sec 1002.40).

DEPARTMENT RESPONSE:
Not Adopted. FDA Form 2579 is not required, making the established monthly notification to the Department necessary.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.3.3

COMMENT:
This change gives BRH the discretion to require an RSC for x-ray. No criteria were specified. Recommend this only be applied to large facilities. Some years ago RHB introduced RSO, and now, it introduces RSC in parallel with RHA. If it is felt that these are needed, let them function and make decisions, especially regarding personnel monitoring in their respective (large) facilities. (see RHB 3.12). Let them manage how the "10% of MPD" standard is applied, please.

DEPARTMENT RESPONSE:
Partially Adopted. Revised language in regulation to enable the Department to make a determination on a case-by-case basis. If the proposed regulations take effect, the Department will develop a policy outlining requirements for radiation safety committees and indicate on registration documents. By existing regulation, RSO's are allowed to make personnel monitoring determinations regarding MPD standards.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	3.3

COMMENT:
Need to define where applicable. For instance, "For Facilites [sic] with more than three modalities". There doesn't seem to be a benefit for a radiation safety committe [sic] considering the small risk for entities, such as doctors [sic] offices, urgent care centers and other small entities having only one or two pieces of x-ray equipment.

DEPARTMENT RESPONSE:
Partially Adopted. Removed "where applicable" language in regulation and added language to enable the Department to make a determination on a case-by-case basis. If the proposed regulations take effect, the Department will develop a policy outlining requirements for radiation safety committees.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.9.4

COMMENT:
Old x-ray rooms, designed for 500 mrem, should not be required to be rebuilt to shield for 100 mrem, since there is no scientific data to justify this decreased limit anyway--it is well below natural background levels. Cost/benefit is very excessive here, so we shouldn't just make this change to align with new construction. Recommend keeping 3.9.4 in original form, or else pay for the unscientific upfit!

DEPARTMENT RESPONSE:
Adopted. Unstruck regulation and added date threshold of January 1, 1994.

NAME	SECTION

David Vassy, Spartanburg Regional Healthcare	3.12.3.1.3

COMMENT:
This revision would require each lost badge replacement dose and projected future dose to be CALCULATED by the RSO for each case. Calculation of lost badge reading requires gathering prior history, and future readings too. This includes those that are trivially low by history. Such calculations are labor-intensive and take manpower away from caring for those that receive doses-of-concern. Recommend change to focus on those that need dose-replacement. Consider change to: "RSO shall be contacted to determine if missing exposure record justifies calculation of missing exposure and edit of permanent record. In any event, a replacement device will be issued."

DEPARTMENT RESPONSE:
Partially Adopted. Revised language to require RSO calculate dose for lost or damaged badges only for individuals meeting RHB 3.12.4

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	3.12.3.1.3

COMMENT:
This requires a dose calculation for each lost badge. This is an overly burdensome process. We recommend that this be limited to individuals that are likely to receive a dose more than 10% MPD.

DEPARTMENT RESPONSE:
Partially Adopted. Revised language to require RSO calculate dose for lost or damaged badges only for individuals meeting RHB 3.12.4

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	3.12.3.1.3

COMMENT:
For the majority of individuals monitored their exposure does not warrant an estimate of their exposure. This requires resources that could be focused on more pressing radiation safety issues. Consider a caveat to perform this task for individuals likley [sic] to exceed 10% of the annual limits.

DEPARTMENT RESPONSE:
Partially Adopted. Revised language to require RSO calculate dose for lost or damaged badges only for individuals meeting RHB 3.12.4

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.12.3.1.5

COMMENT:
This is burden with no benefit. Explaining why badges are late for history below 10% of MPD (annual fetal dose) takes manpower than could be better directed toward managing individuals receiving real exposures. Please add, "for individuals typically receiving more than 10% MPD, documentation....." This would especially help large programs do a better job of radiation monitoring and control, with no losses to smaller facilities. Don't see this elsewhere, inc. CRCPD.

DEPARTMENT RESPONSE:
Not Adopted. This documentation is required to demonstrate compliance. By existing regulation, registrants are only required to monitor occupational dose for individuals meeting RHB 3.12.4.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	3.12.3.1.5

COMMENT:

This requires documentation for any Late, Lost, or unused badge. This is an overly burdensome process. We recommend that this be limited to individuals that are likely to receive a dose more than 10% MPD

DEPARTMENT RESPONSE:
Not Adopted. This documentation is required to demonstrate compliance. By existing regulation, registrants are only required to monitor occupational dose for individuals meeting RHB 3.12.4.

NAME	SECTION
Prisma	3.12.3.1.5

COMMENT:
This regulation requires an explanation to be documented for any late, unreturned and/or unused radiation monitors for Department inspection. It is recommended that this regulation be removed. Documentation of lost/late/unused monitors are not found in the Conference of Radiation Control Program Directors (CRCPD)[1] recommend state regulations. There is no identified benefit for requiring a registrant to document this information. While registrants should identify and work to improve their lost, late and/or unused radiation monitors, documenting the reasons for each such instance is not pertinent to a radiation safety program. This regulation seems unnecessary and over burdensome.

[1] Conference of Radiation Control Program Directors, Suggested State Regulations for Control of Radiation, Volumes I and II, Ionizing and Nonionizing Radiation. (2014). https://www.crcpd.org/page/SSRCR

DEPARTMENT RESPONSE:
Not Adopted. This documentation is required to demonstrate compliance.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	3.12.3.1.4 & 5

COMMENT:
For the majority of individuals monitored their exposure does not warrant time to document late or missing dosimeters. This requires resources that could be focused on more pressing radiation safety issues. Consider a caveat to perform this task for individuals likley [sic] to exceed 10% of the annual limits.

DEPARTMENT RESPONSE:
Not Adopted. This documentation is required to demonstrate compliance. By existing regulation, registrants are only required to monitor occupational dose for individuals meeting RHB 3.12.4.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.12.4.1.4

COMMENT:
This one regulation is causing hundreds of people to be monitored unnecessarily. Recommend deleting and let 3.12.4.1.1 (monitor everyone over 10% MPD) protect everybody. Second Best option: be consistent with 3.12.4.1.1 by adding "...who would receive in excess of 10% of any applicable limits in RHB 3.4. Satisfying this condition should be demonstrated by radiation monitoring under supervision of RSO for a period of time." In this fashion, there will be data to show that not everyone in surgery needs to be monitored, and will create a pathway to taper monitoring of people that get less than fetal dose, or background in Denver!

DEPARTMENT RESPONSE:
Not adopted. The wording is consistent with Suggested State Regulations. RHB 3.3.4 requires the RSO implement a program of radiation safety for effective compliance with the applicable

requirements of this regulation. The RSO is expected to make determination as to which individuals work with fluoroscopy.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	3.12.4.1.4

COMMENT:
This requires all people working with fluoroscopy to be badged. We recommend that the RSO should be able to describe the individuals who would meet this definition.

DEPARTMENT RESPONSE:
Acknowledged. Current regulation allows the RSO to make determinations as to which individuals work with fluoroscopy.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	3.12.4.1.4

COMMENT:
The term "working with medical fluoroscopic equipment" is up for interpretation. Recommend wording the regulations in such a way that it covers individuals working with medical fluoroscopic equipment and likely to receive in excess of 10% of the occupational dose limits. Otherwise define "working with medical fluoroscopic equipment" or allow the radiation safety officer to define who is actually working with medical fluoroscopic equipment.

DEPARTMENT RESPONSE:
Not adopted. The wording is consistent with Suggested State Regulations. RHB 3.3.4 requires the RSO implement a program of radiation safety for effective compliance with the applicable requirements of this regulation. The RSO is expected to make determination as to which individuals work with fluoroscopy.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.12.5.1

COMMENT:
add: "except as noted below" because otherwise, 3.12.5.1 conflicts with 3.12.5.2.1.1 and 2 because, in EDE2 cases, the one collar badge "reported deep dose equivalent" READING on A BADGE is NOT the dose of record.

DEPARTMENT RESPONSE:
Adopted.

NAME	SECTION
Prisma	3.12.5.1

COMMENT:
Section 3.12.5.1 states 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.

Since 3.12.5.2.1.1 allows for effective dose equivalent assignment when utilizing one monitor, it is recommended to add “except as provided in 3.12.5.2.1.1” to the end of regulation 3.12.5.1 for clarification.

DEPARTMENT RESPONSE:
Adopted.

NAME	SECTION

David Vassy, Spartanburg Regional Healthcare	3.12.5.2.1.1

COMMENT:
Don't require use of EDE2 at 25% MPD. Let RSO decide. CRCPD got this wrong. Otherwise, a surgeon that leans their badge into a fluoro beam one quarter (Landauer's "Dynamic Exposure") will be FORCED to go on EDE. Once on EDE, the badge reports show the corrected, lower number. Then, future high readings become less obvious when one globally reviews exposure history. Their exposures become less obvious to reviewers. Plus, observation requirements kick in (3.12.5.2.2), that are of declining value over time. All because of one "lean-in" by the surgeon. Please let the RSO have discretion about when to apply EDE2. Monitoring is improved by delaying its use until you see if the need is chronic or is just an isolated incident. Consider change to "...and the reported dose begins to approach the limit specified in RHB 3.4, the RSO may report the deep dose equivalent value multiplied by 0.3 as the effective dose...." Remember that this is just a way to get credit for wearing an apron, so don't force it if it's not REALLY needed. You always have the ultimate protection of not exceeding 5 rem/yr.

DEPARTMENT RESPONSE:
Adopted. Allows for RSO discretion.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.12.5.2.1.2

COMMENT:
For all the reasons above, application of EDE1 should be at RSO discretion. Change to: "neck...the RSO may elect to apply the following determination of effective dose equivalent: multiply the under-apron badge reading by 1.5 and sum that with the collar reading multiplied by 0.04."

DEPARTMENT RESPONSE:
Acknowledged. RHB 3.12.5.2.1 states the RSO may give consideration that an effective dose equivalent be used as the permanent record.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	3.12.5.2.2

COMMENT:
My experience has shown that such observations become unnecessary over time, becoming redundant and unnecessary after 1 or 2 visits. Things like this have a way of trivializing radiation protection, making such efforts appear silly. Recommend removing the requirement. If not, change "quarterly" to "initially, then on a frequency determined by the RSO." If you must, then cap it with " no less often than biennially".

DEPARTMENT RESPONSE:
Partially Adopted. Replaced quarterly documented visits to semi-annual documented visits.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	3.12.5.2.2

COMMENT:
Recommend removing the requirement for "quarterly" observations. Recommend initial observations and additional observations based on the discretion of the radiation safety officer.

DEPARTMENT RESPONSE:
Partially Adopted. Replaced quarterly documented visits to semi-annual documented visits.

NAME	SECTION
Michael Ludkowski, Upstate Carolina Radiology	4.2.2

COMMENT:
The wording in this section would prohibit the use of radiation by licensed Physician Assistants and Nurse Practitioners. Currently, PAs and NPs can use Fluoroscopy under the supervision of a Licensed Practitioner. This should be allowed to continue.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.2.10

COMMENT:
"Gonadal/supplemental" shielding replaced with limiting beam to area of interest. Good change.

DEPARTMENT RESPONSE:
Acknowledged.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	4.2.13.2

COMMENT:
The limits in Appendix D are specified at various body thicknesses. Puting [sic] a cap on the exposure limits could result in larger indivdual [sic] being underexposed. Recommend that the regulation be worded to specify that limit for patients at the specified thickness rather than for all patients.

DEPARTMENT RESPONSE:
Adopted. Clarified exposure at skin entrance limits based on anatomical size.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.2.13.2

COMMENT:
Please note that this does not take into account patient body habitus. Appendix D applies to a specific patient thickness and the blanket use of "shall not exceed limits listed in Appendix D" should be clarified. Possible solution would be to indicate on Appendix D that the dose should not exceed the limits below for the specified patient anatomical thicknesses.

DEPARTMENT RESPONSE:
Adopted. Clarified exposure at skin entrance limits based on anatomical size.

NAME	SECTION
Paula Jeter, Spartanburg Regional Healthcare System	4.2.15.2

COMMENT:
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.

Recommend updating the regulation to allow for recording the displayed air kerma or dose area product in addition to or in lieu of time.

DEPARTMENT RESPONSE:
Not Adopted. Fluoroscopic time is reviewed during inspections to assist in determining ALARA principles. Air kerma and dose area product are not provided by all x-ray equipment.

NAME	RESECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.3.5

COMMENT:
I wanted to bring it to your attention that the FDA has updated its required HVL tables. The table listed in this document does not match the current FDA standards. This is for x-ray systems manufactured after 2006.

DEPARTMENT RESPONSE:
Adopted.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.4.1.1

COMMENT:
Class VIII Vendors (non-healing arts) should not be permitted to perform shielding designs for Healing Arts facilities unless they have experience in Healing Arts shielding. They should be removed from relevant regulations.

DEPARTMENT RESPONSE:
Partially Adopted. It is not the intent of the Department to allow a class VIII vendor (non-healing arts vendor) to complete healing arts shielding plans. In the interest of consistency, all parts of this regulation reference Section 4.4 for Shielding requirements. The Scope has been amended to reflect this.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.4.1

COMMENT:
Class VIII (non-healing arts consultants) have been added as those who can perform/review shielding for healing arts. No justification for this addition was included in Sept 8 Att A rationales. The didactic training requirements outlined for Class VIII and IX (healing arts) are similar, but sufficient practical experience needed for healing arts shielding is not guaranteed in Class VIII definition. Healing arts shielding without healing arts experience is counter to safety. Recommend returning to previous standard by removing Class VIII from this edit. Review in conjunction with new 2.7.8.7 and 2.7.8.8

DEPARTMENT RESPONSE:
Partially Adopted. It is not the intent of the Department to allow a class VIII vendor (non-healing arts vendor) to complete healing arts shielding plans. In the interest of consistency, all parts of this regulation reference Section 4.4 for Shielding requirements. The Scope has been amended to reflect this.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.4.1.2

COMMENT:
No justification provided to reduce from 5 to 4 days the limit over which an x-ray location can be considered temporary and not require shielding assessment. A 5-day (1 week) limit is easier to administer. Recommend return to original 5 days, or at least provide a justification.

DEPARTMENT RESPONSE:
Partially Adopted. The original intent of this regulation was to allow for temporary use for any space as a radiation area. The greater than 5 consecutive day limit created a loophole for the majority of facilities as they only operate 5 days per week. This has allowed spaces to be utilized permanently as a radiation area with no evaluation. "Greater than" has been removed and "or more" has been added to keep the monitoring level at 5 days. If a space is utilized as a radiation area for 5 or more consecutive days, a shielding plan is required.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.4.1.2

COMMENT:
I believe that the original 5 days or 1 work week is an easier thing to monitor. Is there a justification for reducing this to 4 days rather than 5?

DEPARTMENT RESPONSE:
Partially Adopted. The original intent of this regulation was to allow for temporary use for any space as a radiation area. The greater than 5 consecutive day limit created a loophole for the majority of facilities as they only operate 5 days per week. This has allowed spaces to be utilized permanently as a radiation area with no evaluation. "Greater than" has been removed and "or more" has been added to keep the monitoring level at 5 days. If a space is utilized as a radiation area for 5 or more consecutive days, a shielding plan is required.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.4.1.3

COMMENT:
This addition prescribes the parameters to be considered when assessing changes that might trigger new shielding. That's good. Allowing a non-healing-arts-designer is not. Remove Class Vlll here and everywhere in Part IV—the section on "Healing Arts". See above.

DEPARTMENT RESPONSE:
Partially Adopted. It is not the intent of the Department to allow a class VIII vendor (non-healing arts vendor) to complete healing arts shielding plans. In the interest of consistency, all parts of this regulation reference Section 4.4 for Shielding requirements. The Scope has been amended to reflect this.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.4.1.3

COMMENT:
Class VIII Vendors should not be permitted to perform shielding designs for Healing Arts facilities unless they have experience in Healing Arts shielding.

DEPARTMENT RESPONSE:
Acknowledged.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.4.6.2

COMMENT:
Please note that the survey should be completed within 30 days and the vendor should have the normal 30 days to complete the report. Otherwise, this is overly burdensome and deviates from the normal

timeframe for report turnaround. Any deficiencies would still be evaluated in the 30-day time frame and would give the facility time to correct the deficiency.

DEPARTMENT RESPONSE:
Adopted. Text has been revised to require the completion of the survey within thirty (30) calendar days of installation of the x-ray equipment. The survey must be submitted to the Department within thirty (30) calendar days of the completion of the survey.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.8.8

COMMENT:
I believe that the original 5 days or 1 work week is an easier thing to monitor. Is there a justification for reducing this?

DEPARTMENT RESPONSE:
Partially Adopted. The original intent of this regulation was to allow for temporary use for mobile and portable x-ray systems in a single location. The greater than 5 consecutive day limit created a loophole for the majority of facilities as they only operate 5 days per week. This has allowed these systems to be utilized permanently in a single location with no evaluation. "Greater than" has been removed and "or more" has been added to keep the monitoring level at 5 days. If a mobile or portable system is used in a single location for 5 consecutive days, a shielding plan is required.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.11.2.1

COMMENT:
Current version does not seem to allow one to use the beam-on switch in the room on the scanner that is used on certain protocols. Modify to allow this.

DEPARTMENT RESPONSE:
Adopted. Added language allowing the use of exposure switches to support the performance of common procedures.

NAME	SECTION
Prisma	4.11.2.1

COMMENT:
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. R61-64, Part IV, Appendix C allows for these gantry switches. Should they also be referenced in 4.11.2.1?

DEPARTMENT RESPONSE:
Adopted. Added language allowing the use of exposure switches to support the performance of common procedures.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.11.2.1

COMMENT:
Please note that all modern CTs have an exposure button inside the room to initiate a scan and verify the contrast did not infiltrate. Please consider removing or clarifying this requirement.

DEPARTMENT RESPONSE:
Adopted. Added language allowing the use of exposure switches to support the performance of common procedures.

NAME	SECTION
Prisma	4.11.3.1.2

COMMENT:
This section requires that the CT performance testing and quality control measure standards and tolerances be established by a Class IX vendor. In-house medical physicists and/or other qualified individuals (e.g., medical health physicists, radiation safety officers, etc.) that are not registered with the state should also be able to establish these standards and tolerances as well.

DEPARTMENT RESPONSE:
Acknowledged. In-house personnel may provide these services and are exempt from the vendor registration requirement provided the requirements of RHB 2.7.1.1 are met.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.11.3.2.1.4

COMMENT:
During the process of routine QC it is highly likely that a day or two will be missed from time to time. This would not be considered a major failure. How is DHEC going to interpret and enforce this requirement? Please provide guidance on possible allowances for missed QC.

DEPARTMENT RESPONSE:
Acknowledged. If the proposed regulations take effect, the Department will develop a policy for citation vs. recommendations.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.11.3.1.2, 4.11.3.2.1, 4.11.5.1

COMMENT:
These are weakened because they mandate a Class IX vendor to perform tests and advise on CT QC. However, these are tasks that ACR and others insist be done by board-certified physicists. Yet, one of the definitions of Class IX vendor is only a Masters+40 hours. So this equates Class IX with ABR cert, which is not actually true. For such clinical advice, this should come from let's say not "a Class IX vendor", but "an ABR-certified physicist registered with the state". Or else beef up the definition of Class IX.

DEPARTMENT RESPONSE:
Not Adopted. This requirement is consistent with CRCPD Suggested State Regulations. Facilities seeking accreditation may contact a Class IX vendor with the qualifications required by the accrediting body.

NAME	SECTION
Prisma	4.11.3.2.1 and 4.11.5.1

COMMENT:
These sections require that a Class IX vendor either write or approve the routine quality control program. In-house medical physicists and/or other qualified individuals (e.g., medical health physicists, radiation safety officers, etc.) that are not registered with the state should be able to write/approve these routine quality control programs as well.

DEPARTMENT RESPONSE:

Acknowledged. In-house personnel may provide these services and are exempt from the vendor registration requirement provided the requirements of RHB 2.7.1.1 are met.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.11.5.4

COMMENT:
This test may be difficult to perform on some CBCT units due to their configurations. Some units enclose the detector which challenges the ability to delineate the detector position. I understand that this is from the CRCPD Suggested State Regulations Part F. The AAPM does not have criteria published for this modality at this time. The EFOMP-ESTRO IAEA has published the following protocol:

"QUALITY CONTROL IN CONE-BEAM COMPUTED TOMOGRAPHY (CBCT)"
EFOMP-ESTRO-IAEA PROTOCOL

Beam collimation

Citing reference 2, "limiting the radiation field to the area of interest will both reduce the radiation risk and improve image quality (as, for a smaller irradiated volume, less scattered radiation will reach the image detector)". In CBCT it is particularly important to check that the radiation field is not larger than the dimensions of the detector. Fluorescent screens, film or the recently developed electronic x-ray ruler can be used for this purpose, the same way they have been used in the past to check proper collimation in mammography, tomosynthesis or fluoroscopy

Using these tools, the decay of the x-ray intensity along the field edge (beam penumbra) is measured. The position at which the intensity decays to one half of its maximum is assumed to be the actual position of the edge. This position should ideally not deviate from the expected beam edge by more than 2 % of the focus-to-detector distance (FDD). However, a larger deviation is acceptable if the total deviation (of all four edges) is not larger than 4 % of the FDD. It should also be noted that they do not include criteria for centering. If the alignment test is met, then the total alignment including centering should be acceptable. I would remove the centering requirement.

I would recommend revising this requirement to meet these requirements or providing an alternative to meet the manufacturer's specifications.

Example of recommended revision:

<u>4.11.5.4 Beam alignment. The total deviation (of all four edges) of the x-ray field in the plane of the image receptor shall not exceed 4 % of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Alternatively, the unit shall be evaluated to meet the manufacturer's specifications for these tests.</u>

DEPARTMENT RESPONSE:
Not Adopted. The provided publication outlines guidance for this testing and indicates the ideal limit values. The proposed limits are described in the publication as ideal and are consistent with CRCPD Suggested State Regulations.

NAME	SECTION
Thomas Ruckdeschel, Alliance Medical Physics LLC	4.13.2

COMMENT:

I wanted to point out a cabinet unit would need a radiation survey before use, but a CT would have 30 days to be tested. The CT has orders of magnitude more scatter than a cabinet unit. I would recommend having 30 days to test the Medical Specimen unit, provided the engineer completes manufacturer testing before initial use.

DEPARTMENT RESPONSE:
Not Adopted. A survey is required prior to use to ensure radiation safety for the operator and other employees in the potential radiation area.

NAME	SECTION
David Vassy, Spartanburg Regional Healthcare	4.13 and 8.13

COMMENT:
X-ray-based blood irradiators are swiftly replacing isotope-based irradiators. They are technically and operationally very close to specimen units. To assure that blood irradiators would be regulated as "Medical Specimen Systems" and not as industrial cabinet x-ray systems covered in Part 8, I recommend re-titling RHB 4.13 as "Medical Specimen AND BLOOD IRRADIATION Systems"

DEPARTMENT RESPONSE:
Not Adopted. Blood irradiation systems must meet the requirements of Part VIII, Radiation Safety Requirement for Industrial Uses of Radiographic Sources.

NAME	SECTION
Prisma	8.12.1.12

COMMENT:
The Department is proposing to remove Section 8.12.1.12. Section 8.12.1.12 allows for exemptions from some of the cabinet radiography requirements in Section 8.13 (previously 8.12) if the unit is maintained as a Certified Cabinet X-ray unit. Without this exemption, x-ray blood irradiators (e.g., Radsource RS 3400) will require enhanced training that does not apply to its use. It will also require operators to be monitored for radiation exposure. Neither of these should be required. X-Ray blood irradiators are more similar to x-ray medical specimen units (Section 4.13). There is no measurable exposure on the exterior of the unit and the interlocks do not allow operation when it is open. It is recommended that the Department include x-ray blood irradiators as part of Section 4.13. This will maintain the appropriate amount of control of those units.

DEPARTMENT RESPONSE:
Not Adopted. Blood irradiation systems must meet the requirements of Part VIII, Radiation Safety Requirement for Industrial Uses of Radiographic Sources.

NAME	SECTION
Russell Chapin, SC Radiological Society	9.137

COMMENT:
The South Carolina Radiological Society submits the following comments in response to the proposed definition change for a "Licensed Practitioner" within Title B, found under **existing numeration Part IX Definitions 9.137 "Licensed Practitioner" (proposed revised numeration Part X 10.132)**[1]. That proposed change is as follows:

Notice of Proposed Regulation drafted amending language:
"Licensed practitioner" means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state.

The South Carolina Radiological Society appreciates and applauds the hard work and effort by the DHEC Bureau of Radiological Health to prepare the amendments to **R.61-64, X-rays (Title B)**; however, the SCRS **opposes** the above proposed language for the definition of a "Licensed

Practitioner." We understand that the definition within the existing regulation is different than the definition found in the Medical Radiation Health and Safety Act (MRHSA); however, we do not believe that is dispositive of the issue.

The MRHSA created the South Carolina Radiation Quality Standards Association (SCRQSA) and the SCRQSA Board in 1999 to certify Radiologic Technologists in the state. Section 44-74-40(B) of the MRHSA states "Nothing in this chapter limits, enlarges, or affects the practice of a licensed practitioner." The writing of this act necessitated a definition of "Licensed Provider" to draw a distinction from the Radiologic Technologists requiring certification by SCRQSA. This definition does not constrain DHEC's ability to modernize its regulations under Section 13-7-40. The quarter-century old MRHSA definition of "Licensed Practitioner" also does not supersede the authority of the Board of Medical Examiners or the Board of Nursing under more recent and modernized aspects of Title 40, Professions and Occupations.

South Carolina Physician Assistants Have Been Properly Performing Fluoroscopy Under DHEC's Current Regulatory Definition

In South Carolina, physician assistants have been performing fluoroscopy under the supervision and within Approved Written Scope of Practice Guidelines since at least 2009.

Within the Medical Practice Act, the South Carolina Physician Assistants Practice Act, Article 7, in 2000 established the mechanism for licensure of a Physician Assistant to perform medical acts, tasks, or functions within written scope of practice guidelines (40-47-930, 40-47-935). "Approved written scope of practice guidelines" (section 40-47-20(5)) are a required component of the normal licensing process for PAs by the South Carolina Board of Medical Examiners. The Radiology Physician Assistants SOP guideline, issued by the South Carolina Board of Medical Examiners, explicitly includes the use of fluoroscopy, provided that "The Physician Assistant is required to successfully complete a radiation safety course approved by the Board in order to perform this procedure(s)." (https://llr.sc.gov/med/Pdf/PAScopeApproval/Radiology.pdf). Under longstanding precedent in multiple instances, the SCBME has accepted a radiation safety course that has been offered jointly by the American Academy of Physician Assistants and the American Society of Radiologic Technologists for over ten years, the "AAPA/ASRT Fluoroscopy Online Test Preparatory Course" (40 Category 1 CME credits).

The current definition of Licensed Practitioner in DHEC's Regulation 61-64 **allows the Board of Medical Examiners to establish this criteria.**

Current language:
"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.**

SCBME licensed PAs who do not have radiation safety training and who do not have a Radiology PA SOP inclusive of fluoroscopy should be prohibited from performing fluoroscopy in South Carolina and any delegation to such a PA would be in violation of the prohibition found in the Medical Practice Act at 40-47-30(C).

South Carolina APRNS Have Performed Fluoroscopy Until Very Recently

The Nurse Practice Act, updated most recently in 2018, establishes licensure of Nurse Practitioners through the Board of Nursing. Nurse Practitioners establish relationships with physicians through formal "Practice Agreements" (40-33-20(45)) to perform specific medical acts (40-33-34). NPs have

entered into Practice Agreements with radiology practices in South Carolina, inclusive of fluoroscopy. Further, NPs have completed the same radiation safety training via the "AAPA/ASRT Fluoroscopy Online Test Preparatory Course" as described above that PAs have used to satisfy the SCBME's requirements.

NPs that join radiology practices are fully capable of being mentored and trained in substantively the same manner as PAs in the safe use of fluoroscopy, and they have demonstrated such capability in South Carolina. An NP that has taken the same radiation safety fluoroscopy course as a PA and that has been appropriately trained and monitored by a Radiologist should be allowed to use fluoroscopy in South Carolina when its use has been explicitly outlined in their Practice Agreement with a Radiologist.

After discussion with the SCRQSA Board in late 2021, the Board of Nursing issued a statement indicating that operating x-ray producing equipment is not within the scope of Advanced Practice Registered Nurses. The SCRS agrees that APRNs or NPs who do not have radiation safety training and who do not have a Practice Agreement with a Radiologist inclusive of fluoroscopy should be prohibited from performing fluoroscopy in South Carolina.

Disallowing This Long-Standing Practice Will Lead to Loss of Valuable Healthcare Practitioners and Limit Access to Care in SC

Through established precedent, Physician Assistants and Nurse Practitioners have become an integral part of the practice of radiology both in South Carolina and throughout the country. Seventy percent of other states allow PAs to use fluoroscopy or do not explicitly prohibit its use (AK, AL, AZ, CA, CO, CT, DE, FL, GA, HI, ID, IL, IA, KS, MD, MA, MI, MN, MS, MO, NE, NV, NC, OK, OR, RI, SD, TN, TX, UT, VA, WA, WI, WY) (communication, American College of Radiology, Government Relations). These states include multiple South Carolina neighboring states and other Southeast states, notably Maryland, Virginia, North Carolina, Tennessee, Georgia, Florida, Alabama, Mississippi, and Texas.

Nearly half of other states allow NPs to use fluoroscopy or do not explicitly prohibit its use (AL, AK, CO, DC, GA, ID, KS, MI, MS, MO, NE, NV, NM, NC, ND, OH, OK, PA, TN, TX, WA, WI) (communication, American College of Radiology, Government Relations). These states include multiple South Carolina neighboring states and other Southeast states, notably North Carolina, Tennessee, Georgia, Alabama, Mississippi, and Texas.

Ultimately, the SCRS views PAs and NPs on a level playing field concerning the use of fluoroscopy when they have appropriate safety training and are working collaboratively with Radiologists and Radiologic Technologists. They provide excellent care to patients and are very skilled at the delegated medical acts that they perform.

We are proud that PAs and NPs have found satisfying and fulfilling careers through the delivery of patient care in our radiology practices. Their presence is vital to many of the groups in the state of South Carolina, due to population growth as well as an ongoing and worsening nationwide shortage of Radiologists. Curtailing the current role of these critical physician extenders in radiology practices would have a serious negative impact on access to specific imaging healthcare services in this state.

Further, curtailing their current role with radiology practices may lead to loss of employment, as their functionality and flexibility would be seriously undermined. Prohibiting the ability of PAs and NPs to use fluoroscopy would certainly decrease the future employment opportunities of new graduates to work in the field of radiology. The efficiency gains in health care through the employment of these

advanced practice licensed providers should be available to radiology practices, particularly in this era of limited human resources and overall economic conditions.

These professional colleagues have dedicated their careers to health care and they have found satisfaction in doing so in the field of radiology. They should be allowed to continue doing what they have been trained and are currently doing. If South Carolina were to prohibit the use of fluoroscopy by PAs and NPs, then the state should expect a brain drain of this valuable resource, as some of these professionals inevitably relocate to our neighboring states with better career opportunities.

SCRS Proposes the Following Definition

The 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)] states in section 13-7-40(F): "The department in connection with the control and regulation of radiation sources, in addition to its other duties as imposed by law shall:"…"(10) promulgate and repeal regulations pertaining to the qualifications of operators applying ionizing or nonionizing radiation to humans.". DHEC has laudably done so through R.61-64, *X-rays (Title B)*. Pursuant this authority, the SCRS proposes DHEC adopt the following definition of Licensed Practitioner, instead of the currently proposed one.

SCRS Proposed Definition:
"Licensed practitioner" means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state; a person licensed as a Radiology Physician Assistant and granted scope of practice inclusive of fluoroscopy by the South Carolina Board of Medical Examiners and included in an Approved Written Scope of Practice Guideline with a radiologist; a person licensed as a Nurse Practitioner by the Board of Nursing when in a Practice Agreement with a Radiologist inclusive of fluoroscopy and with commensurate radiation safety training.

The Use of Fluoroscopy by Licensed Practitioners in the Presence of SCRQSA Certified Radiologic Technologists is a Best Practice

Nothing about these comments negates SCRS's belief that it is best practice for Licensed Practitioners of all advanced degree backgrounds, including MDs, to utilize fluoroscopy with a SCRQSA certified Radiologic Technologist present alongside us as we care for patients. Radiologic Technologists are our colleagues and friends and we have great regard for their specialized training. As a matter of course, in our radiology departments and facilities where fluoroscopy is utilized, it is uniformly done so with a certified Radiologic Technologist present.

The Definition of Licensed Practitioner Should Be Updated in the MRHSA to Comport with Current Practice

The definition under the MRHSA, passed in 1999, was developed in 1998, 25 years before the 2023 South Carolina Legislative Session. That definition is out of date and does not account for the evolution of the practice of heath care in South Carolina over the ensuing quarter of a century. In addition to the amendments to Regulation 61-64, the SCRS believes this definition should be amended.

The SCRS looks forward to working with the DHEC Bureau of Radiological Health and SCRQSA to ensure that revisions to the Title B regulations and timely amendment to the MRHSA in the 2023 South Carolina Legislative Session will serve to improve the access to and safety of care delivered to the citizens of South Carolina. To further enshrine South Carolina citizens' access to safe, responsible, and high-quality radiological care, the MRHSA and Title B definitions of "Licensed Practitioner" should be brought into resonance with each other, as well as law and precedent under the **Medical Practice Act**

and **Nurse Practice Act**.

An updated definition should include appropriately trained and licensed Radiology Physician Assistants who possess relevant licensed scope of practice as well as Nurse Practitioners in appropriately structured Practice Agreements with radiology practices

[1] Section 13-7-40(C) establishes the Technical Advisory Radiation Control Council and designates one of the six members of the council to be from the South Carolina Radiological Society. It further states "No standards or regulations may be adopted, modified, promulgated, or repealed by the department except after consultation with the council.". No members of the TARCC are currently appointed, and the SCRS was not contacted by DHEC to assist with the drafting of revisions to Title B in 2022. Thus, we are commenting here.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute. Further, the Department notes the following provision in the Physician Practice Act: "Nothing in this chapter may be construed to authorize a physician to delegate the performance of radiological services in violation of Chapter 74 of Title 44." S.C. Code Ann. § 40-47-30(C).

NAME	SECTION
Matthew Brady, Roper Radiologists, PA	10.132

COMMENT:
existing numeration Part IX Definitions 9.137 "Licensed Practitioner" (proposed revised numeration Part X 10.132)

I am in support of the SCRS submitted comments of Oct 5th by the SCRS President Dr. Chapin. I am the President of Roper Radiologists, PA. Our group covers a sizable healthcare system and utilizing Advanced Practice Providers has allowed us to provide safe and efficient care in a dynamic ever-evolving healthcare environment. That ability would be impaired by the drafted definition of "Licensed Practitioner" as it relates to the usage of fluoroscopy.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Holly Pisarik, SC Medical Association	10.132

COMMENT:
Our comments are limited to and submitted in opposition to the proposed change to the definition for a "Licensed Practitioner" in Part X 10.132. The current and proposed amended definitions are as follows:

- **Current** - A 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.

- **Proposed Amended Definition** - A Licensed Practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state.

As noted in Regulation 61-64, DHEC is granted the authority to 'promulgate and repeal regulations pertaining to **the qualifications of operators** applying ionizing or nonionizing radiation to humans.' S.C. Code Section 13-7-40(F). Under the current definition, DHEC has allowed, among others, the South Carolina Board of Medical Examiners (BME) to determine the 'professional specialization' and 'criteria' required to perform fluoroscopy.

Under Scope of Practice Guidelines (SOPG) issued by the BME attached hereto as Exhibit A, physician assistants (PA) have been performing fluoroscopy under the supervision of physicians and within Approved Written Scope of Practice Guidelines in South Carolina since at least 2009.[1] That SOPG was amended by the BME as recently as 2019 and requires PAs, 'to successfully complete a radiation safety course approved by the Board in order to perform this procedure(s)." And, 'an adequate number of these examinations must be observed and conducted by the PA under the direct supervision of the supervising or alternate physician(s) to satisfy the supervising physician that the PA is competent enough to perform the procedure.' The BME has accepted a radiation safety course that has been offered jointly by the American Academy of Physician Assistants and the American Society of Radiologic Technologists for over ten years, attached hereto as Exhibit B.

Further, advanced nurse practitioners (NP) have entered into Practice Agreements with radiology practices in South Carolina that includes fluoroscopy[2] [3]. These NPs complete the same radiation safety training via the "AAPA/ASRT Fluoroscopy Online Test Preparatory Course" that PAs have used to satisfy the BME's requirements.

DHEC's revised definition, depriving the BME of the ability to determine how physicians work with PAs and NPs, represents an abrupt departure in practice and will disrupt the work of radiologists in South Carolina. We understand that the definition within the existing regulation is different than the definition found in the Medical Radiation Health and Safety Act (MRHSA); however, DHEC and the South Carolina Radiation Quality and Safety Association (SCRQSA) should work together to allow this long-standing practice that has occurred in South Carolina since at least 2009.

The SCMA's suggested solution is for DHEC to retain the current definition of 'Licensed Practitioner' in Regulation 61-64, recognizing the BME's ability to determine what is appropriate for physicians in SC, or if DHEC adopts the definition from the MRHSA for the SCRQSA to accept the BME approved training as a recognized 'certificate' for PAs and NPs. This certification will satisfy the statutory requirement in S.C. Code Section 44-74-30(E) ('No person, other than a licensed practitioner, may operate any x-ray machinery in the health care setting ... **without possessing a current valid certificate from the South Carolina Radiation Quality Standards Association)**. Further, a certificate from the SCRQSA will satisfy the statutory requirement in S.C.Code Section 40-47-30(() since delegating to or collaborating with a person holding a certificate by the SCRQSA will not violate the MRHSA. (Nothing in this chapter may be construed to authorize a physician to delegate the performance of radiological services **in violation of Chapter 74 of Title 44)**.[4]

[1] A number of other states allow PAs to use fluoroscopy or do not explicitly prohibit its use (AK, AL, AZ, CA, CO, CT, DE, FL, GA, HI, ID, IL, IA, KS, MD, MA, MI, MN, MS, MO, NE, NV, NC, OK, OR, RI, SD, TN, TX, UT, VA, WA, WI, WY).

[2] After discussion with the South Carolina Radiation Quality and Safety Association in late 2021, the Board of Nursing issued a statement indicating that operating x-ray producing equipment is not within the scope of Advanced Practice Registered Nurses.
[3] Many states allow NPs to use fluoroscopy or do not explicitly prohibit its use (AL, AK, CO, DC, GA, ID, KS, MI, MS, MO, NE, NV, NM, NC, ND, OH, OK, PA, TN, TX, WA, WI).
[4] We agree that licensed PAs or NPs who do not have radiation safety training and who do not have a Radiology SOPG or PA inclusive offluoroscopy should be prohibited from performing fluoroscopy in South Carolina and any delegation to or collaboration with such a PA of NP would be in violation of the prohibition found in the Medical Practice Act at 40-47-30(().

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

NAME	SECTION
Prisma Health	10.132

COMMENT:
The proposed definition (10.132) states:
· Licensed Practitioner means person licensed to practice medicine, dentistry, podiatry, chiropractic, or osteopathy in this state

The definition of a licensed practitioner is important as it relates to who can operate x-ray producing equipment and/or directly supervise someone operating fluoroscopy equipment. Two (2) sections in RHB 61-64 limit the use of x-ray producing equipment to only a licensed practitioner and/or certified radiologic technologist.

· RHB 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.

· Section 4.2.2 – The registrant shall assure that all 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.

Changing the definition of a licensed practitioner could potentially affect individuals currently approved by South Carolina Department of Labor, Licensing and Regulation's Board of Medical Examiners (SCBME) to practice as a Radiology Physician Assistant (PAs). It is not clear if a Radiology PA is "licensed to practice medicine" and/or who determines that.

For the past 20 years, Radiology PAs have been approved by the SCBME to function within an Approved Scope of Practice to perform minor fluoroscopic interventional procedures such as arthrograms, PICC line placement, etc. The SCBME has issued a Scope of Practice (SOP) guideline for Radiology PAs, which specifically includes operation of fluoroscopy. The Radiology PA SOP guideline states "the Physician Assistant is required to successfully complete a radiation safety course approved by the Board". The SCBME has historically accepted fluoroscopy safety training courses that are designed/approved for medical providers such as FluoroSafety's "Advanced Training Program on

the Safe Use of Fluoroscopy", https://fluorosafety.com/advanced-training-program/. The proposed definition of a licensed practitioner could potentially remove the ability for the SCBME to determine if a Radiology PA can operate fluoroscopy and/or direct a radiologic technologist to operate fluoroscopy during a procedure.

Radiology practice has evolved over the past decade due to increased need for radiological procedures and physician shortages. Radiology PAs have become an integral part of a radiology practice to meet the needs of our patients and community. If Radiology PAs are not able to perform these functions, it would negatively impact the care of patients across our state.

We recommend that the proposed definition of a Licensed Practitioner as found in Section 10.132 include "Radiology Physician's Assistant as defined by the South Carolina Board of Medical Examiners". Otherwise, the Department of Health and Environmental Control, Radiological Health, should issue a position statement noting that Radiology PAs approved by SCBME meets the definition of a licensed practitioner.

We would oppose other Physician Assistants and/or Advanced Practicing Nurses (e.g., Nurse Practitioners) that do not meet the same scope of practice criteria to that of a Radiology PA operating x-ray producing equipment. However, RHB 61-64, 1.2.9, specifies that a licensed practitioner must be physically present during fluoroscopy use. We feel that any Physician Assistant (e.g., Orthopedic, Neurology, Urology, etc.) or Advanced Practicing Nurse that is trained to perform a specific medical procedure requiring fluoroscopy would be able to directly supervise a certified radiologic technologist to operate fluoroscopy during that medical procedure.

DEPARTMENT RESPONSE:
Not adopted. However, the proposed change to the definition of "licensed practitioner" in the Notice of Proposed Regulation (NPR) has been replaced with a reference to the definition in the Medical Radiation Health and Safety Act, S.C. Code Ann. §§ 44-74-10, et seq. The change in the definition of "licensed practitioner" in the regulation is proposed for consistency with the definition of "licensed practitioner" in the Medical Radiation Health and Safety Act. See S.C. Code Ann. § 44-74-20(3). A regulation may not alter or add to the terms of a statute.

Date: December 8, 2022

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

From: Bureau of Water

Re: Public Hearing for Notice of Final Regulation for Amending R.61-9, *Water Pollution Control Permits,* Document No. 5137

I. Introduction

The Bureau of Water (Bureau) proposes the attached Notice of Final Regulation amending R.61-9, *Water Pollution Control Permits.* 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, exempts these proposed amendments from General Assembly review; however, the Department is proposing to send the proposed amendments to the General Assembly for review.

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 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,* and to improve regulatory clarity.

2. The Department had a Notice of Drafting published in the July 22, 2022, *State Register*.

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

4. Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received public comments from a legal environmental advocacy organization on behalf of several conservation organizations by the October 24, 2022, close of the public comment period. See Attachment B. The Department's response to these comments is summarized in Attachment C.

5. A stakeholder meeting was hosted by Bureau staff after publication of the Notice of Proposed Regulation, on October 17, 2022. The in-person meeting was held in the Linton Conference room in the Sims / Aycock Building. Several members of conservation organizations, Department staff, and the regulated community attended. After a brief presentation by Department staff, open discussion and questions and answers took place.

6. After consideration of all timely received comments, no changes are proposed to the regulatory text of the Notice of Proposed Regulation approved by the Board in the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*.

III. Request for Approval

The Bureau respectfully requests the Board to find need and reasonableness of the attached proposed amendment of R.61-9, *Water Pollution Control Permits,* for submission to the General Assembly.

Jennifer R. Hughes
Bureau Chief

Myra Reece
Director

Attachments:
A. Notice of Final Regulation
B. Southern Environmental Law Center Comment Letter, October 24, 2022
C. DHEC response to SELC Comments

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R. 61-9, WATER POLLUTION CONTROL PERMITS

December 8, 2022

Document No. 5137
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 48-1-10 et seq.

61-9. Water Pollution Control Permits.

Synopsis:

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* and to improve regulatory clarity. Although the Administrative Procedures Act, S.C. Code Section 1-23-120, exempts these proposed amendments from General Assembly review, the Department is sending the proposed amendments to the General Assembly for review.

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.

Instructions: Amend R.61-9.122.23, Concentrated Animal Feeding Operations, by striking the existing language and replacing it with language that conforms to current federal regulation as set forth below.

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).

Fiscal Impact Statement:

There is no anticipated increase in costs to the state or its political subdivisions, or to the regulated community, resulting from these proposed revisions.

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, for conformity with the federal regulation at 40 CFR Section 122.23 and to improve regulatory clarity

Legal Authority: 1976 Code Section(s) 48-1-10 et seq.

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 REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department proposes to amend R.61-9.122.23 for conformity with federal regulations and to improve regulatory clarity.

DETERMINATION OF COSTS AND BENEFITS:

Amending R.61-9.122.23 for conformity 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.

Statement of Rationale:

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* and to improve regulatory clarity.

ATTACHMENT B

SOUTHERN ENVIRONMENTAL LAW CENTER COMMENT LETTER
October 24, 2022

SOUTHERN ENVIRONMENTAL LAW CENTER

525 East Bay Street, Suite 200
Charleston, SC 29403

Telephone 843-720-5270
Facsimile 843-414-7039

October 24, 2022

Via Email

Joseph M. Koon
SC Department of Health and Environmental Control, Bureau of Water
2600 Bull Street
Columbia, South Carolina 29201
koonjm@dhec.sc.gov

Re: Notice of Proposed Regulations Amending R.61-9.122.23, National Pollutant Discharge Elimination System

Dear Mr. Koon:

The Southern Environmental Law Center ("SELC"), on behalf Congaree Riverkeeper, South Carolina Coastal Conservation League, South Carolina Environmental Law Project, South Carolina Native Plant Society, South Carolina Wildlife Federation, Sierra Club, Audubon South Carolina, Save Our Saluda, and Upstate Forever ("Conservation Organizations"), submits these comments on the Department of Health and Environmental Control's ("DHEC's") Notice of Proposed Regulations Amending S.C. Reg. 61.9-122.23 ("Proposed Regulations"), which regulates discharges from concentrated animal feeding operations ("CAFOs").

1. Summary of Comments

DHEC proposes to amend Regulation 61.9-122.23 to remove the requirement that all CAFOs apply for a NPDES permit, unless the facility can demonstrate that it has no potential to discharge. In the new rules, only CAFOs that propose to discharge will be required to apply for a NPDES permit. DHEC has stated that this change is necessary because the existing regulatory framework is inconsistent and that the change will not result in weaker regulation of CAFO pollution in South Carolina. DHEC has also stated that General Assembly review is not required because the new regulation is promulgated to maintain compliance with federal law. These claims are incorrect. As explained below, South Carolina's existing regulations are fully authorized by federal law and the permitting framework is consistent, providing strong substantive and procedural safeguards for water quality and public health. The additional substantive and procedural protections the NPDES regulations impose on large industrial animal facilities—including increased permit limits and monitoring, mandatory permit renewal periods, citizen enforcement, and a 30-day public comment period—would be lost if DHEC moved forward with the proposed rollback.

DHEC should abandon this unnecessary effort to roll back environmental protections and begin enforcing the strong regulations on the books in South Carolina. Should DHEC decide to proceed with the proposed changes, it cannot lawfully bypass General Assembly review. More, if DHEC moves forward with the proposed regulation, it should amend Regulation 61-43 governing agricultural permits to include the substantive and procedural safeguards that will be lost with the proposed rollback.

2. The Proposed Regulations are not exempt from General Assembly review.

As a preliminary matter, DHEC's claim that the South Carolina Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1) exempts these regulatory changes from General Assembly review because they are promulgated for compliance with federal law is inaccurate. *See* DHEC, Notice of Proposed Regulations at 1, Doc. No. 5137 (Sept. 23, 2022). We explained in earlier comments that South Carolina's CAFO permitting regulations are fully authorized by federal law. *See* SELC, Comments on Notice of Drafting, to Amend R. 61-9.122 (Aug. 22, 2022). DHEC's Notice of Drafting pointed 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 NPDES permits 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[.]"[1] South Carolina's regulations do just that. Because South Carolina's existing CAFO NPDES regulations are fully authorized by federal law, the proposed regulations are not necessary to "maintain compliance with federal law," and in turn are not exempt from review by the General Assembly.

DHEC further explained at the October 17, 2022, stakeholder meeting that the change was necessary to "comply" with federal law in light of a Second Circuit Court of Appeals decision vacating the federal regulations upon which South Carolina's current CAFO NPDES regulations are based. But that case—*Waterkeeper Alliance Inc. v. U.S. EPA*—also does not necessitate the regulatory change here. The court in *Waterkeeper* reviewed the 2003 version of EPA's CAFO NPDES regulations—South Carolina's regulations mirror this version of the federal regulations. 399 F.3d 486 (2d Cir. 2005). The court vacated certain provisions of the 2003 federal regulations—including the provision requiring a NPDES permit if the facility could not demonstrate it had "no potential to discharge"—because the court found that the federal Clean Water Act does not authorize EPA to regulate *potential* discharges, as opposed to actual discharges. *Id.* at 504–06. Importantly, though, the South Carolina Pollution Control Act ("PCA") provides South Carolina with more authority than the Clean Water Act provides EPA.
As the South Carolina Court of Appeals explained in *Blackmon v. DHEC*, South Carolina's CAFO NPDES regulations "are based not only on the federal NPDES regulations but also upon the South Carolina [PCA], which specifically authorizes the Department to 'prevent pollution.'" 436 S.C. 529, 543 (S.C. Ct. App. 2022). As such, DHEC is authorized to regulate *potential* and *actual* discharges from CAFOs. So, the *Waterkeeper* decision does not implicate South Carolina's regulations, necessitate a rollback, or justify exempting this regulatory change from General Assembly review.

Should DHEC finalize these regulations without General Assembly review, the agency will be exposed to the risk of litigation.

3. CAFOs pose a significant threat to water quality and public health.

Over the past few decades, the livestock industry has transitioned from small, familyowned farms to large, industrial operations confining thousands, hundreds of thousands, or even millions of animals.

[1] 40 C.F.R. § 123.25(a).

Currently, South Carolina has over one thousand permitted industrial animal facilities, including 661 chicken facilities.[2] These chicken facilities produce about 250 million birds each year.[3]

One of the most significant public health and environmental threats posed by industrial animal facilities is from the extraordinary amount of waste they produce which ultimately pollute surface waters and groundwater, which can be an important source of drinking water for rural residents, and lead to adverse public health outcomes. Some of the contaminants present in livestock waste include nutrients, such as phosphorous, nitrogen, and ammonia; pharmaceuticals, such as the antibiotics that facilities use to combat the unsanitary animal living conditions and promote rapid growth; heavy metals, including zinc and copper; and pathogens (disease-causing organisms such as bacteria and viruses).[4] These contaminants can pollute surface waters through "spills and other dry-weather discharges, overflows from storage 'lagoons,' and discharges to the air[,]" as well as through the "land application of manure, litter, and process wastewater." *Waterkeeper Alliance*, 399 F.3d at 494. Stormwater runoff from production areas and land application sites is also a significant pathway for pollution from these facilities.

Industrial animal facility pollution in turn leads to toxic algae blooms that kill fish, degrades recreational waterways, and contaminates drinking water. Indeed, South Carolina has a number of impaired watersheds due to excessive levels of fecal bacteria.[5] Poultry waste also emits ammonia, which can deposit on soil or directly in water and contribute to algal blooms and fish kills. In addition, ammonia emissions are harmful to human health.[6] More, researchers

recently found that residents living close to hog facilities in North Carolina are at higher risk for kidney disease, anemia, tuberculous, and other serious diseases.[7]

Given these significant environmental and public health threats posed by industrial animal facilities, it is critical that South Carolina keep and enforce its existing, strong permitting framework to regulate pollution from CAFOs.

4. DHEC should enforce South Carolina's existing permitting framework to regulate CAFO pollution.

[2] DHEC, Agricultural Animals Facility Maps, https://scdhec.gov/environment/your-water-coast/agricultural-runoffwaste/agricultural-animals-facility-maps (last visited Oct. 15, 2022).

[3] Sammy Fretwell, The State, *State agency gave chicken farmers improper breaks from pollution rule, SC court says* (June 5, 2022), https://www.thestate.com/news/local/environment/article262066487.html.

[4] JoAnn M Burkholder et al., *Impacts of Waste from Concentrated Animal Feeding operations on Water Quality*, 115 Envtl. Health Perspectives 308, 308 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1817674/.

[5] *See* DHEC, Approved TMDLs, https://scdhec.gov/environment/your-water-coast/approved-tmdls. Although DHEC's agricultural permit regulations provide for more stringent measures when a CAFO is proposed in an impaired watershed, S.C. Reg. Code § 61-43 Part 200.140, DHEC has failed to enforce those measures. *See Blackmon*, 436 S.C. 529.

[6] Nina G.G. Domingo et al., *Air quality-related health damages of food*, 118 PROCEEDINGS OF THE NAT'L ACAD. SCIS. 1 (May 18, 2021), https://www.pnas.org/content/118/20/e2013637118

DHEC has made a number of statements in support of this regulatory rollback. DHEC has stated that the existing regulatory framework is inconsistent, that the agricultural permit requirements are stronger than the NPDES permit requirements, and has suggested that the "no potential to discharge" determination is impossible to meet. None of these statements are correct.

a. South Carolina's permitting framework is consistent and enforceable.

Beginning with DHEC's statement that the existing regulatory framework is inconsistent, DHEC has stated that because the state agricultural permits are "no discharge" permits, and the NPDES permits are "discharge" permits, it would be incompatible for a CAFO to hold both types of permits. But this superficial explanation of the two permitting schemes is misleading. Contrary to DHEC's claim, the two permits are consistent with respect to discharges. DHEC explained at the October 17 stakeholder meeting that the agricultural "no discharge" permit does not prohibit stormwater discharges, or runoff of manure into waterways after rainfall events.[7] That is, stormwater discharges and runoff from the production area or land application site of a CAFO would *not* violate the agricultural permit. So, the agricultural permit prohibits non-related related pollution only. Consistent with that prohibition, the federal effluent standards and limitations for CAFOs, which would be incorporated in a CAFO NPDES permit, also prohibit non-precipitation related discharges.[8] The only discharges authorized by the CAFO NPDES effluent limits would be precipitation related.[9] So, the NPDES permit would not authorize any discharge prohibited by the agricultural permit, and a CAFO could consistently possess both types of permits.

[7] Julia Kravchenko et al, Mortality and Health Outcomes in North Carolina Communities Located in Close Proximity to Hog Concentrated Animal Feeding Operations, 79 N.C. MEDICAL JOURNAL, No. 5 at 278 (2018), https://www.ncbi.nlm.nih.gov/pubmed/30228132.

b. The state agricultural permits and state NPDES permits complement each other, and the NPDES permits provide additional substantive and procedural safeguards.

Turning to DHEC's claim that the State's agricultural permits are stronger than the CAFO NPDES permits, this is misleading. The current regulatory framework does not present an "either-or" between the two permits. Rather, the agricultural permit and NPDES permit work together, with the NPDES permit ensuring there are additional safeguards required for large AFOs.

[7] We understand from the stakeholder meeting that these facilities are required to have a stormwater permit for construction and that DHEC does not believe these facilities are discharging stormwater because of certain siting requirements, manure storage requirements, and other best management practices. A construction stormwater permit would not address stormwater from an operating CAFO and Conservation Organizations disagree with the assumption, absent consistent monitoring records, that there is no contaminated stormwater from CAFOs in South Carolina. Regardless, this is beside the point, which is that the NPDES and agricultural permits are not inconsistent.

[8] *See, e.g.*, 40 C.F.R. §§ 412.31, 412.46; *see also* NPDES Permit Regulation and Effluent Limitation Guidelines and Standards for CAFOs, 68 Fed. Reg. 7176, 7197 (Feb. 12, 2003) (Explaining that "were such [land application] practices [required by the regulations] have been used, EPA believes it is reasonable to conclude that any remaining discharge is agricultural storm water," which is exempt from regulation) (this portion of the 2003 Rule was unaffected by subsequent litigation and rule changes).

[9] *See, e.g.*, 40 C.F.R. § 412.31 (prohibiting discharges from existing source production areas except overflow caused by certain precipitation events and prohibiting discharges from land application areas not in compliance with,

Beginning with the agricultural permit, any AFO with a lagoon, manure storage pond, liquid manure treatment system, or with 30,000 pounds or more of production live weight are required to obtain an agricultural permit.[10] As noted above, an agricultural permit prohibits nonprecipitation related discharges.[11] Substantively, these permits require facilities to submit an animal facility management plan ("AFMP"), which includes, among other things, a description of the facility, an assessment of the nutrients in the facility's manure, a crop management plan, soil information, and location maps.[12] Agricultural permits also include certain siting requirements, such as setbacks from waterways, manure storage requirements, such as covers, manure application requirements, annual sampling of groundwater in land application areas controlled by the permittee, and soil sampling in land application areas controlled by the permittee.[13]

Despite these generally good measures, there are significant procedural and substantive gaps in DHEC's agricultural permit. For example, there are no monitoring or inspection requirements for dry manure storage areas, which can be a significant source of pollution. There is also no citizen enforcement mechanism for violations of agricultural permits. So, all enforcement of these agricultural permits is left to DHEC—a chronically underfunded and understaffed agency. More, there is no mandatory renewal period for non-swine agricultural permits, and the renewal period for swine agriculture permits is seven years.[14] For non-swine

among other things, the NMP); id. § 412.46 (prohibiting all discharges from new source production areas for certain CAFOs and prohibiting discharges from land application areas not in compliance with, among other things, the NMP).

agricultural permits, this means that after the permit is issued, there may never again be an opportunity for public review and comment on the permit or facility. By contrast, and as discussed below, NPDES permits are required to be renewed—and in turn reopened for public comment—at least every five years.[15]

Last, DHEC only provides a 15-day notice period for agricultural permits, there is no requirement for an email or classified ad in a paper with broad circulation. And even less publication is required for expanding operations.[16] DHEC also only provides a public meeting if it determines "significant comment exists" or if 20 or more "affected persons"—that is, a person living within one-mile of the facility—request

[10] S.C. Code Reg. § 61-43.200.30.

[11] *Id*.§ 200.20(B).

[12] *Id.* § 200.50.

[13] *Id.* §§ 200.80; 200.100; 200.170.

[14] *See* S.C. Code Reg. § 61-43 Part 200.70(H) (discussing construction permit expiration, but not expiration of the no discharge permit); S.C. Code Reg. § 61.43 Part 100.70(O) (requiring permits to be renewed at least every seven years); *see also* Administrative Record at 1702, *Blackmon v. SC DHEC*, Case No. 2017-002598 (filed July 28, 2018) (agricultural no discharge permit includes an effective date, and a construction permit expiration date, but no

[15] S.C. Code Reg. § 61-9.122.46(a).

[16] S.C. Code Reg. §§ 61.43 Part 200.60(C).

a public meeting.[17] This 20-comment public meeting threshold is particularly troubling as it essentially eliminates the availability of a public meeting given that many industrial animal facilities are located in rural areas where it is unlikely there are 20 different individuals living within one-mile of the proposed facility. We understand from the stakeholder meeting that, in practice, DHEC will hold a public meeting if 20 comments are submitted, regardless of the proximity of those commenters to the facility. Nevertheless, the actual text of the regulation remains and that, in addition to the inadequate notice publication and notice period, could be used to all but guarantee there will be no public meeting. So, while DHEC's agricultural permits appear to provide certain environmental safeguards through discharge prohibitions, siting requirements, and monitoring, the regulatory framework and permit provide little to ensure these safeguards are effective and enforced.

Fortunately, South Carolina law requires additional protection when large AFOs are concerned—filling in the gaps left by the agricultural permit. In addition to an agricultural permit, large AFOs—referred to as CAFOs—must also apply for a NPDES permit or request a case specific determination by DHEC that the facility has "no potential to discharge . . . under any circumstance or climatic condition."[18] Substantively, NPDES permits include a "no discharge" standard for non-precipitation related discharges from certain existing and new source production areas, a complete "no discharge" standard for certain new source production areas, and only authorizes discharges from land application areas that are in compliance with a nutrient management plan ("NMP")—those discharges are referred to as agricultural stormwater.[19] In addition, NPDES permits require additional monitoring and recordkeeping for production areas, weekly inspections of stormwater and runoff diversion structures, and require facilities to submit a nutrient management plan ("NMP"), compliance with which becomes an enforceable condition

agricultural permit expiration date). DHEC also confirmed at the stakeholder meeting that these is no expiration or renewal period for non-swine agricultural permits.

of the permit.[20] NPDES permits also require facilities to take corrective action if any deficiencies are found during facility inspections and the facilities must document that corrective action.[21] Procedurally, NPDES permits must be renewed after five years, and the NPDES regulations provide a 30-day public comment period on draft permits and allow concerned citizens to petition for a public hearing on a draft permit.[22] The federal Clean Water Act also provides a citizen enforcement provision that allows concerned citizens to assist DHEC in enforcing violations of NPDES permits.[23]

So, while DHEC has developed an acceptable agricultural permit for animal facilities in the State, the NPDES regulations currently in force provide additional scrutiny and procedural safeguards for larger

[17] S.C. Code Reg. §§ 61.43 Part 200.60 (public meeting rules for non-swine CAFOs); Part 100.70 (public meeting rules for swine CAFOs, which expands the affected person radius to 2-miles); Part 50 (defining "affected person").

[18] S.C. Code Reg. § 61-9.122.23(f).

[19] 40 C.F.R. §§ 412.31; 412.46.

[20] *Id.* §§ 412.4; 412.37.

[21] *Id.* § 412.37.

[22] S.C. Code Reg. §§ 61-9.122.46(a) (duration of permits); 124.10 (30-day public comment period); 124.12 (requests of public hearing).

[23] 33 U.S.C. § 1365.

industrial animal facilities—including increased monitoring, mandatory permit renewal periods, citizen enforcement, and increased public participation in the permitting process. These critical protections will be lost if DHEC proceeds with the proposed regulatory change.

c. The "no potential to discharge" standard in the current NPDES regulations is enforceable.

Last, DHEC has suggested that federal courts have concluded that the "no potential to discharge" ("NPTD") determination required by the existing regulations to be exempt from NPDES coverage is "impossible" to meet. Not so. No federal court that Conservation Organizations are aware of has concluded that the NPTD determination is impossible to meet. Rather, the only federal court to consider the NPTD provision merely concluded that the Clean Water Act did not authorize EPA to promulgate such a provision. As noted above, that finding does not implicate South Carolina's regulations.

5. Conclusion

In sum, the existing framework in South Carolina is consistent and provides comparatively strong substantive regulations and procedural safeguards to help ensure our State has adequate environmental protections, accountability, and transparency when it comes to permitting large industrial animal facilities. DHEC should abandon its efforts to rollback these substantive and procedural safeguards.

Should DHEC choose to proceed with the proposed rollback, it cannot bypass General Assembly review without exposing the agency to the risk of litigation because the existing regulations are fully authorized by federal law. More, if DHEC proceeds with this rollback, it should amend the agricultural permit regulations to add increased monitoring requirements, add

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a maximum five-year renewal period for all agricultural permits, and increase public participation and citizen enforcement tools—protections that will be lost with the proposed rollback.

We appreciate the opportunity to provide comments on DHEC's Proposed Regulations and would welcome additional conversations with DHEC and other decisionmakers on this important topic.

Sincerely,

/s/ Emily Wyche
Southern Environmental Law Center
525 East Bay Street, Suite 200
Charleston, South Carolina 29403

Cc (via email only):
Bill Stangler, Congaree Riverkeeper
Betsy La Force, South Carolina Coastal Conservation League
Jeff Leath, South Carolina Coastal Conservation League

Rick Huffman, South Carolina Native Plant Society
Leslie Lenhardt, South Carolina Environmental Law Project
Emily Nellermoe, South Carolina Environmental Law Project
Bob Guild, Sierra Club
Sara Green, South Carolina Wildlife Federation
Steve Gilbert, South Carolina Wildlife Federation
Trip King, South Carolina Wildlife Federation and Audubon South Carolina Julia Dietz, Audubon South Carolina
Melanie Ruhlman, Save Our Saluda
Megan Chase, Upstate Forever
Chris DeScherer, SELC
Blakely Hildebrand, SELC
Sara Martinez, DHEC

ATTACHMENT C

DHEC RESPONSES TO
SOUTHERN ENVIRONMENTAL LAW CENTER COMMENT LETTER
October 24, 2022

Comment:
The state agricultural permits and state NPDES permits complement each other, with the NPDES permits providing additional substantive and procedural safeguards. The proposed amendments will result in weaker regulation of CAFOs, specifically the loss of substantive and procedural protections - including increased permit limits and monitoring, mandatory permit renewal periods, citizen enforcement, and a 30-day public comment period.

Department Response:

The state agricultural permit regulation, R. 61-43, and the state NPDES permit regulation, R. 61-9.122.23, both apply to CAFOS, but are distinct regulations. R. 61-43 prohibit all discharge into the waters of our state, whereas R. 61-9.122.23 requires CAFOs to seek a permit to discharge. These regulations are inherently ambiguous and create conflicting requirements on regulated entities.

The proposed amendments to R. 61-9-122.23 will not result in weaker regulation of CAFOs. The requirements of R. 61-43 prohibit discharge and include robust requirements for facility setbacks, manure management, and other environmental protections. Under R. 61-43, CAFOs cannot discharge, period. Under R. 61-9-122.23, discharges are permissible. CAFOSs are more comprehensively regulated under R. 61-43 which alone is protective of the environment and human health, without the application of the additional monitoring requirements under Regulation 61-9.122.23

Additionally, a CAFO that discharges will be subject to enforcement under both regulations. In other words, the same ultimate result occurs if a CAFO discharges whether the Department issues a single no discharge permit under R.61-43 or also is forced to superfluously issue a conflicting "no potential to discharge" determination under 61-9-122.23.

Comment:
General Assembly review is required for the proposed amendments.

Department Response:
R. 61-9.122.23 was originally passed without legislative review in 2003 as was required by federal law. It has not been changed although it goes beyond the minimum requirements to be consistent with the federal regulation. The proposed amended regulation would not exceed these minimum requirements to maintain consistency with the federal regulation.

The proposed amendments are exempt from legislative review pursuant to S.C. Code 1-23-120(H)(1) as they are proposed to maintain compliance with federal law. Although legislative review is not required, the Department will send the proposed amendments to the General Assembly and provide them the opportunity for the first time to review R. 61-9.122.23.

Comment:
If the proposed amendments move forward, DHEC should amend Regulation 61-43 governing agricultural permits to include increased monitoring requirements, add a maximum five-year renewal period for all agricultural permits, and increase public participation and citizen enforcement tools.

Department Response:
The Department initiates regulation development actions pursuant to governing law, public comment, internal analysis, or other relevant circumstances. Regulation 61-43 was implemented in 1998 and amended in 2002 and 2021 after thorough stakeholder consultation. There is no current pending regulation development activity for R. 61-43, but the Department acknowledges the comments pertaining to R. 61-43.

Date: December 8, 2022

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

From: Bureau of Air Quality

Re: Public Hearing for Notice of Final Regulation Amending R.61-62, *Air Pollution Control Regulations and Standards*, Document No. 5139

I. Introduction

The Bureau of Air Quality (Bureau) submits the attached Notice of Final Regulation amending R.61-62, *Air Pollution Control Regulations and Standards*, for publication in the December 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 of Health and Environmental Control (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. The amendments will take legal effect as of the December 23, 2022, publication in the *State Register*.

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. The Department is 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.

3. The Department is 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.

4. The Department is also making other changes to R.61-62, *Air Pollution Control Regulations and Standards*, as deemed necessary to maintain compliance with federal law. These changes include corrections and other changes for internal consistency, clarification, punctuation, and overall improvement to the text of R.61-62.

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

6. Appropriate Department staff conducted an internal review of the proposed amendments on July 12, 2022.

7. The Bureau published the Notice of Drafting 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. On August 3, 2022, the Bureau contacted via email all facilities subject to R.61-62.70 to inform them of the anticipated proposed amendment to the regulation.

8. Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. Additionally, the Bureau sent a notice of publication of the Notice of Proposed Regulation to interested stakeholders via the Department email list on September 23, 2022. The Bureau also shared information about the Notice of Drafting and the Notice of Proposed Regulation and Public Hearing with stakeholders during the SC Chamber EAC Air Committee meeting on October 7, 2022, and the Carolinas Air Pollution Control Association (CAPCA) meeting on October 13, 2022. The Department received comments from two stakeholders during aforementioned email outreach occurring prior to the public comment period. The Department received a public comment from one other stakeholder by the October 24, 2022, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

9. After consideration of all timely received comments, staff has made a substantive change to the regulatory text of the Notice of Proposed Regulation approved by the Board in the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*. A description of the change appears in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

The Bureau of Air Quality respectfully requests the Board to find need and reasonableness of the attached amendments of R.61-62, *Air Pollution Control Regulations and Standards*, for legal effect as of December 23, 2022, publication in the *State Register*.

Rhonda B. Thompson, P.E.
Chief
Bureau of Air Quality

Myra C. Reece
Director
Environmental Affairs

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-62, AIR POLLUTION CONTROL REGULATIONS AND STANDARDS

December 8, 2022

Document No. 5139
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.

Synopsis:

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 is 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 is also 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 is also making other changes to R.61-62, Air Pollution Control Regulations and Standards, as deemed necessary to maintain compliance with federal law. These changes include corrections and other changes for internal consistency, clarification, punctuation, 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 promulgates 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 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.

Instructions:

Amend R.61-62 pursuant to each individual instruction provided with the text of the amendments below.

~~Indicates Matter Stricken~~
Indicates New Matter

Text:

61-62. Air Pollution Control Regulations and Standards.

Statutory Authority: 1976 Code Sections 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]
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]

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
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]
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]

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
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]
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]

40 CFR Part 63 Subpart A			
Federal Register Citation	**Volume**	**Date**	**Notice**
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]
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]

40 CFR Part 63 Subpart YY			
Federal Register Citation	**Volume**	**Date**	**Notice**
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]

40 CFR Part 63 Subpart MMMMM			
Federal Register Citation	**Volume**	**Date**	**Notice**
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]
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 hazardous air pollutant or 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:

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, amends R.61-62 to incorporate these amendments to federal standards promulgated from January 1, 2021, through December 31, 2021. Additionally, the Department amends 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 makes 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 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 adopts 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. These amendments include the correction of an error in an earlier amendment as required by the EPA to maintain compliance with federal law These amendments also include corrections for internal consistency, clarification, and codification, to improve the overall text as necessary for 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 revisions. The amendments 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 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 amendments 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 amendments to R.61-62 provides 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.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 5139
R.61-62, *Air Pollution Control Regulations and Standards*

As of the October 24, 2022, close of the Notice of Proposed Regulation comment period:

Name	Section
Kim A. Wolfe, SRNS	R.61-62.70.5(c)

Comment (received via email prior to public comment period):

1. Will SCDHEC maintain their current Standard No. 8 regulatory language and the instructions for DHEC 2944 (Insignificant Activity Equipment Instructions)?

2. When I submit my TV renewal application I will be required to submit an Emission Unit, Equipment and Processes form (D-2940), Regulatory Information form (D-2946), and list the equipment ID on and provide the calculation method with supporting documentation to complete the Facility Wide Emissions form (D-2943) for any equipment ID that exceeds 1000 lb/year of any single TAP and each of these equipment IDs will be listed in the TV permit with permit conditions. If that is accurate, this will result in a significant increase in workload to submit the TV renewal application and manage/comply with permit conditions. The benefit of doing this is not clear to me since any insignificant activities listed due to emission levels (regardless of emission rate) must be included in my facility wide emissions that are reported in TPY (form D-2943) and included in my modeling demonstration. My facility is a major source and will remain that way for the foreseeable future regardless of the single HAP insignificant activities limit being set at 1000 lbs/month or 1000 lbs/year. Will the Permitting section of SCDHEC provide clarification/guidance or briefing on the implementation of this change and its impacts to Title V permitted facilities?

3. Is it correct to state, "Equipment IDs that are documented to be exempt from construction permitting under R.61-62.1, Section II.B(2)(h) (this regulation will continue to utilize the 1000 lbs/month value by reference to Standard No. 8) can continue to be added to my facility's insignificant activities list under permit condition H.1 as exempt. When I submit the renewal application equipment IDs that exceed the 1000 lbs/year TAP emission rate, they will not be considered insignificant activities and they must be included on all applicable TV application forms (even though exempt from construction permitting). Any activity that emits over 1000 lbs/year TAP will be included in the TV permit as a major source"?

Department Response:

The Department responded by email to the commenter and further clarifies and supplements its response herein.

1. Standard No. 8 is a state-only regulation, and the levels referenced in that standard are to determine if the Bureau may require a permit for that source. The insignificant activities provision is strictly part of the Title V regulations, and the designation only indicates if a source must be included as an emission point in the Title V permit. The EPA has indicated to the Department that an insignificant activities level of 1000 lbs/month is not appropriate, since at that level a facility could emit six tons per year of a single HAP, which is 60% of the major source level. The 1000 lb/year threshold was set forth in R.61-62.70.5(c) prior to 2015, and the Department's existing regulatory language is not federally approved. To address this error and ensure federal compliance, the Department is reverting to the previously approved

language, with one additional update in response to comments (described below) to allow the designation of insignificant activities on the basis of hazardous air pollutant emissions.

2. The Department responded that the commenter would need to complete the application to include, as emissions units, any activity that emits greater than the insignificant activities threshold. If an applicant has an activity that emits greater than 1000 lbs/year it will become an emission point in the operating permit. As discussed above, this approach is necessary to ensure consistency with the federally approved insignificant activities threshold of 1000 lbs/year.

3. A source such as that described by the commenter may be exempt from construction permitting, but not exempt from the operating permit. Facilities may work with their permit writer to determine the best way to add the source(s) to the permit. Such situations may be handled through a 502(b)10 request or a minor modification request, whichever is appropriate.

Name	Section
Shara Kay Dine, Core Molding Technologies, Inc.	R.61-62.70.5(c)

Comment (received via email prior to public comment period):

We have several bond dispense units that are exempt from the construction permit requirements but will now be required to be included in the next Title V application as significant emissions units. Does this mean that these units, while exempt from construction permitting, will now be required to have an operating permit (Title V permit)? Will existing emissions units that are in the Title V permit as insignificant have to be changed to significant, or will they be grandfathered under the old language? Lastly, has a general permit been finalized for this industry yet?

Department Response:

The Department responded by email to the commenter and further clarifies its response herein.

Even if units as described by the commenter do not require a construction permit, they will need to be included in the operating permit where Title V applies to the source and unit emissions exceed the 1000 lb/year threshold approved by EPA. The EPA has indicated to the Department that an insignificant activities level of 1000 lbs/month is not appropriate, since at that level a facility could emit six tons per year of a single HAP, which is 60% of the major source level. The 1000 lbs/year threshold was set forth in R.61-62.70.5(c) prior to 2015, and the Department is simply reverting to the previously approved language, with one additional update in response to comments (described below) to allow the designation of insignificant activities on the basis of hazardous air pollutant emissions. Correction of this error is required by EPA, so there will be no grandfathering of any units. The comment was forwarded to the permit writer to follow up with the commenter on the process to update the TV permit.

Name	Section
Bob Morgan, SC Chamber of Commerce	R.61-62.70.5(c)

Comment (received during public comment period):

The SC Chamber is providing comment on the change and proposing alternate language to reduce the regulatory burden for regulated entities as well as the Department. The proposed revision is too restrictive and is unnecessary. The SC Chamber proposes the following alternate language:

“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, any compound listed in

Regulation 61- 62.5, Standard No. 8, Toxic Air Pollutants, or any hazardous air pollutants on the list of hazardous air pollutants established by Clean Air Act (CAA) section 112(b)(1), 42 U.S.C. 7412(b)(1) and as amended to remove or add compounds.

The change from 1,000 pounds per month to 1,000 pound per year is not necessary and will require insignificant projects related to, for example, changes in raw materials or equipment operations, to be handled as Title V modifications. Title V modifications are more complicated and take longer to implement than addition of insignificant activities. The 5 tpy threshold is established for criteria pollutants and may be extended to cover hazardous air pollutants.

Department Response:

The EPA has indicated to the Department that an insignificant activities level of 1000 lbs/month is not appropriate, since at that level a facility could emit six tons per year of a single HAP, which is 60% of the major source level. The 1000 lb/year threshold was set forth in R.61-62.70.5(c) prior to 2015, and the Department's existing regulatory language is not federally approved. To address this error and ensure federal compliance, the Department is reverting to the previously approved language with respect to compounds listed under Standard No. 8.

The Department acknowledges and appreciates the comment regarding extension of insignificant activities designation under Title V to emissions of hazardous air pollutants listed under Section 112 of the Clean Air Act below approvable threshold levels. Upon consideration of this comment, the Department has made a substantive change to also include emissions or emissions units with potential to emit less than 1000 lbs/year of any hazardous air pollutant within the scope of "insignificant activity." This change is made to ensure the provision properly captures the intended scope of insignificant activities under Title V and is approvable and in compliance with federal law.

Date: December 8, 2022

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

From: Bureau of Water

Re: Public Hearing for Notice of Final Regulation Amending R.61-58, State Primary Drinking Water Regulations , Document No. 5135

I. Introduction

The Bureau of Water proposes the attached Notice of Final Regulation amending R.61-58, State Primary Drinking Water Regulations for publication in the December 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, 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 they are for compliance with federal law. These amendments will take legal effect as of the December 23, 2022, publication in the *State Register*.

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*.

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 on August 17, 2022.

5. Upon receiving approval during the September 8, 2022 Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received public comments from 1 person by the October 24, 2022, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

III. Request for Approval

The Bureau of Water respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-58, State Primary Drinking Water Regulations, for legal effect as of December 23, 2022, publication in the *State Register*.

Jennifer R. Hughes
Bureau Chief

Myra C. Reece
Director of Environmental Affairs

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R. 61-58, State Primary Drinking Water Regulations

December 8, 2022

Document No. 5135
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.

Synopsis:

Pursuant to Pursuant to 1976 Code Sections 44-55-10 et seq., the Department of Health and Environmental Control ("Department") amends 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). The amendments 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 makes 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), exempted these amendments from General Assembly review, as the Department promulgates 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 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.

Instructions:

(Give exact directions to the publishers for placement of the new regulation or amendment in the South Carolina Code of Regulations. For a repeal, instruct publisher to repeal the regulation in the Code of Regulations.)

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-58. State Primary Drinking Water Regulations.

Statutory Authority: 1976 Code Sections 44-55-10 et seq.

Amend R.61-58.B. Definitions to read:

(1) "Act" means the State Safe Drinking Water Act of 1976, and amendments.

(2) "Action level" is the concentration of lead or copper in water specified in R.61-58.11.B(1), Lead and Copper Action Levels, which determines~~, in some cases, the treatment requirements contained~~

requirements under R.61-58.11, Control of Lead and Copper ~~that a water system is required to complete~~. The action for lead is 0.015 mg/L and the action level for copper is 1.3 mg/L.

(3) "Administrator" means the Administrator of the United States Environmental Protection Agency.

(4) "Aerator" means the device embedded in the water faucet to enhance air flow with the water stream and to prevent splashing.

~~(4)~~(5) "Annular space" means the space between the well casing and the formation or the space between the inner casing and outer casing where two casings are used.

~~(5)~~(6) "Aquifer" means a geologic formation, group of formations, or part of a formation that contains sufficient saturated permeable material to yield significant quantities of groundwater to wells and springs.

~~(6)~~(7) "Aquifer Storage and Recovery (ASR) Well" means a water well which allows potable water to be injected into a subsurface aquifer to be recovered by pumping at a later date.

~~(7)~~(8) "Artificial filter" means filter material which is placed in the annular space to increase the effective diameter of the well, and to prevent fine-grained sediments from entering the well.

~~(8)~~(9) "Backflow prevention device" means any device approved by the Department for use in preventing backflow under prescribed limited conditions of use.

~~(9)~~(10)"Bag filters" are pressure-driven separation devices that remove particulate matter larger than 1 micrometer using an engineered porous filtration media. They are typically constructed of a non-rigid, fabric filtration media housed in a pressure vessel in which the direction of flow is from the inside of the bag to outside.

~~(10)~~(11) "Bank filtration" is a water treatment process that uses a well to recover surface water that has naturally infiltrated into ground water through a river bed or bank(s). Infiltration is typically enhanced by the hydraulic gradient imposed by a nearby pumping water supply or other well(s).

~~(11)~~(12) "Bedrock" means the parent solid rock formation underlying weathered rock and soil.

~~(12)~~(13) "Best available technology" or "BAT" means the best technology, treatment techniques, or other means which either the Department or the Environmental Protection Agency (EPA) finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration).

~~(13)~~(14) "Board" means the South Carolina Board of Health and Environmental Control charged with responsibility for implementation of the Safe Drinking Water Act.

~~(14)~~(15) "Boil Water Notice/Advisory" means a notice, whether written or verbal, issued by the Department, or the owner or operator of a public water system, notifying the users of the water system that the water is/may be contaminated and to boil the water (vigorous rolling boil for at least one minute) prior to using it for drinking or cooking. The notice shall give the reason for its issuance and corrective actions being taken.

~~(15)~~(16) "Booster Pump" means any pump installed within a water distribution system for the purpose of increasing the water pressure in the water distribution system, including distribution storage facilities

downstream from the pump. The term booster pump does not apply to the so called low service and high service pumps at water treatment plants.

~~(16)~~(17) "Business Plan" for the purpose of these regulations means a document consisting of three sub-plans, a "Facilities Plan", a "Management Plan", and a "Financing Plan" which is intended to show how a water system will be self-sustaining and have the commitment and the financial, managerial and technical capability to consistently comply with the State Safe Drinking Water Act and these Regulations.

~~(17)~~(18) "Cartridge filters" are pressure-driven separation devices that remove particulate matter larger than 1 micrometer using an engineered porous filtration media. They are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in pressure vessels in which flow is from the outside of the cartridge to the inside.

~~(18)~~(19) "Centralizer" means device to keep the casing and screen aligned in the center of the borehole to ensure proper emplacement of grout around the casing and artificial filter around the screens.

~~(19)~~(20) "Certified Laboratory" means a laboratory approved by the Department under Regulation 61-81.

~~(20)~~(21) "Certified Tester" means any person holding an up-to-date backflow prevention assembly tester certification card issued by the Department. Certified testers fall into one of the following classifications:

(a) General Tester -any person who has successfully completed an approved backflow prevention training and certification course which is sponsored by or approved by the Department, and who has personal possession of or whose employer owns a backflow prevention assembly test kit. This person provides the service of testing backflow prevention assemblies to the general public.

(b) Inspector Tester -any person with the same qualifications as the General Tester, except the Inspector Tester must be employed by a municipality, water district, subdivision, or other public water system. The Inspector Tester is normally involved in the management of a backflow prevention program, and does not sell his services to the general public.

(c) Limited Tester -any person with the same qualifications as the General Tester except the prescribed test(s) is (are) conducted only on backflow prevention assemblies which are owned by his employer. The Limited Tester does not provide testing services to the general public.

(d) Manufacturer's Agent -any person with the same qualifications as the General Tester except the prescribed test(s) is (are) conducted as an extension of his duties as a representative of a particular backflow prevention company.

~~(21)~~(22) "Certified Well Driller" means any person currently certified by the State Environmental Certification Board to practice as a well driller in South Carolina.

(23) "Child care facility" means a location that houses a licensed provider of child care, day care, or early learning services to children, as determined by the state, local, or tribal licensing agency.

~~(22)~~(24) "Clay" means fine-grained inorganic material (grains less than 0.0005 mm in diameter) which has very low permeability and is plastic.

~~(23)~~(25) "Clean compliance history" is, for the purposes of R.61-58.17, a record of no MCL violations under R.61-58.5.F; no monitoring violations under R.61-58.5.G or R.61-58.17; and no coliform treatment technique trigger exceedances or treatment technique violations under R.61-58.17.

~~(24)~~(26) "Coagulation" means a process using coagulant chemicals and mixing by which colloidal and suspended materials are destabilized and agglomerated into flocs.

~~(25)~~(27) "Coliform Bacteria" means all aerobic and facultative anaerobic, gram-negative, non-spore forming, rod-shaped bacteria which ferment lactose with gas formation within forty eight hours at thirty-five degrees Celsius.

~~(26)~~(28) “Combined distribution system” is the interconnected distribution system consisting of the distribution systems of wholesale systems and of the consecutive systems that receive finished water.

~~(27)~~(29) "Commissioner" means the duly constituted Commissioner of the Department or his authorized agent.

~~(28)~~(30) "Community Water Systems" means a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents. This may include, but not be limited to, subdivisions, municipalities, mobile home parks, apartments, etc.

~~(29)~~(31) "Compliance cycle" means the nine-year calendar year cycle during which public water systems must monitor. Each compliance cycle consists of three three-year compliance periods. The first calendar year cycle begins January 1, 1993 and ends December 31, 2001; the second begins January 1, 2002 and ends December 31, 2010; the third begins January 1, 2011 and ends December 31, 2019.

~~(30)~~(32) "Compliance period" means a three-year calendar year period within a compliance cycle. Each compliance cycle has three three-year compliance periods. Within the first compliance cycle, the first compliance period runs from January 1, 1993 to December 31, 1995; the second from January 1, 1996 to December 31, 1998; the third from January 1, 1999 to December 31, 2001.

~~(31)~~(33) "Comprehensive Performance Evaluation" (CPE) is a thorough review and analysis of a treatment plant’s performance-based capabilities and associated administrative, operation and maintenance practices. It is conducted to identify factors that may be adversely impacting a plant’s capability to achieve compliance and emphasizes approaches that can be implemented without significant capital improvements. For purposes of compliance with R.61-58.10.H and (I) the comprehensive performance evaluation must consist of at least the following components: assessment of plant performance; evaluation of major unit processes; identification and prioritization of performance limiting factors; assessment of the applicability of comprehensive technical assistance; and preparation of a CPE report.

~~(32)~~(34) "Cone of Depression" means the depression in the water table or potentiometric surface in an aquifer caused by pumping water from a well and usually having the shape of an inverted cone.

~~(33)~~(35) "Confluent growth" means a continuous bacterial growth covering the entire filtration area of a membrane filter, or a portion thereof, in which bacterial colonies are not discrete.

~~(34)~~(36) “Consecutive system” is a public water system that receives some or all of its finished water from one or more wholesale systems. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems.

~~(35)~~(37) "Contaminant" means any physical, chemical, biological, or radiological substance or matter in water.

~~(36)~~(38) "Conventional filtration treatment" means a series of processes including coagulation, flocculation, sedimentation, and filtration resulting in substantial particulate removal.

~~(37)~~(39) "Corrosion inhibitor" means a substance capable of reducing the corrosivity of water toward metal plumbing materials, especially lead and copper, by forming a protective film on the interior surface of those materials.

~~(38)~~(40) "Cross-connection" means any actual or potential connection or structural arrangement between a public water supply and any other source or system through which it is possible to introduce into any part of the potable system any used water, industrial fluid, gas or substance other than the intended potable water which the system is supplied. Bypass arrangements, jumper connections, removable sections, swivel or changeover devices and other temporary or permanent devices through which or because of which backflow can or may occur are considered to be cross-connections.

~~(39)~~(41) "CT" or "CTcalc" is the product of "residual disinfectant concentration" (C) in mg/L determined before or at the first customer, and the corresponding "disinfectant contact time (T) in minutes, i.e., "C" × "T". If a public water system applies disinfectants at more than one point prior to the first customer, it shall determine the CT of each disinfectant sequence before or at the first customer to determine the total percent inactivation or "total inactivation ratio." In determining the total inactivation ratio, the public water system shall determine the residual disinfectant concentration of each disinfection sequence and corresponding contact time before any subsequent disinfection application point(s). "CT_{99}." is the CT value required for 99.9 percent (3-log) inactivation of Giardia lamblia cysts. CT_{99}. for a variety of disinfectants and conditions appear in Tables 1.1 -1.6, 2.1, and 3.1 of R.61-58.10.F(2)(c).

$$\frac{CTcalc}{CT_{99.9}}$$

is the inactivation ratio. The sum of the inactivation ratios, or total inactivation ratio shown as

$$\sum \frac{(CTcalc)}{(CT_{99.9})}$$

is calculated by adding together the inactivation ratio for each disinfection sequence. A total inactivation ratio equal to or greater than 1.0 is assumed to provide a 3-log inactivation of Giardia lamblia cysts.

~~(40)~~(42) "Dedicated Fire Line" means a water line connected to a public water system which is designed and used solely for a fire protection system. Such lines must be provided with an acceptable and approved backflow prevention device and must not connect at any point downstream of that device with water lines or fixtures that are used for potable water.

~~(41)~~(43) "Department" means the South Carolina Department of Health and Environmental Control, including personnel thereof authorized and empowered by the Board to act on behalf of the Department or Board.

~~(42)~~(44) "Development" means repairing damage to the aquifer caused by drilling procedures and increasing the porosity and permeability of the geologic materials surrounding the intake portion of the well.

~~(43)~~(45) "Diatomaceous earth filtration" means a process resulting in substantial particulate removal in which (1) a precoat cake of diatomaceous earth filter media is deposited on a support membrane (septum), and (2) while the water is filtered by passing through the cake on the septum, additional filter media known as body feed is continuously added to the feed water to maintain the permeability of the filter cake.

~~(44)~~(46) "Direct filtration" means a series of processes including coagulation and filtration but excluding sedimentation resulting in substantial particulate removal.

~~(45)~~(47) "Disinfectant" means any oxidant, including but not limited to chlorine, chlorine dioxide, chloramines and ozone added to water in any part of the treatment or distribution process, that is intended to kill or inactivate pathogenic microorganisms.

~~(46)~~(48) "Disinfectant contact time" ("T" in CT calculations) means the time in minutes that it takes for water to move from the point of disinfectant application or the previous point of disinfectant residual measurement to a point before or at the point where residual disinfectant concentration ("C") is measured. Where only one "C" is measured, "T" is the time in minutes that it takes for water to move from the point of disinfectant application to a point before or where residual disinfectant concentration ("C") is measured. Where more than one "C" is measured, "T" is (a) for the first measurement of "C", the time in minutes that it takes for water to move from the first or only point of disinfectant application to a point before or at the point where the first "C" is measured and (b) for subsequent measurements of "C", the time in minutes that it takes for water to move from the previous "C" measurement point to the "C" measurement point for which the particular "T" is being calculated. Disinfectant contact time in pipelines shall be calculated based on "plug flow" by dividing the internal volume of the pipe by the maximum hourly flow rate through that pipe. Disinfectant contact time within mixing basins and storage reservoirs shall be determined by tracer studies or an equivalent demonstration.

~~(47)~~(49) "Disinfected" means that the water is free of harmful or pathogenic organisms.

~~(48)~~(50) "Disinfection" means a process which inactivates pathogenic organisms in water by chemical oxidants or equivalent agents.

~~(49)~~(51) "Disinfection profile" is a summary of daily Giardia lamblia inactivation through the treatment plant. The procedure for developing a disinfection profile is contained in R.61-58.10.H(3) (Disinfection profiling and bench marking) and in R.61-58.10.I(4) (Disinfection profile).

~~(50)~~(52) "Dispensing Station" means a facility where additional treatment is provided to water from an approved public water system, and that treated water is available to the general public. This does not apply to point of use devices in public buildings (e.g., restaurants and cafeterias, etc.).

~~(51)~~(53) "Distribution Treatment Plant" means any facility located within the distribution system capable of altering the physical, chemical, radiological or bacteriological quality of the water in a public water system (i.e. chlorine booster station).

~~(52)~~(54) "Domestic or other non-distribution system plumbing problem" means a coliform contamination problem in a public water system with more than one service connection that is limited to the specific service connection from which the coliform-positive sample was taken.

~~(53)~~(55) "Dose equivalent" means the product of the absorbed dose from ionizing radiation and such factors as account for differences in biological effectiveness due to the type of radiation and its distribution in the body as specified by the International Commission on Radiological Units and Measurements (ICRU).

~~(54)~~(56) "Drawdown" means the difference in levels between the static water level in a well and the surface of the depressed water level that occurs when the well is pumped.

~~(55)~~(57) "Drilling Fluid" means a water or air based fluid used in drilling to remove cuttings from the hole, to clean and cool the drill bit, to reduce friction between the drill pipe and the sides of the hole and to seal the bore hole.

~~(56)~~(58) ‘‘Dry Line’’ means a water line project not connected to a source at the time application is made for the permit to construct.

~~(57)~~(59) “Dual sample set” is a set of two samples collected at the same time and same location, with one sample analyzed for TTHM and the other sample analyzed for HAA5. Dual sample sets are collected for the purposes of conducting an IDSE under subpart U of this part and determining compliance with the TTHM and HAA5 MCLs under subpart V of this part.

~~(58)~~(60) "Dug well" means large diameter (24 to 60-inch) well generally of low yield which is usually excavated by hand and which penetrates only a few feet below the water table.

~~(59)~~(61) "Effective corrosion inhibitor residual" for the purpose of R.61-58.11, Control of Lead and Copper, means a concentration sufficient to form a passivating film on the interior walls of a pipe.

~~(60)~~(62) "Effective (grain) size" means the sieve size that retains 90 percent of the materials.

(63) “Elementary school,” for the purposes of R.61-58.11 only, means a school classified as elementary by state and local practice and composed of any span of grades (including pre-school) not above grade eight (8).

~~(61)~~(64) "Emergency" means any event which adversely impacts the ability of the system to produce or deliver safe drinking water to the consumer.

~~(62)~~(65) "Emergency Well" means a well that is operable and connected to the distribution system, but is not routinely operated or sampled. Such wells are only available to be used during emergency situations and only in conjunction with a boil water advisory.

~~(63)~~(66) "Enhanced coagulation" means the addition of sufficient coagulant for improved removal of disinfection byproduct precursors by conventional filtration treatment.

~~(64)~~(67) "Enhanced softening" means the improved removal of disinfection byproduct precursors by precipitative softening.

~~(65)~~(68) "Expansion" means installation of additions, extensions, changes, or alterations to a public water system's existing source, transmission, storage or distribution facilities which will enable the system to increase in size its existing service area and/or number of authorized service connections.

~~(66)~~(69) "Facilities Plan" means a document which consists of an assessment of the current and foreseeable water supply needs of a water system's service area; a detailed description of alternatives considered for meeting those needs; detailed cost estimates for the construction, operation and maintenance of the different alternatives, and the rationale for the alternative selected. For existing systems, the description of alternatives would include but not be limited to: a detailed description of existing facilities (source, treatment and distribution); description of any upgrade necessary to bring the existing facilities into compliance with the Act and these regulations; an assessment of the ability of the existing facilities,

along with any necessary upgrade, to supply the current and foreseeable water supply needs of the area (including the ability to comply with any foreseeable regulatory changes); and a description of any other alternatives considered for meeting the water supply needs.

~~(67)~~(70) "Federal Act" means the Federal Safe Drinking Water Act, as amended.

(71) "Fifth liter sample," for purposes of R.61-58.11, Control of Lead and Copper, means a one-liter (1 L) sample of tap water collected in accordance with R.61-58.11.H(2).

~~(68)~~(72) "Filter profile" is a graphical representation of individual filter performance, based on continuous turbidity measurements or total particle counts versus time for an entire filter run, from startup to backwash inclusively, that includes an assessment of filter performance while another filter is being backwashed.

~~(69)~~(73) "Filtration" means a process for removing particulate matter from water by passage through porous media.

~~(70)~~(74) "Financial Plan" means a document which consists of projections that a water system's revenues and cash flow will be sufficient for meeting the cost of construction, operation and maintenance for at least five full years from the initiation of operations. The financial plan must also include assurances deemed necessary for the system to remain viable. Such assurances may include but not be limited to: 1) a projection of rates showing a significant coverage ratio, 2) escrow funds, 3) bonding and 4) letter of credit.

(75) "Find-and-fix" means the requirements under R.61-58.11, Control of Lead and Copper, that water systems must perform at every tap sampling site that yielded a lead result above fifteen micrograms per liter (15 µg/L).

~~(71)~~(76) "Finished water" is water that is introduced into the distribution system of a public water system and is intended for distribution and consumption without further treatment, except as treatment necessary to maintain water quality in the distribution system (e.g., booster disinfection, addition of corrosion control chemicals).

~~(72)~~(77) "Fire Flow" means five hundred (500) gallons per minute or the flow required for fire protection by the local government or public water system, whichever is greater.

~~(73)~~(78) "First draw sample" means ~~a one-liter sample of tap water, collected in accordance with R.61-58.11(H)(2), Sample Collection Methods, that has been standing in plumbing pipes at least 6 hours and is collected without flushing the tap~~the first one-liter (1 L) sample of tap water collected in accordance with R.61-58.11.H(2)(b).

~~(74)~~(79) "Flocculation" means a process to enhance agglomeration or collection of smaller floc particles into larger, more easily settleable particles through gentle stirring by hydraulic or mechanical means.

~~(75)~~(80) "Flowing stream" is a course of running water flowing in a definite channel.

~~(76)~~(81) "Formation" means any substantial interval penetrated during the drilling of a well in which the geologic materials have distinct compositional characteristics with respect to adjacent overlying and underlying intervals.

~~(77)~~(82) "Fracture Zone" means any level or interval penetrated during drilling which has void spaces caused by breakage of the formation.

(83) “Full lead service line replacement” means the replacement of a lead service line (as well as galvanized service lines requiring replacement), as defined in R.61-58.B, that results in the entire length of the service line, regardless of service line ownership, meeting the federal Safe Drinking Water Act (SDWA) Section 1417 definition of lead-free applicable at the time of the replacement. A full lead service line replacement includes a replacement where only one portion of the service line is lead, such as where a partial lead service line was previously conducted, as long as, upon completion of the replacement, the entire service line meets the SDWA Section 1417 definition of lead-free applicable at the time of the replacement. Galvanized service lines that are or were downstream of a lead service line must also be replaced for a service line to be a full lead service line replacement. A lead service line that is left in place in the ground but remains out of service may be full lead service line replacement where a new non-lead service line is installed for use instead of the out-of-service lead service line.

~~(78)~~(84) "GAC10" means granular activated carbon filter beds with an empty-bed contact time of 10 minutes based on average daily flow and a carbon reactivation frequency of every 180 days, except that the reactivation frequency for GAC10 used as a best available technology for compliance with R.61-58.5.P(2)(b) MCLs shall be 120 days.

~~(79)~~(85) “GAC20” means granular activated carbon filter beds with an empty-bed contact time of 20 minutes based on average daily flow and a carbon reactivation frequency of every 240 days.

(86) “Galvanized service line” means iron or steel piping that has been dipped in zinc to prevent corrosion and rusting.

~~(80)~~(87) "Geologic Material" means naturally occurring matter derived from or consisting of rock and sediment.

~~(81)~~(88) "Geophysical logging" means any number of techniques that measure some electrical, chemical or radioactive property of the subsurface, either characteristic of the ground water or of the rocks in which the ground water occurs.

(89) “Gooseneck, pigtail, or connector” is a short section of piping, typically not exceeding two feet (2 ft), which can be bent and used for connections between rigid service piping. For purposes of this subpart, lead goosenecks, pigtails, and connectors are not considered to be part of the lead service line, but may be required to be replaced pursuant to R.61-58.11.F(3).

~~(82)~~(90) "Gross alpha particle activity" means the total radioactivity due to alpha particle emission as inferred from measurements on a dry sample.

~~(83)~~(91) "Gross beta particle activity" means the total radioactivity due to beta particle emission as inferred from measurements on a dry sample.

~~(84)~~(92) "Groundwater" means subsurface water found in void spaces in geologic materials within the zone of saturation.

~~(85)~~(93) "Groundwater Treatment Plant" means any facility capable of altering the physical, chemical, radiological or bacteriological quality of groundwater for public consumption in a public water system.

~~(86)~~(94) "Ground water under the direct influence of surface water (GWUDI)" means any water beneath the surface of the ground with (1) significant occurrence of insects or other microorganisms, algae, or large-diameter pathogens such as Giardia lamblia, or (2) Cryptosporidium, or (3) significant and relatively rapid

shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions. Direct influence shall be determined for individual sources in accordance with criteria established by the Department. The Department's determination of direct influence may be based on site-specific measurements of water quality and/or documentation of well construction characteristics and geology with field evaluation.

~~(87)~~(95) "Grout" means a fluid mixture of cement and water (neat cement) of a consistency that can be forced through a pipe and placed as required. Various additives, such as sand, bentonite, and hydrated lime, may be included in the mixture to meet certain requirements. For example, sand is added when a considerable volume of grout is needed.

~~(88)~~(96) "Haloacetic acids (five)" (HAA5) mean the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

~~(89)~~(97) "Halogen" means one of the chemical elements chlorine, bromine or iodine.

~~(90)~~(98) "Hardpan" means hard impervious layer cemented by relatively insoluble secondary material.

~~(91)~~(99) "High Rate Gravity Filter" means any gravity filter which filters water at a rate in excess of four (4) gallons per minute per square foot.

~~(92)~~(100)"Initial compliance period" means the first full three-year compliance period which begins at least 18 months after promulgation, except for contaminants listed at R.61-58.5.B(2)(l)-(p) and those listed at R.61-58.5.D(2)(b)(xix)-(xxxiii) and R.61-58.5.N(2)(s)-(u), initial compliance period means the first full three-year compliance period after promulgation for systems with 150 or more service connections (January 1993-December 1995), and first full three-year compliance period after the effective date of the regulation (January 1996-December 1998) for systems having fewer than 150 service connections.

~~(93)~~(101)"Lake/reservoir" refers to a natural or man made basin or hollow on the Earth's surface in which water collects or is stored that may or may not have a current or single direction of flow.

~~(94)~~(102)"Large water system" for the purpose of R.61-58.11, Control of Lead and Copper, only, means a water system that serves more than 50,000 persons.

~~(95)~~(103)"Lead free" means: (i) when used with respect to solders and flux, those containing not more than 0.2 percent lead; and (ii) ~~when used with respect to pipes and pipe fittings, those containing not more than 8.0 percent lead.~~ not more than a weighted average of 0.25 percent lead when used with respect to the wetted surfaces of pipes, pipe fittings, plumbing fittings, and fixtures as defined in 40 CFR 143.12.

~~(96) "Lead service line" means a service line made of lead which connects the water main to the building inlet and any lead pigtail, gooseneck or other fitting which is connected to such lead line.~~

(104) "Lead service line" means a portion of pipe that is made of lead, which connects the water main to the building inlet. A lead service line may be owned by the water system, owned by the property owner, or both. For the purposes of this subpart, a galvanized service line is considered a lead service line if it ever was or is currently downstream of any lead service line or service line of unknown material. If the only lead piping serving the home is a lead gooseneck, pigtail, or connector, and it is not a galvanized service line that is considered a lead service line the service line is not a lead service line. For purposes of R.61-58.11.H(1) only, a galvanized service line is not considered a lead service line.

(105) “Lead status unknown service line” means a service line that has not been demonstrated to meet or not meet the federal SDWA Section 1417 definition of lead free. It is not necessary to physically verify the material composition (for example, copper or plastic) of a service line for its lead status to be identified (e.g., records demonstrating the service line was installed after a municipal, state, or federal lead ban).

(106) “Lead trigger level” means a particular concentration of lead in water that prompts certain activities under R. 61-58.11, Control of Lead and Copper. The trigger level for lead is a concentration of ten micrograms per liter (10µg/L).

~~(97)~~(107)"Legionella" means a genus of bacteria, some species of which have caused a type of pneumonia called Legionnaires Disease.

~~(98)~~(108)"Level 1 assessment" is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the system triggered the assessment. It is conducted by the system operator or owner. Minimum elements include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (e.g., whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing. The system must conduct the assessment consistent with any Department directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system.

~~(99)~~(109)"Level 2 assessment" is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the system triggered the assessment. A Level 2 assessment provides a more detailed examination of the system (including the system’s monitoring and operational practices) than does a Level 1 assessment through the use of more comprehensive investigation and review of available information, additional internal and external resources, and other relevant practices. It is conducted by an individual approved by the Department, which may include the system operator. Minimum elements include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (e.g., whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing. The system must conduct the assessment consistent with any Department directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system. The system must comply with any expedited actions or additional actions required by the Department in the case of an E. coli MCL violation.

~~(100)~~(110) "Limestone" means a sedimentary formation composed chiefly of calcium carbonate, consolidated or unconsolidated, which may be in the form of shell pieces or calcareous muds or sands.

~~(101)~~(111) “Locational running annual average (LRAA)” is the average of sample analytical results for samples taken at a particular monitoring location during the previous four calendar quarters.

~~(102)~~(112) "Man-made beta particle and photon emitters" means all radionuclides emitting beta particles and/or photons listed in Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure, NBS Handbook 69, except the daughter products of thorium-232, uranium-235, and uranium-238.

~~(103)~~(113) "Management Plan" means a document which consists of the identification of a water system's owner; description of the management structure; an organizational chart; staffing requirements and duties; identification of any outside services and a copy of any service agreements; a copy of the system's operation and maintenance procedures required by R.61-58.7.B; and a detailed estimate of costs for the operation and maintenance of the system as it relates to the management plan, unless included in the cost estimate for the facilities plan.

~~(104)~~(114) "Marl" means calcareous clay. In South Carolina, the term is mostly applied to the Cooper Marl or Eocene Age, characterized by its dark greenish drab to grayish green color.

~~(105)~~(115) "Maximum contaminant level" means the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

~~(106)~~(116) "Maximum residual disinfectant level" (MRDL) means a level of a disinfectant added for water treatment that may not be exceeded at the consumer's tap without an unacceptable possibility of adverse health effects. For chlorine and chloramines, a PWS is in compliance with the MRDL when the running annual average of monthly averages of samples taken in the distribution system, computed quarterly, is less than or equal to the MRDL. For chlorine dioxide, a PWS is in compliance with the MRDL when daily samples are taken at the entrance to the distribution system and no two consecutive daily samples exceed the MRDL. MRDLs are enforceable in the same manner as maximum contaminant levels under Section 1412 of the Safe Drinking Water Act. There is convincing evidence that addition of a disinfectant is necessary for control of waterborne microbial contaminants. Notwithstanding the MRDLs listed in R.61-58.5.Q, operators may increase residual disinfectant levels of chlorine or chloramines (but not chlorine dioxide) in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems caused by circumstances such as distribution line breaks, storm runoff events, source water contamination, or cross-connections.

~~(107)~~(117) "Maximum residual disinfectant level goal" (MRDLG) means the maximum level of a disinfectant added for water treatment at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MRDLGs are nonenforceable health goals and do not reflect the benefit of the addition of the chemical for control of waterborne microbial contaminants.

~~(108)~~(118) "Maximum Total Trihalomethane Potential" means the maximum concentration of total trihalomethanes produced in a given water containing a disinfectant residual after seven days at a temperature of 25°C or above.

~~(109)~~(119) "Mechanical logging" means any number of techniques that measure some physical property of the subsurface.

~~(110)~~(120) "Medium-size water system" for the purpose of R.61-58.11, Control of Lead and Copper, only, means a water system that serves greater than ~~3,300~~10,000 persons and less than or equal to 50,000 persons.

~~(111)~~(121) “Membrane filtration” is a pressure or vacuum driven separation process in which particulate matter larger than 1 micrometer is rejected by an engineered barrier, primarily through a size- exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test. This definition includes the common membrane technologies of microfiltration, ultrafiltration, nanofiltration, and reverse osmosis.

(122) “Method detection limit (MDL)” means the minimum concentration of a substance that can be measured and reported with ninety-nine percent (99%) confidence that the analyte concentration is greater than zero (0) and is determined from analysis of a sample in a given matrix containing the analyte.

~~(112)~~(123) "National Primary Drinking Water Regulations" means primary drinking water regulations promulgated by the Administrator pursuant to the Federal Act and contained in 40 CFR Part 141, as amended.

~~(113)~~(124) "Natural filter" means the material adjacent to the screens in Type II wells which is part of the screened formation and which is relatively free of fine-grained material as a result of well development.

~~(114)~~(125) "National Secondary Drinking Water Regulations" means secondary drinking water regulations promulgated by the Administrator pursuant to the Federal Act, and contained in 40 CFR Part 143, as amended.

~~(115)~~(126) "Near the first service connection" means at one of the 20 percent of all service connections in the entire system that are nearest the water supply treatment facility, as measured by water transport time within the distribution system.

~~(116)~~(127) "Non-caving formation" means formation which will not collapse into an open borehole drilled through it such as igneous and metamorphic crystalline rocks, limestone, tight clay, etc.

~~(117)~~(128) "Non-coliform growth (NCG)" means any bacterial growth other than coliform type which appears in a membrane filter test for coliform bacteria.

~~(118)~~(129) "Non-community water system" means a public water system which serves at least fifteen (15) service connections or regularly serves an average of at least twenty-five (25) individuals daily at least sixty (60) days out of the year, and does not meet the definition of a community water system.

~~(119)~~(130) "Non-transient non-community water system" means a public water system that is not a community water system and that regularly serves at least twenty-five (25) of the same persons over six months per year.

~~(120)~~(131) "Operator" means a person certified by the South Carolina Environmental Certification Board as being qualified to operate and maintain a public water system. Operation and maintenance responsibilities shall include, but not be limited to, conducting tests of the raw and treated water, adjusting chemical feed rates, and/or operating equipment so as to change the physical, chemical, radiological or bacteriological quality of surface or ground water to meet established standards.

~~(121)~~(132) "Optimal corrosion control treatment" for the purpose of R.61-58.11, Control of Lead and Copper, only, means the corrosion control treatment that minimizes the lead and copper concentrations at users' taps while insuring that the treatment does not cause the water system to violate any national primary drinking water regulations.

(133) “Partial lead service line replacement” means replacement of any portion of a lead service line or galvanized service line requiring replacement, as defined in this section, that leaves in service any length of lead service line or galvanized service line requiring replacement upon completion of the work. Partial lead service line replacements are permitted under limited circumstances under R.61-58.11.F(4) but do not count towards the mandatory or goal-based lead service line replacement rate.

~~(122)~~(134) "Penetration rate log" means tabulation of the time required to drill unit depth intervals such as minutes per foot, minutes per 5-feet, minutes per drill rod section, etc.

~~(123)~~(135) "Performance evaluation sample" means a reference sample provided to a laboratory for the purpose of demonstrating that the laboratory can successfully analyze the sample within limits of performance specified by the Department. The true value of the concentration of the reference material is unknown to the laboratory at the time of the analysis.

~~(124)~~(136) "Person" means an individual, partnership, co-partnership, cooperative, firm, company, public or private corporation, political subdivision, agency of the State, trust, estate, joint structure company or any other legal entity or their legal representative, agent or assigns.

~~(125)~~(137) "Picocurie (pCi)" means that quantity of radioactive material producing 2.22 nuclear transformations per minute.

(138) Pitcher filter means a non-plumbed water filtration device which consists of a gravity-fed water filtration cartridge and a filtered drinking water reservoir that is certified by an American National Standards Institute accredited certifier to reduce lead in drinking water.

~~(126)~~(139) “Plant intake” refers to the works or structures at the head of a conduit through which water is diverted from a source (e.g., river or lake) into the treatment plant.

~~(127)~~(140) "Point of disinfectant application" is the point where the disinfectant is applied and water downstream of that point is not subject to recontamination by surface water runoff.

~~(128)~~(141) "Point-of-entry treatment device (POE)" is a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building.

~~(129)~~(142) "Point-of-use treatment device or point of use device (POU)" is a water treatment device ~~applied to a single tap used for the purpose of reducing contaminants in drinking water at that one tap~~ physically installed or connected to a single fixture, outlet, or tap to reduce or remove contaminants in drinking water. For the purposes of R.61-58.11, Control of Lead and Copper, it must be certified by an American National Standards Institute accredited certifier to reduce lead in drinking water.

~~(130)~~(143) "Pollution Source" means a facility or activity which may introduce any dangerous material to the groundwater system below the water table in concentrations sufficient to cause drinking water quality standards to be exceeded or to decrease the quality of the drinking water. pollution sources shall include, but not be limited to, the following:

a. Septic tank

b. Tile Field

c. Sewer line

d. Abandoned unprotected well

e. Waste treatment lagoon

f. Storage lagoon

g. Animal feedlot

h. Chemical handling area

i. Chemical storage area

j. Petroleum storage area

k. Waste disposal area

l. Mine

(144) “Practical quantitation limit (PQL)” means the minimum concentration of an analyte (substance) that can be measured with a high degree of confidence that the analyte is present at or above that concentration.

~~(131)~~(145) "Presedimentation" is a preliminary treatment process used to remove gravel, sand and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant. May be with or without chemical addition.

(146) Pre-stagnation flushing is the opening of tap(s) to flush standing water from plumbing prior to the minimum six (6)-hour stagnation period in anticipation of lead and copper tap sampling under R.61-58.11, Control of Lead and Copper.

~~(132)~~(147) "Primary Drinking Water Regulation" means the maximum contaminant limits, the requirements for monitoring, the requirements for reporting, record retention requirements and public notification specified in R.61-58.5, Maximum Contaminants in Drinking Water, and R.61-58.6, Reports, Record Retention and Public Notification of Drinking Water Violations.

~~(133)~~(148) "Professional Engineer" means a person properly qualified to perform engineering work as provided in Title 40 of the 1976 Code of Laws of South Carolina, as amended, Chapter 22, Engineers and Land Surveyors.

~~(134)~~(149) "Professional Geologist" means a person registered as a professional geologist by the South Carolina State Board of Registration for Geologists.

~~(135)~~(150) "Public Water System" means (1) any public or privately owned waterworks system which provides drinking water, whether bottled or piped, for human consumption, including the source of supply whether the source of supply is of surface or subsurface origin; (2) all structures and appurtenances used for the collection, treatment, storage or distribution of drinking water delivered to consumers; (3) any part or portion of the system and including any water treatment facility which in any way alters the physical, chemical, radiological, or bacteriological characteristics of drinking water; provided, that public water system shall not include a drinking water system serving a single private residence or dwelling. A separately owned system with its source of supply from another waterworks system shall be a separate public water system.

~~(136)~~(151) "Rapid Mix" means the rapid dispersion of chemicals throughout the water to be treated, usually by violent agitation.

~~(137)~~(152) "Rapid Rate Gravity Filter" means a gravity filter not to exceed 4 gallons per minute per square foot of surface area.

~~(138)~~(153) "Raw water" means untreated water as obtained from the source.

~~(139)~~(154) "Rem" means the unit of dose equivalent from ionizing radiation to the total body or any internal organ or organ system. A "millirem (mrem)" is one one-thousandth of a rem.

~~(140)~~(155) "Repeat compliance period" means any subsequent compliance period after the initial compliance period.

~~(141)~~(156) "Residual disinfectant concentration" ("C" in CT calculations) means the concentration of disinfectant measured in mg/L in a representative sample of water.

~~(142)~~(157) "Sand" means a detrital geologic material in the form of un-cemented particles having a size range from two (2) millimeters to one-sixteenth (1/16) of a millimeter and composed of mineral crystals or rock fragments.

~~(143)~~(158) "Sanitary defect" is a defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure in a barrier that is already in place.

~~(144)~~(159) "Sanitary Seal" means a cap on the top of the well casing usually fitted with a rubber expansion gasket, which seals off surface drainage, thereby protecting the well from contamination directly down the casing.

(160) "School," for the purpose of R.61-58.11 only, means any building(s) associated with public, private, or charter institutions that primarily provides teaching and learning for elementary or secondary students.

~~(145)~~(161) "Seasonal system" is a non-community water system that is not operated as a public water system on a year-round basis and starts up and shuts down at the beginning and end of each operating season.

~~(146)~~(162) "Secondary Containment" means a basin constructed to receive the liquids spilled from any chemical storage tank or solution tank, and shall be designed to prevent migration of any accumulated liquid out of the basin to the soil, ground-water, or surface water at any time. The volume of the secondary containment shall equal or exceed the volume of the tank. Where more than one (1) tank is located in the secondary containment area, the volume of the secondary containment shall be equal to or greater than the volume of the largest tank.

~~(147)~~(163) "Secondary maximum contaminant level" means the maximum contaminant levels which, in the judgment of the Department, are requisite to protect the public welfare. Such levels may apply to any contaminant in drinking water (1) which may adversely affect the odor or appearance of such water and consequently may cause a substantial number of the persons served by the public water system providing such water to discontinue its use, or (2) which may otherwise adversely affect the public welfare. Such levels may vary according to geographic and other circumstances.

(164) "Secondary school," for the purpose of R.61-58.11 only, means a school comprising any span of grades beginning with the next grade following an elementary or middle school (usually grades seven

through nine (7-9) and ending with or below grade twelve (12). Both junior high schools and senior high schools are included.

~~(148)~~(165) "Sedimentation" means a process for removal of solids before filtration by gravity or separation.

~~(149)~~(166) "Service line sample" means a one-liter sample of water, collected in accordance with R.61-58.11.H(2)(c), Sample Collection Methods, that has been standing for at least 6 hours in a service line.

~~(150)~~(167) "7Q10" means the minimum average annual stream flow that can statistically be expected to occur for a seven day period once every ten years.

~~(151)~~(168) "Sieve analysis" means a method of determining grain-size distribution by mechanically separating the various size portions using a set of graduated sieves and weighing the portion of the sample retained on each sieve. These weights are converted to percent retained and graphically plotted against grain size to show the grain size distribution in a well.

~~(152)~~(169) "Single family structure" for the purpose of R.61-58.11, Control of Lead and Copper, only, means a building constructed as a single-family residence that is currently used as either a residence or a place of business.

~~(153)~~(170) "Slow sand filtration" means a process involving passage of raw water through a bed of sand at low velocity (generally less than 0.4 m/h) resulting in substantial particulate removal by physical and biological mechanisms.

~~(154)~~(171) "Small water system" for the purpose of R.61-58.11, Control of Lead and Copper, only, means a water system that serves 3,300 persons or fewer.

~~(155)~~(172) "Specific Capacity" means the rate of well yield per unit of drawdown. It is usually expressed as gallons-per-minute per foot of drawdown and is a required measurement in selecting pump setting and size.

~~(156)~~(173) "Stabilized Water" means water which has been physically or chemically altered to reduce its aggressiveness or corrosiveness.

~~(157)~~(174) "Stand-by Well" means a well that is not routinely used , but which can be immediately placed into operation if needed. Such wells are routinely exercised and sampled by the water system to ensure operability and water quality.

~~(158)~~(175) "Standard sample" means the aliquot of finished drinking water that is examined for the presence of coliform bacteria.

~~(159)~~(176) "State Water System" or SWS means any water system that serves less than fifteen (15) service connections or regularly serves an average of less than twenty-five (25) individuals daily.

~~(160)~~(177) "Static water level" means the stable water level which has not been affected by pumping the well in which it is measured.

~~(161)~~(178) "Subpart H systems" means public water systems using surface water or ground water under the direct influence of surface water as a source that are subject to the requirements of 40 CFR 141, subpart H.

~~(162)~~(179) "Supplier of water" means any person who owns or operates a public water system.

~~(163)~~(180) "Surface water" means all water which is open to the atmosphere and subject to surface runoff.

~~(164)~~(181) "Surface Water Treatment Plant" means any facility capable of altering the physical, chemical, radiological or bacteriological quality of surface water to produce water for public consumption in a public water system.

~~(165)~~(182) "SUVA" means Specific Ultraviolet Absorption at 254 nanometers (nm), an indicator of the humic content of a water. It is a calculated parameter obtained by dividing a sample's ultraviolet absorption at a wavelength of 254 nm (UV_{254}) (in m^{-1}) by its concentration of dissolved organic carbon (DOC) (in mg/L).

~~(166)~~(183) "System with a single service connection" means a system which supplies drinking water to consumers via a single service line.

(184) "System without corrosion control treatment" means a public water system that does not have or purchases all of its water from a system that does not have: (1) An optimal corrosion control treatment approved by the Department; or (2) Any pH adjustment, alkalinity adjustment, and/or corrosion inhibitor addition resulting from other water quality adjustments as part of its treatment train infrastructure.

~~(167)~~(185) "Tap" means a service connection, the point at which water is delivered to the consumer (building, dwelling, commercial establishment, camping space, industry, etc.) from a distribution system, whether metered or not and regardless of whether there is a user charge for consumption of the water.

(186) "Tap sampling monitoring period," for the purposes of R.61-58.11, Control of Lead and Copper, means the period of time during which each water system must conduct tap sampling for lead and copper analysis. A tap sampling monitoring period is determined by lead and copper concentrations in tap samples and the frequency can range from every six (6) months (i.e., semi-annual) up to once every nine (9) years. Water systems on semi-annual tap sampling monitoring must collect samples no less frequently than every six (6) months while those on annual monitoring must sample no less frequently than every year. Water systems on triennial monitoring must collect samples no less frequently than every three (3) years; and those on monitoring waivers must sample no less frequently than every nine (9) years. The start of each new tap sampling monitoring period, with the exception of semi-annual monitoring, must begin on January 1.

(187) "Tap sampling period," for the purpose of R.61-58.11 only, means the time period, within a tap sampling monitoring period, during which the water system is required to collect samples for lead and copper analysis. For systems monitoring at a reduced frequency, the tap sampling period must be between the months of June and September, unless a different four (4)-month period of time is approved in writing to be more appropriate by the Department.

(188) "Tap sampling protocol" means the instructions given to residents or those sampling on behalf of the water system to conduct tap sampling under R.61-58.11, Control of Lead and Copper.

~~(168)~~(189) "Too numerous to count" means that the total number of bacterial colonies exceeds 200 on a 47-mm diameter membrane filter used for coliform detection.

~~(169)~~(190) "Total Organic Carbon" (TOC) means total organic carbon in mg/L measured using heat, oxygen, ultraviolet irradiation, chemical oxidants, or combinations of these oxidants that convert organic carbon to carbon dioxide, rounded to two significant figures.

~~(170)~~(191) "Total Trihalomethanes" means the sum of the concentration in milligrams per liter of the trihalomethane compounds [trichloromethane (chloroform), dibromochloromethane, bromodichloromethane, tribromomethane (bromoform)], rounded to two significant figures.

~~(171)~~(192) "Transient non-community water system" or TWS means a non-community water system that does not regularly serve at least 25 of the same persons over six months per year.

~~(172)~~(193) "Tremie pipe" means a device, usually a small diameter pipe, that carries grouting materials to the bottom of the zone to be grouted and which allows pressure grouting from the bottom up without introduction of appreciable air pockets.

~~(173)~~(194) "Trihalomethane" means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

~~(174)~~(195) “Two-stage lime softening” is a process in which chemical addition and hardness precipitation occur in each of two distinct unit clarification processes in series prior to filtration.

~~(175)~~(196) “Uncovered finished water storage facility” is a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens except residual disinfection and is directly open to the atmosphere.

~~(176)~~(197) "Uniformity coefficient" means the ratio of the sieve size that will retain 40 percent of the aquifer materials to the effective size.

~~(177)~~(198) "Viable Water System" means a water system which is self-sustaining and has the commitment and the financial, managerial and technical capability to consistently comply with the State Safe Drinking Water Act (44-55-10 et seq.) and these regulations.

~~(178)~~(199) "Virus" means a virus of fecal origin which is infectious to humans by waterborne transmission.

~~(179)~~(200) "Vending Machine" means any self-service device which upon insertion of a coin, coins, or token, or upon receipt of payment by other means, dispenses unit servings of water in bulk, without the necessity of refilling the machine between each operation.

~~(180)~~(201) "Waterborne disease outbreak" means the significant occurrence of acute infectious illness, epidemiologically associated with the ingestion of water from a public water system which is deficient in treatment, as determined by the Department.

~~(181)~~(202) "Well" means a bored, drilled or driven shaft, or a dug hole whose depth is greater than the largest surface dimension, from which water is extracted or injected. This shall include, but not be limited to, wells used for water supply for irrigation, industrial or manufacturing processes or drinking water; wells used for underground injection of waste for disposal, storage, or drainage disposal; wells used in mineral or geothermal recovery, and any other special process well. In South Carolina, wells used for public water supplies fall into one of the following types of construction:

a. Type I -open hole wells into bedrock aquifers.

b. Type II -screened, natural filter wells into unconsolidated aquifers.

c. Type III -screened, artificial filter (gravel pack) wells into unconsolidated aquifers.

d. Type IV -open hole wells into limestone aquifers.

~~(182)~~(203) "Well Casing" means tubular retaining structure, generally metal, which is installed in the excavated hole to maintain the well opening.

~~(183)~~(204) "Well interference" means the additive drawdown effects to two or more wells pumping from the same aquifer in the same vicinity.

~~(184)~~(205) "Wholesale system" is a public water system that treats source water as necessary to produce finished water and then delivers some or all of that finished water to another public water system. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems.

(206) "Wide-mouth bottles," for the purpose of R.61-58.11only, means bottles configured with a mouth that is at least fifty-five millimeters (55 mm) wide that are one liter (1 L) in size.

Amend 61-58.6.B, Reporting Requirements, to read:

B. Reporting Requirements.

(1) Except where a shorter reporting period is specified in this regulation, the supplier of water shall report to the Department the results of any test, measurement or analysis required to be made by the primary drinking water regulation within ten calendar days following the end of the month in which the result is received or within ten calendar days following the end of the monitoring period specified by the Department, whichever of these is shortest. Such report shall be in form established by the Department.

(2) If the result of an analysis made pursuant to the requirements of R.61-58.5, Maximum Contaminant Levels in Drinking Water, indicates that the level of any contaminant listed in said regulation exceeds the maximum contaminant level, the supplier of water shall report these findings to the Department within seven days of receiving the results.

(3) Except where a different reporting period is specified in these regulations, the supplier of water shall report to the Department within 48 hours the failure to comply with any national primary drinking water regulations (including failure to comply with monitoring requirements) as set forth in these regulations.

(4) The supplier of water is not required to report analytical results to the Department in cases where a State Laboratory performs the analysis and reports the results to the Department.

(5) Certification and notification of public notice issued

(a) The public water system, within ten (10) days of completing the public notification requirements under Section E below for the initial public notice and any repeat notices, must submit to the Department a certification that it has fully complied with the public notification regulations. For Tier 2 and 3 notices, ~~The~~ the public water system must include with this certification a representative copy of each type of notice distributed, published, posted, and made available to the persons served by the system and to the media.

(b) For Tier 1 notices for a lead action level exceedance, public water systems must provide a copy of any Tier 1 notice to the Administrator and the head of the Department as soon as practicable, but not later than twenty-four (24) hours after the public water system learns of the violation or exceedance.

(6) The public water system shall submit to the Department, when requested, within the time stated in the request, copies of any records required to be maintained under R.61-58.6.D or copies of any documents then in existence which the Department or the EPA Administrator is entitled to inspect pursuant to the authority of section 1445 of the Safe Drinking Water Act or the equivalent provisions of State law.

Amend R.61-58.6.E(1) through (2), to read:

E. Public Notification of Drinking Water Violations.

(1) General public notification requirements:

(a) Who must give public notice? Each owner or operator of a public water system (community water systems, non-transient non-community water systems, and transient non community water systems) must give notice for all violations of State Primary Drinking Water Regulations (SPDWR) and for other situations, as listed in Table 1. The term "SPDWR violations" is used in this regulation to include violations of the maximum contaminant level (MCL), maximum residual disinfection level (MRDL), treatment technique (TT), monitoring requirements, and testing procedures in this regulation. Appendix A to this regulation identifies the tier assignment for each specific violation or situation requiring a public notice.

TABLE 1: VIOLATION CATEGORIES AND OTHER SITUATIONS REQUIRING A PUBLIC NOTICE

(1) SPDWR violations:

(i) Failure to comply with an applicable maximum contaminant level(MCL) or maximum residual disinfectant level (MRDL).

(ii) Failure to comply with a prescribed treatment technique (TT).

(iii) Failure to perform water quality monitoring, as required by the drinking water regulations.

(iv) Failure to comply with testing procedures as prescribed by a drinking water regulation.

(2) Variance and exemptions under R.61-58.9:

(i) Operation under a variance or an exemption.

(ii) Failure to comply with the requirements of any schedule that has been set under a variance or exemption.

(3) Special public notices:

(i) Occurrence of a waterborne disease outbreak or other waterborne emergency.

(ii) Exceedance of the nitrate MCL by non-community water systems (NCWS), where granted permission by the Department under R.61-58.5.B(3).

(iii) Exceedance of the secondary maximum contaminant level (SMCL) for fluoride.

(iv) Availability of unregulated contaminant monitoring data.

(v) Other violations and situations determined by the Department to require a public notice under this regulation, not already listed in Appendix A to this regulation.

(vi) Exceedance of the lead action level.

(b) What type of public notice is required for each violation or situation? Public notice requirements are divided into three (3) tiers, to take into account the seriousness of the violation or situation and of any potential adverse health effects that may be involved. The public notice requirements for each violation or situation listed in Table 1 of this section are determined by the tier to which it is assigned. Table 2 of this section provides the definition of each tier. Appendix A to this regulation identifies the tier assignment for each specific violation or situation.

TABLE 2: DEFINITION OF PUBLIC NOTICE TIERS

(1) Tier 1 public notice — required for SPDWR violations and situations with significant potential to have serious adverse effects on human health as a result of short-term exposure.

(2) Tier 2 public notice — required for all other SPDWR violations and situations with potential to have serious adverse effects on human health.

(3) Tier 3 public notice — required for all other SPDWR violations and situations not included in Tier 1 and Tier 2.

(c) *Who must be notified?*

(i) Each public water system must provide public notice to persons served by the water system, in accordance with this regulation. Public water systems that sell or otherwise provide drinking water to other public water systems (i.e., to consecutive systems) are required to give public notice to the owner or operator of the consecutive system; the consecutive system is responsible for providing public notice to the persons it serves.

(ii) If a public water system has a violation in a portion of the distribution system that is physically or hydraulically isolated from other parts of the distribution system, the Department may allow the system to limit distribution of the public notice to only persons served by that portion of the system which is out of compliance. Permission by the Department for limiting distribution of the notice must be granted in writing.

(iii) A copy of the notice must also be sent to the Department and the Administrator (as applicable), in accordance with the requirements of R.61-58.6.B(5).

(2) Tier 1 Public Notice: Form, Manner, and Frequency of Notice

(a) **Which violations or situations require a Tier 1 public notice?** Table 1 of this section lists the violation categories and other situations requiring a Tier 1 public notice. Appendix A to this regulation identifies the tier assignment for each specific violation or situation.

TABLE 1: VIOLATION CATEGORIES AND OTHER SITUATIONS REQUIRING A TIER 1 PUBLIC NOTICE

(1) Violation of the MCL for total coliforms when fecal coliform or E. coli are present in the water distribution system (as specified in R.61-58.5.F(2)), or when the water system fails to test for fecal coliforms or E. coli when any repeat sample tests positive for coliform (as specified in R.61-58.5.G(5)), violation of the MCL for E. coli (as specified in R.61-58.5.F);

(2) Violation of the MCL for nitrate, nitrite, or total nitrate and nitrite, as defined in R.61-58.5.B, or when the water system fails to take a confirmation sample within 24 hours of the system's receipt of the first sample showing an exceedance of the nitrate or nitrite MCL, as specified in R.61-58.5.C(12)(b);

(3) Exceedance of the nitrate MCL by non-community water systems, where permitted to exceed the MCL by the Department under R.61-58.5.B(3), as required under paragraph (9) of this section;

(4) Violation of the MRDL for chlorine dioxide, as defined in R.61-58.5.Q(1), when one or more samples taken in the distribution system the day following an exceedance of the MRDL at the entrance of the distribution system exceed the MRDL, or when the water system does not take the required samples in the distribution system, as specified in R.61-58.13.D(3)(b)(i);

(5) Violation of the turbidity MCL under R.61-58.10(C), (E), (H), or (I), where the Department determines after consultation that a Tier 1 notice is required or where consultation does not take place within 24 hours after the system learns of the violation;

(6) Violation of the Surface Water Treatment Rule (SWTR), Interim Enhanced Surface Water Treatment Rule (IESWTR) or Long Term 1 Enhanced Surface Water Treatment Rule (LT1EWSTR) treatment technique requirement resulting from a single exceedance of the maximum allowable turbidity limit (as identified in Appendix A to this regulation), where the Department determines after consultation that a Tier 1 notice is required or where consultation does not take place within twenty-four (24) hours after the system learns of the violation;

(7) Occurrence of a waterborne disease outbreak, as defined in R.61-58(B)(174), or other waterborne emergency (such as a failure or significant interruption in key water treatment processes, a natural disaster that disrupts the water supply or distribution system, or a chemical spill or unexpected loading of possible pathogens into the source water that significantly increases the potential for drinking water contamination);

(8) Detection of E. coli, enterococci, or coliphage in source water samples as specified in R.61-58.16.E(1) or R.61-58.16.E(2).

(9) Other violations or situations with significant potential to have serious adverse effects on human health as a result of short-term exposure, as determined by the Department either in its regulations or on a case-by-case basis.

(10) Exceedance of the Action Level for lead as specified in R.61-58.11.B(3).

(b) *When is the Tier 1 public notice to be provided? What additional steps are required?* Public water systems must:

(i) Provide a public notice as soon as practical but no later than twenty-four (24) hours after the system learns of the violation;

(ii) Initiate consultation with the Department as soon as practical, but no later than twenty-four (24) hours after the public water system learns of the violation or situation, to determine additional public notice requirements; and

(iii) Comply with any additional public notification requirements (including any repeat notices or direction on the duration of the posted notices) that are established as a result of the consultation with the Department. Such requirements may include the timing, form, manner, frequency, and content of repeat notices (if any) and other actions designed to reach all persons served.

(c) *What is the form and manner of the public notice?* Public water systems must provide the notice within twenty-four (24) hours in a form and manner reasonably calculated to reach all persons served. The form and manner used by the public water system are to fit the specific situation, but must be designed to reach residential, transient, and non-transient users of the water system. In order to reach all persons served, water systems are to use, at a minimum, one or more of the following forms of delivery:

(i) Appropriate broadcast media (such as radio and television);

(ii) Posting of the notice in conspicuous locations throughout the area served by the water system;

(iii) Hand delivery of the notice to persons served by the water system; or

(iv) Another delivery method approved in writing by the Department.

Amend R.61-58.6. Appendix A, to read:

APPENDIX A. VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE

APPENDIX A TO 61-58.6: VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE[1]

CONTAMINANT	MCL/MRDL/TT/VIOLATIONS[2]		MONITORING & TESTING PROCEDURE VIOLATIONS	
	TIER OF PUBLIC NOTICE REQUIRED	CITATION	TIER OF PUBLIC NOTICE REQUIRED	CITATION
I. Violations of the State Primary Drinking Water Regulations (SPDWR):[3]				
A. Microbiological Contaminants				
1.a Total coliform†	2	61-58.5.F(1)	3	61-58.5.G(1) – (5)
1.b Total coliform (TT violations resulting from failure to perform assessments or corrective actions, monitoring violations, and reporting violations)‡	2	61-58.17.K(2)(a)	3	61-58.17.K(3)(a) 61-58.17.K(4)(a)
1.c Seasonal system failure to follow Department-approved start-up plan prior to serving water to the public or failure to provide certification to the Department.‡	2	61-58.17.K(2)(b)	3	61-58.17.K(4)(c)
2.a Fecal coliform/E. coli†	1	61-58.5.F(2)	[4]1, 3	61-58.5.G(5)
2.b *E.coli* (MCL, monitor-	1	61-58.17.K(1)	3	61-58.17.K(3)(b)

CONTAMINANT	MCL/MRDL/TT/VIOLATIONS[2]		MONITORING & TESTING PROCEDURE VIOLATIONS	
	TIER OF PUBLIC NOTICE REQUIRED	CITATION	TIER OF PUBLIC NOTICE REQUIRED	CITATION
ing, and reporting violations.‡				61-58.17.K(4)(a) 61-58.17.K(4)(b)
2.c E. coli (TT violations resulting from failure to perform level 2 Assessments or corrective action)‡	2	61-58.17.K(2)(a)		
3. Turbidity MCL	2	61-58.10.E, H, & I	3	61-58.10.F
4. Turbidity MCL (average of 2 days samples great than 5 NTU)	[5]2,1	61-58.10.C, E, H & I	3	61-58.10.F
5. Turbidity (for TT violations resulting from a single exceedance of maximum allowable turbidity level)	[6] 2, 1	61-58.10.C(i)(b) 61-58.10.C.(3)(b) 61-58.10.F(2)(b), 61-58.10.E(1)(b), 61-58.10.E(2)(b), 61-58.10.E(3)(b), 61-58.10.E(4), 61-58.10.H(4)(a)(ii), 61-58.10.H(4)(b), 61-58.10.I(6)(b)	3	61-58.10.F 61-58.10(F)(3) 61-58.10.H 61-58.10(I)(7)(a) (i)-(iii) & (b)
6. Surface Water Treatment Rule violations, other than violations resulting from single exceedance of max. allowable turbidity level (TT).	2	61-58.10.B - E		61-58.10
7. Interim Enhanced Surface Water Treatment Rule violations, other than violations resulting from single exceedance of max. turbidity level (TT)	[7] 2	61-58.10.B - E 61-58.10.I(1)-(7)	3	61-58.10.H(3), (5) 61-58.10.I(4) & (5) 61-58.10.I(7)
8. Filter Backwash Recycling Rule violations	2	61-58.10.J(3)	3	61-58.10.J(2) & (4)
9. Long Term 1 Enhanced Surface Water Treatment Rule Violations.	2	61-58.10.I(1)-(7)	3	61-58.10.I(4) & (5) 61-58.10.I(7)
10. LT2ESWTR violations	2	61-58.10.K(11)-(21)	[22]2,3	61-58.10.K(2) - (6) & 61-58.10.K(9) - (10)
11. Ground Water Rule Violations	2	61-58.16.G	3	61-58.16.E(8) 61-58.16.F(4)
B. Inorganic Chemicals (IOCs)				
1. Antimony	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
2. Arsenic	2	61-58.5.B(2)	3	[9]61-58.5.C(7)
3. Asbestos (fibers>10µm)	2	61-58.5.B(2)	3	61-58.5.C(7), (8)
4. Barium	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
5. Beryllium	2	61-58.5.B(2)	3	61-58.5.C(7), (9)

CONTAMINANT	MCL/MRDL/TT/VIOLATIONS[2]		MONITORING & TESTING PROCEDURE VIOLATIONS	
	TIER OF PUBLIC NOTICE REQUIRED	CITATION	TIER OF PUBLIC NOTICE REQUIRED	CITATION
6. Cadmium	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
7. Chromium (total)	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
8. Cyanide	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
9. Fluoride	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
10. Mercury (inorganic)	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
11. Nitrate	1	61-58.5.B(2)	[10]1,3	61-58.5.C(7), (10) 61-58.5.C(12)
12. Nitrite	1	61-58.5.B(2)	[10] 1,3	61-58.5.C(7), (10) 61-58.5.C(12)
13. Total Nitrate and Nitrite	1	61-58.5.B(2)	3	61-58.5.C(7)
14. Selenium	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
15. Thallium	2	61-58.5.B(2)	3	61-58.5.C(7), (9)
C. Lead and Copper Rule (Action Level for lead is 0.015 mg/L, for copper is 1.3 mg/L)				
1. Lead and Copper Rule (TT)	2	~~61-58.11.B – G~~ 61-58.11.B (except 61-58.11.B(3)), 61-58.11.F, 61-58.11.G(1) – (3) and (8), and 61-58.11.O	3	61-58.11.H - ~~K~~L
2. Exceedance of the action Level for Lead	1	61-58.11.B(3)		
D. Synthetic Organic Chemicals (SOCs)				
1. 2,4-D	2	61-58.5.D	3	61-58.E(7)
2. 2,4,5-TP (Silvex)	2	61-58.5.D	3	61-58.5.E(7)
3. Alachlor	2	61-58.5.D	3	61-58.5.E(7)
4. Atrazine	2	61-58.5.D	3	61-58.5.E(7)
5. Benzo(a)pyrene (PAHs)	2	61-58.5.D	3	61-58.5.E(7)
6. Carbofuran	2	61-58.5.D	3	61-58.5.E(7)
7. Chlordane	2	61-58.5.D	3	61-58.5.E(7)
8. Dalapon	2	61-58.5.D	3	61-58.5.E(7)
9. Di (2-ethylhexyl) adipate	2	61-58.5.D	3	61-58.5.E(7)
10. Di (2-ethylhexyl) phthalate	2	61-58.5.D	3	61-58.5.E(7)
11. Dibromochloropropane	2	61-58.5.D	3	61-58.5.E(7)
12. Dinoseb	2	61-58.5.D	3	61-58.5.E(7)
13. Dioxin (2,3,7,8-TCDD)	2	61-58.5.D	3	61-58.5.E(7)
14. Diquat	2	61-58.5.D	3	61-58.5.E(7)
15. Endothall	2	61-58.5.D	3	61-58.5.E(7)
16. Endrin	2	61-58.5.D	3	61-58.5.E(7)
17. Ethylene dibromide	2	61-58.5.D	3	61-58.5.E(7)
18. Glyphosate	2	61-58.5.D	3	61-58.5.E(7)
19. Heptachlor	2	61-58.5.D	3	61-58.5.E(7)
20. Heptachlor epoxide	2	61-58.5.D	3	61-58.5.E(7)
21. Hexachlorobenzene	2	61-58.5.D	3	61-58.5.E(7)
22. Hexachlorocyclo-pentadiene	2	61-58.5.D	3	61-58.5.E(7)
23. Lindane	2	61-58.5.D	3	61-58.5.E(7)
24. Methoxychlor	2	61-58.5.D	3	61-58.5.E(7)

CONTAMINANT	MCL/MRDL/TT/VIOLATIONS[2]		MONITORING & TESTING PROCEDURE VIOLATIONS	
	TIER OF PUBLIC NOTICE REQUIRED	CITATION	TIER OF PUBLIC NOTICE REQUIRED	CITATION
25. Oxamyl (Vydate)	2	61-58.5.D	3	61-58.5.E(7)
26. Pentachlorophenol	2	61-58.5.D	3	61-58.5.E(7)
27. Picloram	2	61-58.5.D	3	61-58.5.E(7)
28. Polychlorinated biphenyls (PCBs)	2	61-58.5.D	3	61-58.5.E(7)
29. Simazine	2	61-58.5.D	3	61-58.5.E(7)
30. Toxaphene	2	61-58.5.D	3	61-58.5.E(7)
E. Volatile Organic Chemicals (VOCs)				
1. Benzene	2	61-58.5.N	3	61-58.5.O
2. Carbon tetrachloride	2	61-58.5.N	3	61-58.5.O
3. Chlorobenzene (monochlorobenzene)	2	61-58.5.N	3	61-58.5.O
4. o-Dichlorobenzene	2	61-58.5.N	3	61-58.5.O
5. p-Dichlorobenzene	2	61-58.5.N	3	61-58.5.O
6. 1,2-Dichloroethane	2	61-58.5.N	3	61-58.5.O
7. 1,1-Dichloroethylene	2	61-58.5.N	3	61-58.5.O
8. cis-1,2-Dichloroethylene	2	61-58.5.N	3	61-58.5.O
9. trans-1,2-Dichloroethylene	2	61-58.5.N	3	61-58.5.O
10. Dichloromethane	2	61-58.5.N	3	61-58.5.O
11. 1,2-Dichloropropane	2	61-58.5.N	3	61-58.5.O
12. Ethylbenzene	2	61-58.5.N	3	61-58.5.O
13. Styrene	2	61-58.5.N	3	61-58.5.O
14. Tetrachloroethylene	2	61-58.5.N	3	61-58.5.O
15. Toluene	2	61-58.5.N	3	61-58.5.O
16. 1,2,4-Trichlorobenzene	2	61-58.5.N	3	61-58.5.O
17. 1,1,1-Trichloroethane	2	61-58.5.N	3	61-58.5.O
18. 1,1,2-Trichloroethane	2	61-58.5.N	3	61-58.5.O
19. Trichloroethylene	2	61-58.5.N	3	61-58.5.O
20. Vinyl chloride	2	61-58.5.N	3	61-58.5.O
21. Xylenes (total)	2	61-58.5.N	3	61-58.5.O
F. Radioactive Contaminants				
1. Beta/photon emitters	2	61-58.5.H(4)	3	61-58.5.K(1), 61-58.5.I.(3)
2. Alpha emitters	2	61-58.5.H(3)	3	61-58.5.K(1), 61-58.5.I(2)
3. Combined radium (226 & 228)	2	61-58.5.H(2)	3	61-58.5.K(1), 61-58.5.I2)
4. Uranium	[11]2	61-58.5.H(5)	[12] 3	61-58.5.K(1), 61-58.5.I(2)
G. Disinfection Byproducts (DBPs), Byproduct Precursors, Disinfectant Residuals. Where disinfection is used in the treatment of drinking water, disinfectants combine with organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBPs). EPA sets standards for controlling the levels of disinfectants and DBPs in drinking water, including trihalomethanes (THMs) and haloacetic acids (HAAs).[13]				
1. Total trihalomethanes (TTHMs)	2	[14]61-58.5.L, 61-58.5.P	3	[14] 61-58.5.M 61-58.13.C(1), (2) 61-58.14, 61-58.15
2. Haloacetic Acids (HAA5)	2	61-58.5.P	3	61-58.13.C(1), (2) 61-58.14, 61-58.15
3. Bromate	2	61-58.5.P	3	61-58.13.C(1), (2)
4. Chlorite	2	61-58.5.P	3	61-58.13.C(1), (2)
5. Chlorine (MRDL)	2	61-58.5.Q	3	61-58.13.C(1), (3)

CONTAMINANT	MCL/MRDL/TT/VIOLATIONS[2]		MONITORING & TESTING PROCEDURE VIOLATIONS	
	TIER OF PUBLIC NOTICE REQUIRED	CITATION	TIER OF PUBLIC NOTICE REQUIRED	CITATION
6. Chloramine (MRDL)	2	61-58.5.Q	3	61-58.13.C(1), (3)
7. Chlorine dioxide (MRDL) where any 2 consecutive daily samples at entrance to distribution system only are above MRDL	2	61-58.5.Q, 61-58.13.D	2[15], 3	61-58.13.C(1), (3), 61-58.13.C(3)(b)
8. Chlorine dioxide (MRDL), where sample(s) in distribution system the next day are also above MRDL	[16] 1	61-58.5.Q, 61-58.13.D(3)	1	61-58.13.C(1), (3), 61-58.13.D(3)(b)
9. Control of DBP precursors—TOC (TT)	2	61-58.13.F(1), (2)	3	61-58.13.C(1), (4)
10. Bench marking and disinfection profiling.	N/A	N/A	3	61-58.10.G(3) 61-58.10.H(3) 61-58.10.I(4) & (5)
11. Development of monitoring plan	N/A	N/A	3	61-58.13.C(6)
H. Other Treatment Techniques				
1. Acrylamide (TT)	2	61-58.5.AA	N/A	N/A
2. Epichlorohydrin (TT)	2	61-58.5.AA	N/A	N/A
II. Unregulated Contaminant Monitoring:[17]				
A. Unregulated contaminants	N/A	N/A	3	61-58.5.T
B. Nickel	N/A	N/A	3	61-58.5.C(9), (17)
III. Public Notification for Variances and Exemptions:				
A. Operation under a variance or exemption	3	1861-58.9	N/A	N/A
B. Violation of conditions of a variance or exemption	2	1961-58.9	N/A	N/A
IV. Other Situations Requiring Public Notification:				
A. Fluoride secondary maximum contaminant level (SMCL) exceedance	3	61-58.5.R	N/A	N/A
B. Exceedance of nitrate MCL for non-community systems, as allowed by Department	1	61-58.5.B(3)	N/A	N/A
C. Availability of unregulated contaminant monitoring data	3	61-58.5.T	N/A	N/A
D. Waterborne disease outbreak	1	61-58.B(156) 61-58.10.C(3)(b)(ii)	N/A	N/A
E. Other waterborne emergency[20]	1	N/A	N/A	N/A
F. Source water sample positive for Ground Water	1	61-58.16.E(7)	N/A	N/A

CONTAMINANT	MCL/MRDL/TT/VIOLATIONS[2]		MONITORING & TESTING PROCEDURE VIOLATIONS	
	TIER OF PUBLIC NOTICE REQUIRED	CITATION	TIER OF PUBLIC NOTICE REQUIRED	CITATION
Rule fecal indicators: E. coli, enterococci, or coliphage				
G. Other situations as determined by the Department	[21]1, 2, 3	N/A	N/A	N/A

Appendix A to R.61-58.6 - Endnotes

† Until March 31, 2016

‡ Beginning April 1, 2016

[1] Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the Department. The Department may, at its option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under R.61-58.6.E(2)(a) and (3)(a).

[2] MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique

[3] The term Violations of State Primary Drinking Water Regulations (SPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

[4] Failure to test for fecal coliform or E. coli is a Tier 1 violation if testing is not done after any repeat sample tests positive for coliform. All other total coliform monitoring and testing procedure violations are Tier 3.

[5] Systems that violate the turbidity MCL of 5 NTU based on an average of measurements over two consecutive days must consult with the Department within 24 hours after learning of the violation. Based on this consultation, the Department may subsequently decide to elevate the violation to Tier 1. If a system is unable to make contact with the Department in the 24-hour period, the violation is automatically elevated to Tier 1.

[6] Systems with treatment technique violations involving a single exceedance of a maximum turbidity limit under the Surface Water Treatment Rule (SWTR) Interim Enhanced Surface Water Treatment Rule (IESWTR), or the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) are required to consult with the Department within 24 hours after learning of the violation. Based on this consultation, the Department may subsequently decide to elevate the violation to Tier 1. If a system is unable to make contact with the Department in the 24-hour period, the violation is automatically elevated to Tier 1.

[7] Most of the requirements of the Interim Enhanced Surface Water Treatment Rule, R.61-58.10.B - C become effective January 1, 2002 for surface water systems and ground water systems under the direct influence of surface water serving at least 10,000 persons. However, R.61-58.10.H(3) has some requirements that become effective as early as April 16, 1999. The Surface Water Treatment Rule remains in effect for systems serving at least 10,000 persons even after 2002; the Interim Enhanced Surface Water Treatment Rule adds additional requirements and does not in many cases supersede the SWTR.

[8] The arsenic MCL citations are effective January 23, 2006. Until then the citations are R.61-58.5(B)(2).

[9] The arsenic Tier 3 violations MCL citations are effective January 23, 2006. Until then, the citations are R.61-58.C(7).

[10] Failure to take a confirmation sample within 24 hours for nitrate or nitrite after an initial sample exceeds the MCL is a Tier 1 violation. Other monitoring violations for nitrate are Tier 3.

[11] The uranium MCL, Tier 2 violation citations are effective December 8, 2003 for all community water systems.
[12] The uranium Tier 3 violation citations are effective December 8, 2000 for all community water systems.
[13] Community and non-transient non-community surface water systems and ground water systems under the direct influence of surface water serving 10,000 must comply with new DBP MCLs, disinfectant MRDLs, and related monitoring requirements beginning January 1, 2002. All other community and non-transient non-community systems must meet the MCLs and MRDLs beginning January 1, 2004. Transient non-community surface water systems and ground water systems under the direct influence of surface water serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2002. Transient non-community surface water systems and ground water systems under the direct influence of surface water serving fewer than 10,000 persons and using only ground water not under the direct influence of surface water and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2004.
[14] R.61-58.5.L, and R.61-58.13.C(1) - (2) apply until R.61-58.14 and R.61-58.15 take effect under the schedule in R.61-58.14.
[15] Failure to monitor for chlorine dioxide at the entrance to the distribution system the day after exceeding the MRDL at the entrance to the distribution system is a Tier 2 violation.
[16] If any daily sample taken at the entrance to the distribution system exceeds the MRDL for chlorine dioxide and one or more samples taken in the distribution system the next day exceed the MRDL, Tier 1 notification is required. Failure to take the required samples in the distribution system after the MRDL is exceeded at the entry point also triggers Tier 1 notification.
[17] Some water systems must monitor for certain unregulated contaminants listed in R.61-58.5.T
[18] This citation refers to the requirements of R.61-58.9 that "a schedule prescribed ...for a public water system granted a variance [or exemption] shall require compliance by the system ..."
[19] In addition to R.61-58.9 specifies the items and schedule milestones that must be included in a variance for small systems.
[20] Other waterborne emergencies require a Tier 1 public notice under R.61-58.6.E(2)(a) for situations that do not meet the definition of a waterborne disease outbreak given in R.61-58.B(174) but that still have the potential to have serious adverse effects on health as a result of short-term exposure. These could include outbreaks not related to treatment deficiencies, as well as situations that have the potential to cause outbreaks, such as failures or significant interruption in water treatment processes, natural disasters that disrupt the water supply or distribution system, chemical spills, or unexpected loading of possible pathogens into the source water.
[21] The Department may place other situations in any tier they believe appropriate, based on threat to public health.
[22] Failure to collect three or more samples for Cryptosporidium analysis is a Tier 2 violation requiring special notice as specified in R.61-58.6.E(11). All other monitoring and testing procedure violations are Tier 3.

Amend R.61-58.6. Appendix B, to read:

APPENDIX B. STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

APPENDIX B TO R.61-58.6: STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
State Primary Drinking Water Regulations (SPDWR):			

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
A. Microbiological Contaminants:			
1a. Total coliform†	Zero	See footnote[3]	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially- harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
1b. Fecal coliform/E. coli‡	Zero	Zero	Fecal coliforms and E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
1c. Fecal Indicators (Ground Water Rule)			Fecal indicators are microbes whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
i. E. coli	Zero	TT	
ii. enterococci	None	TT	
iii. coliphage	None	TT	
1d. Ground Water Rule TT violations	None	TT	Inadequately treated or inadequately protected water may contain disease-causing organisms. These organisms can cause symptoms such as

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			diarrhea, nausea, cramps, and associated headaches.
1e. Revised Total Coliform Rule (R.61-58.17) Coliform Assessment and/or Corrective Action Violations‡	N/A	TT	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessments to identify problems and to correct any problems that are found. ~~[THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.] harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessments to identify problems and to correct any problems that are found.~~ [THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.] <u>We failed to conduct the required assessment.</u> <u>We failed to correct all identified sanitary defects that</u>

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			were found during the assessment(s).
1f. Revised Total Coliform Rule (R.61-58.17) E. coli Assessment and/or Corrective Action Violations‡	N/A		~~We failed to conduct the required assessment.~~ ~~We failed to correct all identified sanitary defects that were found during the assessment(s).~~ E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these waters can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems. We violated the standard for E. coli, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct a detailed assessment to identify problems and to correct any problems that are found. [THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.] We failed to conduct the required assessment. We failed to correct all identified sanitary defects that were found during the assessment that we conducted.
1g. E. coli‡	Zero	In compliance unless one of the following conditions occurs:	~~[THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.]~~

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
		(1) The system has an E. coli-positive repeat sample following a total coliform-positive routine sample. (2) The system has a total coliform-positive repeat sample following an E. coli-positive routine sample. (3) The system fails to take all required repeat samples following an E. coli-positive routine sample. (4) The system fails to test for E. coli when any repeat sample tests positive for total coliform.	~~We failed to conduct the required assessment.~~ ~~We failed to correct all identified sanitary defects that were found during the assessment that we conducted.~~ E. coli are bacteria who presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems.
1h. Revised Total Coliform Rule (R.61-58.17) Seasonal System TT Violations‡	N/A	TT	When this violation includes the failure to monitor for total coliforms or E. coli prior to serving water to the public, the mandatory language found at R.61-58.6.E(5)(d)(ii) must be used. When this violation includes failure to complete other actions, the appropriate elements found in R.61-58.6.E(5)(a) to describe the violation must be used.
2a. Turbidity (MCL)[4]	None	1 NTU[5]/5 NTU	Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate presence of disease-causing organisms.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			These organisms include bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea and associated headaches.
2b. Turbidity (SWTR TT)[6]	None	TT[7]	Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate the presence of disease-causing organisms These organisms include bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea and associated headaches.
2c. Turbidity (IESWTR TT)[8]	None	TT	Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate the presence of disease-causing organisms. These organisms include bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea and associated headaches.
B. Surface Water Treatment Rule (SWTR), Interim Enhanced Surface Water Treatment Rule (IESWTR), Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) and Filter Backwash Recycling Rule (FBRR) violations:			
3. *Giardia lamblia*	Zero	TT[10]	Inadequately treated water may contain disease-causing organisms. These organisms include bacteria, viruses, and parasites which can cause symptoms such as nausea, cramps, diarrhea, and associated headaches.
4. Viruses (SWTR/IESWTR/LT1ESWTR).			
5. Heterotrophic plate count (HPC) bacteria[9] (SWTR/IESWTR/LT1ESWTR).			

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
6. *Legionella* (SWTR/IESWTR/LT1ESWTR).			
7. *Cryptosporidium* (SWTR/IESWTR/LT1ESWTR).			
C. Inorganic Chemicals (IOCs):			
8. Antimony	0.006	0.006	Some people who drink water containing antimony well in excess of the MCL over many years could experience increases in blood cholesterol and decreases in blood sugar.
9. Arsenic[11]	Zero	0.010	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
10. Asbestos (10 μm)	7 MFL[12]	7 MFL	Some people who drink water containing asbestos in excess of the MCL over many years may have an increased risk of developing benign intestinal polyps.
11. Barium	2	2	Some people who drink water containing barium in excess of the MCL over many years could experience an increase in their blood pressure.
12. Beryllium	0.004	0.004	Some people who drink water containing beryllium well in excess of the MCL over many years could develop intestinal lesions.
13. Cadmium	0.005	0.005	Some people who drink water containing cadmium in excess of the MCL over many years could experience kidney damage.
14. Chromium (total)	0.1	0.1	Some people who use water containing chromium well in excess of the MCL over many years could experience allergic dermatitis.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
15. Cyanide	0.2	0.2	Some people who drink water containing cyanide well in excess of the MCL over many years could experience nerve damage or problems with their thyroid.
16. Fluoride	4.0	4.0	Some people who drink water containing fluoride in excess of the MCL over many years could get bone disease, including pain and tenderness of the bones. Fluoride in drinking water at half the MCL or more may cause mottling of children's teeth, usually in children less than nine years old. Mottling, also known as dental fluorosis, may include brown staining and/or pitting of the teeth, and occurs only in developing teeth before they erupt from the gums.
17. Mercury (inorganic)	0.002	0.002	Some people who drink water containing inorganic mercury well in excess of the MCL over many years could experience kidney damage.
18. Nitrate	10	10	Infants below the age of six months who drink water containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
19. Nitrite	1	1	Infants below the age of six months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
20. Total Nitrate and Nitrite	10	10	Infants below the age of six months who drink water containing nitrate and nitrite in

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
21. Selenium	0.05	0.05	Selenium is an essential nutrient. However, some people who drink water containing selenium in excess of the MCL over many years could experience hair or fingernail losses, numbness in fingers or toes, or problems with their circulation.
22. Thallium	0.0005	0.002	Some people who drink water containing thallium in excess of MCL over many years could experience hair loss, changes in their blood, or problems with their kidneys, intestines, or liver.
D. Lead and Copper Rule:			
23. Lead	Zero	TT[13]	~~Infants and children who drink water containing lead in excess of the action level could experience delays in their physical or mental development. Children could show slight deficits in attention span and learning abilities. Adults who drink this water over many years could develop kidney problems or high blood pressure.~~ Exposure to lead in drinking water can cause serious health effects in all age groups. Infants and children can have decreases in IQ and attention span. Lead exposure can lead to new learning and behavior problems. The children of women who are exposed to lead before or during pregnancy can have increased

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			risk of these adverse health effects. Adults can have increased risks of heart disease, high blood pressure, kidney or nervous system problems.
24. Copper	1.3	TT[14]	Copper is an essential nutrient, but some people who drink water containing copper in excess of the action level over a relatively short amount of time could experience gastrointestinal distress. Some people who drink water containing copper in excess of the action level over many years could suffer liver or kidney damage. People with Wilson's Disease should consult their personal doctor.
E. Synthetic Organic Chemicals (SOCs):			
25. 2,4-D	0.07	0.07	Some people who drink water containing the weed killer 2,4-D well in excess of the MCL over many years could experience problems with kidneys, liver, or adrenal glands.
26. 2,4,5-TP (Silvex)	0.05	0.05	Some people who drink water containing silvex in excess of the MCL over many years could experience liver problems.
27. Alachlor	Zero	0.002	Some people who drink water containing alachlor in excess of the MCL over many years could have problems with their eyes, liver, kidneys, or spleen, or experience anemia, and may have an increased risk of getting cancer.
28. Atrazine	0.003	0.003	Some people who drink water containing atrazine well in excess of the MCL over many years could experience

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			problems with their cardiovascular system or reproductive difficulties.
29. Benzo(a)pyrene (PAHs)	Zero	0.0002	Some people who drink water containing benzo(a)pyrene in excess of the MCL over many years may experience reproductive difficulties and may have an increased risk of getting cancer.
30. Carbofuran	0.04	0.04	Some people who drink water containing carbofuran in excess of the MCL over many years could experience problems with their blood, or nervous or reproductive systems.
31. Chlordane	Zero	0.002	Some people who drink water containing chlordane in excess of the MCL over many years could experience problems with their liver or nervous system, and may have an increased risk of getting cancer.
32. Dalapon	0.2	0.2	Some people who drink water containing dalapon well in excess of the MCL over many years could experience minor kidney changes.
33. Di (2-ethylhexyl) adipate	0.4	0.4	Some people who drink water containing di(2-ethylhexyl) adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement or possible reproductive difficulties.
33. Di (2-ethylhexyl) phthalate	Zero	0.006	Some people who drink water containing di(2-ethylhexyl) phthalate well in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
35. Dibromochloropropane (DBCP)	Zero	0.0002	Some people who drink water containing DBCP in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
36. Dinoseb	0.007	0.007	Some people who drink water containing dinoseb well in excess of the MCL over many years could experience reproductive difficulties.
37. Dioxin (2,3,7,8-TCDD).	Zero	3×10^{-8}	Some people who drink water containing dioxin in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
38. Diquat	0.02	0.02	Some people who drink water containing diquat in excess of the MCL over many years could get cataracts.
39. Endothall	0.1	0.1	Some people who drink water containing endothall in excess of the MCL over many years could experience problems with their stomach or intestines.
40. Endrin	0.002	0.002	Some people who drink water containing endrin in excess of the MCL over many years could experience liver problems.
41. Ethylene dibromide	Zero	0.00005	Some people who drink water containing ethylene dibromide in excess of the MCL over many years could experience problems with their liver, stomach, reproductive system, or kidneys, and may have an increased risk of getting cancer.
42. Glyphosate	0.7	0.7	Some people who drink water containing glyphosate in excess of the MCL over many years could experience

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			problems with their kidneys or reproductive difficulties.
43. Heptachlor	Zero	0.0004	Some people who drink water containing heptachlor in excess of the MCL over many years could experience liver damage and may have an increased risk of getting cancer.
44. Heptachlor epoxide	Zero	0.0002	Some people who drink water containing heptachlor epoxide in excess of the MCL over many years could experience liver damage, and may have an increased risk of getting cancer.
45. Hexachlorobenzene	Zero	0.001	Some people who drink water containing hexachlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys, or adverse reproductive effects, and may have an increased risk of getting cancer.
46. Hexachlorocyclo pentadiene	0.05	0.05	Some people who drink water containing Hexachlorocyclo-pentadiene well in excess of the MCL over many years could experience problems with their kidneys or stomach.
47. Lindane	0.0002	0.0002	Some people who drink water containing lindane in excess of the MCL over many years could experience problems with their kidneys or liver.
48. Methoxychlor	0.04	0.04	Some people who drink water containing methoxychlor in excess of the MCL over many years could experience reproductive difficulties.
49. Oxamyl (Vydate)	0.2	0.2	Some people who drink water containing oxamyl in excess of the MCL over many years could experience slight nervous system effects.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
50. Pentachlorophenol	Zero	0.001	Some people who drink water containing pentachlorophenol in excess of the MCL over many years could experience problems with their liver or kidneys, and may have an increased risk of getting cancer.
51. Picloram	0.5	0.5	Some people who drink water containing picloram in excess of the MCL over many years could experience problems with their liver.
52. Polychlorinated biphenyls (PCBs).	Zero	0.0005	Some people who drink water containing PCBs in excess of the MCL over many years could experience changes in their skin, problems with their thymus gland, immune deficiencies, or reproductive or nervous system difficulties, and may have an increased risk of getting cancer.
53. Simazine	0.004	0.004	Some people who drink water containing simazine in excess of the MCL over many years could experience problems with their blood.
54. Toxaphene	Zero	0.003	Some people who drink water containing toxaphene in excess of the MCL over many years could have problems with their kidneys, liver, or thyroid, and may have an increased risk of getting cancer.
F. Volatile Organic Chemicals (VOCs):			
55. Benzene	Zero	0.005	Some people who drink water containing benzene in excess of the MCL over many years could experience anemia or a decrease in blood platelets, and may have an increased risk of getting cancer.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
56. Carbon tetrachloride	Zero	0.005	Some people who drink water containing carbon tetrachloride in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.
57. Chlorobenzene (monochlorobenzene)	0.1	0.1	Some people who drink water containing chlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys.
58. o-Dichlorobenzene	0.6	0.6	Some people who drink water containing o-dichlorobenzene well in excess of the MCL over many years could experience problems with their liver, kidneys, or circulatory systems.
59. p-Dichlorobenzene	0.075	0.075	Some people who drink water containing p-dichlorobenzene in excess of the MCL over many years could experience anemia, damage to their liver, kidneys, or spleen, or changes in their blood.
60. 1,2-Dichloroethane	Zero	0.005	Some people who drink water containing 1,2-dichloroethane in excess of the MCL over many years may have an increased risk of getting cancer.
61. 1,1-Dichloroethylene	0.007	0.007	Some people who drink water containing 1,1-dichloroethylene in excess of the MCL over many years could experience problems with their liver.
62. cis-1,2-Dichloroethylene	0.07	0.07	Some people who drink water containing cis-1,2-dichloroethylene in excess of the MCL over many years could experience problems with their liver.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
63. trans-1,2-Dichloroethylene	0.1	0.1	Some people who drink water containing trans-1,2-dichloroethylene well in excess of the MCL over many years could experience problems with their liver.
64. Dichloromethane	Zero	0.005	Some people who drink water containing dichloromethane in excess of the MCL over many years could have liver problems and may have an increased risk of getting cancer.
65. 1,2-Dichloropropane	Zero	0.005	Some people who drink water containing 1,2-dichloropropane in excess of the MCL over many years may have an increased risk of getting cancer.
66. Ethylbenzene	0.7	0.7	Some people who drink water containing ethylbenzene well in excess of the MCL over many years could experience problems with their liver or kidneys.
67. Styrene	0.1	0.1	Some people who drink water containing styrene well in excess of the MCL over many years could have problems with their liver, kidneys, or circulatory system.
68. Tetrachloroethylene	Zero	0.005	Some people who drink water containing tetrachloroethylene in excess of the MCL over many years could have problems with their liver, and may have an increased risk of getting cancer.
69. Toluene	1	1	Some people who drink water containing toluene well in excess of the MCL over many years could have problems with their nervous system, kidneys, or liver.
70. 1,2,4-Trichlorobenzene	0.07	0.07	Some people who drink water containing 1,2,4-trichlorobenzene well in

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			excess of the MCL over many years could experience changes in their adrenal glands.
71. 1,1,1-Trichloroethane	0.2	0.2	Some people who drink water containing 1,1,1-trichloroethane in excess of the MCL over many years could experience problems with their liver, nervous system, or circulatory system.
72. 1,1,2-Trichloroethane	0.003	0.005	Some people who drink water containing 1,1,2-trichloroethane well in excess of the MCL over many years could have problems with their liver, kidneys, or immune systems.
73. Trichloroethylene	Zero	0.005	Some people who drink water containing trichloroethylene in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.
74. Vinyl chloride	Zero	0.002	Some people who drink water containing vinyl chloride in excess of the MCL over many years may have an increased risk of getting cancer.
75. Xylenes (total)	10	10	Some people who drink water containing xylenes in excess of the MCL over many years could experience damage to their nervous system.
G. Radioactive Contaminants:			
76. Beta/photon emitters	Zero	4 mrem/yr[15]	Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta and photon emitters in excess of the MCL over many years may have an

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			increased risk of getting cancer.
77. Alpha emitters	Zero	15 pCi/L[16]	Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer.
78. Combined radium (226 & 228)	Zero	5 pCi/L	Some people who drink water containing radium 226 or 228 in excess of the MCL over many years may have an increased risk of getting cancer.
79. Uranium17	Zero	30ìg/L	Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity.
H. Disinfection Byproducts (DBPs), Byproduct Precursors, and Disinfectant Residuals: Where disinfection is used in the treatment of drinking water, disinfectants combine with organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBPs). EPA sets standards for controlling the levels of disinfectants and DBPs in drinking water, including trihalomethanes (THMs) and haloacetic acids (HAAs):[18]			
80. Total trihalomethanes (TTHMs)	N/A	0.08017[19,20]	Some people who drink water containing trihalomethanes in excess of the MCL over many years may experience problems with their liver, kidneys, or central nervous system, and may have an increased risk of getting cancer.
81. Haloacetic Acids (HAA)	N/A	0.060[21]	Some people who drink water containing haloacetic acids in excess of the MCL over many years may have an increased risk of getting cancer.
82. Bromate	Zero	0.010	Some people who drink water containing bromate in excess of the MCL over many years

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			may have an increased risk of getting cancer.
83. Chlorite	0.08	1.0	Some infants and young children who drink water containing chlorite in excess of the MCL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorite in excess of the MCL. Some people may experience anemia.
84. Chlorine	4 (MRDLG)[22]	4.0 (MRDL)[23]	Some people who use water containing chlorine well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chlorine well in excess of the MRDL could experience stomach discomfort.
85. Chloramines	4 (MRDLG)	4.0 (MRDL)	Some people who use water containing chloramines well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chloramines well in excess of the MRDL could experience stomach discomfort or anemia.
86a. Chlorine dioxide, where any 2 consecutive daily samples taken at the entrance to the distribution system are above the MRDL.	0.8 (MRDLG)	0.8 (MRDL)	Some infants and young children who drink water containing chlorine dioxide in excess of ~~a~~ the MRDL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia. *Add for public notification only:* The chlorine dioxide

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			violations reported today are the result of exceedances at the treatment facility only not within the distribution system which delivers water to consumers. Continued compliance with chlorine dioxide levels within the distribution system minimizes the potential risk of these violations to consumers.
86b. Chlorine dioxide, where one or more water distribution systems are above the MRDL	0.8 (MRDLG)	0.8 (MRDL)	Some infants and young children who drink water containing chlorine dioxide in excess of the MRDL could experience nervous effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia. *Add for public notification only:* The chlorine dioxide violations reported today include exceedances of the EPA standard within the distribution system which delivers water to consumers. Violations of the chlorine dioxide standard within the distribution system may harm human health based on short-term exposures. Certain groups, including fetuses, infants, and young children, may be especially susceptible to nervous system effects from excessive chlorine dioxide exposure.
87. Control of DBP precursors (DBP)	None	TT	Total organic carbon (TOC) has no health effects. However, total organic carbon provides a medium for the formation of disinfection by-products. These byproducts include trihalomethanes (THMs) and haloacetic acids

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
			(HAAs). Drinking water containing these by-products in excess of the MCL may lead to adverse health effects, liver or kidney problems, or nervous system effects, and may lead to an increased risk of getting cancer.
I. Other Treatment Techniques:			
88. Acrylamide	Zero	TT	Some people who drink water containing high levels of acrylamide over a long period of time could have problems with their nervous system or blood, and may have an increased risk of getting cancer.
89. Epichlorohydrin	Zero	TT	Some people who drink water containing high levels of epichlorohydrin over a long period of time could experience stomach problems, and may have an increased risk of getting cancer.

Appendix B to R.61-58.6 - endnotes

[†]Until March 31, 2016

[‡]Beginning April 1, 2016

[1]MCLG - Maximum contaminant level goal

[2]MCL - Maximum contaminant level

[3]For water systems analyzing at least 40 samples per month, no more than 5.0 percent of the monthly samples may be positive for total coliforms. For systems analyzing fewer than 40 samples per month, no more than one sample per month may be positive for total coliforms.

[4]There are various regulations that set turbidity standards for different types of systems, including the 1989 Surface Water Treatment Rule, the 1998 Interim Enhanced Surface Water Treatment Rule, and the 2002 Long Term 1 Enhanced Surface Water Treatment Rule. The MCL for the monthly turbidity average is 1 NTU; the MCL for the 2-day average is 5 NTU for systems that are required to filter but have not yet installed filtration.

[5]NTU - Nephelometric turbidity unit

[6]There are various regulations that set turbidity standards for different types of systems, including the 1989 Surface Water Treatment Rule (SWTR), the 1998 Interim Enhanced Surface Water Treatment Rule (IESWTR), and the 2001 Long Term 1 Enhanced Surface Water Treatment Rule. Systems subject to the Surface Water Treatment Rule (both filtered and unfiltered) may not exceed 5 NTU. In addition, in filtered systems, 95 percent of samples each month must not exceed 0.5 NTU in systems using conventional or

direct filtration and must not exceed 1 NTU in systems using slow sand or diatomaceous earth filtration or other filtration technologies approved by the Department.

[7]TT - Treatment technique

[8]There are various regulations that set turbidity standards for different types of systems, including the 1989 Surface Water Treatment Rule (SWTR), the 1998 Interim Enhanced Surface Water Treatment Rule (IESWTR), and the 2002 Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). For systems subject to the IESWTR (systems serving at least 10,000 people, using surface water or ground water under the direct influence of surface water), that use conventional filtration or direct filtration, after January 1, 2002, the turbidity level of a system's combined filter effluent may not exceed 0.3 NTU in at least 95 percent of monthly measurements, and the turbidity level of a system's combined filter effluent must not exceed 1 NTU at any time. Systems subject to the IESWTR using technologies other than conventional, direct, slow sand, or diatomaceous earth filtration must meet turbidity limits set by the Department. For systems subject to the LT1ESWTR (systems serving fewer than 10,000 people, using surface water or ground water under the direct influence of surface water) that use conventional filtration or direct filtration, after January 1, 2005 the turbidity level of a system's combined filter effluent may not exceed 0.3 NTU in at least 95 percent of monthly measurements, and the turbidity level of a system's combined filter effluent must not exceed 1 NTU at any time. Systems subject to the LT1ESWTR using technologies other than conventional, direct, slow sand, or diatomaceous earth filtration must meet turbidity limits set by the Department.

[9]The bacteria detected by heterotrophic plate count (HPC) are not necessarily harmful. HPC is simply an alternative method of determining disinfectant residual levels. The number of such bacteria is an indicator of whether there is enough disinfectant in the distribution system.

[10]SWTR, IESWTR, and LT1ESWTR treatment technique violations that involve turbidity exceedances may use the health effects language for turbidity instead.

[11]These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.

[12]Millions fibers per liter.

[13]Action Level = 0.015 mg/L

[14]Action Level = 1.3 mg/L

[15]Millirems per years

[16]Picocuries per liter

[17]The uranium MCL is effective December 8, 2003 for all community water systems.

[18]Surface water systems and ground water systems under the direct influence of surface water are regulated under R.61-58.10. Community and non-transient non-community systems serving greater than, or equal to 10,000 must comply with R.61-58.13 DBP MCLs and disinfectant maximum residual disinfectant levels (MRDLs) beginning January 1, 2002. All other community and non-transient non-community systems must comply with R-61.58.13 DBP MCLs and MRDLs beginning January 1, 2004. Transient non-community surface water systems and ground water systems under the direct influence of surface water serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2002. All other transient non-community systems that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning on January 1, 2004.

[19]Community and non-transient non-community systems that must comply with R.61-58.14 TTHM and HAA5 MCLs of 0.080 mg/L and 0.060 mg/L, respectively (with compliance calculated as a locational running annual average) on the schedule in R.61-58.15.

[20]The MCL for total trihalomethanes is the sum of the concentrations of the individual trihalomethanes.

[21]The MCL for haloacetic acids is the sum of the concentrations of the individual haloacetic acids.

[22]MRDLG—Maximum residual disinfectant level goal.

[23]MRDL—Maximum residual disinfectant level.

Amend 61-58.11, Control of Lead and Copper, to read:

Table of Contents

A. Applicability.

This regulation establishes a treatment technique that includes requirements for corrosion control treatment, source water treatment, lead service line replacement, and public education. These requirements are triggered, in some cases, by lead and copper action levels measured in samples collected at consumers' taps. This regulation shall apply to each community and noncommunity water system, unless the water system meets all of the following conditions:

(1) Consists only of distribution and storage facilities (and does not have any collection and treatment facilities);

(2) Obtains all of its water from, but is not owned or operated by, a public water system to which such regulations apply;

(3) Does not sell water to any person; and

(4) Is not a carrier which conveys passengers in interstate commerce.

B. General Requirements.

(1) Applicability, effective date, and compliance deadlines

The requirements of this regulation, R.61-58.11, Control of Lead and Copper, constitute ~~as~~ the state primary drinking water regulations for lead and copper. ~~Unless otherwise indicated, each of the provisions of this regulation applies to community water systems and non-transient, non-community water systems (hereinafter referred to as "water systems" or "systems").~~

(a) The provisions of R.61-58.11 apply to community water systems and non-transient, non-community water systems (in R.61-58.11, referred to as ‘‘water systems’’ or ‘‘systems’’).

(b) (Reserved).

(c) Community water systems and non-transient, non-community water systems must comply with the requirements of R.61-58.11 no later than October 16, 2024, except where otherwise specified at R.61-58.11.C, R.61-58.11.F, R.61-58.11.G, R.61-58.11.H, and R.61-58.11.L, or where an exemption in accordance with 40 CFR part 142, subpart C or F, has been established by the Administrator or where an exemption in accordance with R. 61-58.9 has been issued by the Department.

(d)(i) Until October 16, 2024, community water systems and non-transient, non-community water systems must comply with R.61-58.11, as effective on September 26, 2014.

(ii) If an exemption from R.61-58.11 has been issued in accordance with 40 CFR part 142, subpart C or F, prior to December 16, 2021, then the water systems must comply with R. 61-58.11 as effective on September 26, 2014, until the expiration of that exemption.

(2) Scope

The regulations in R.61-58.11 establish a treatment technique that includes requirements for corrosion control treatment, source water treatment, lead service line inventory, lead service line replacement, public notice, monitoring for lead in schools and child care facilities, and public education. Several of the requirements in R.61-58.11 are prompted by the lead and copper action levels or the lead trigger level, specified in paragraph (3) of this section, as measured in samples collected at consumers' taps. The requirements for sampling for lead in schools and child care facilities and public education requirements in R.61-58.11 apply to all community water systems regardless of the results of the compliance tap sampling.

~~(1)~~(3) Lead Trigger Level, Lead Action Level, and Copper Action ~~Levels~~ Level

Trigger levels and action levels must be determined based on tap water samples collected in accordance with the tap sampling monitoring requirements of R.61-58.11.H for the purpose of calculating the 90th percentile and tested using the analytical methods specified in R.61-58.11.K. The trigger level and action levels described in this paragraph (3) are applicable to all sections of R.61-58.11. Trigger level and action levels for lead and copper are as follows:

(a) The lead trigger level is exceeded if the 90th percentile concentration of lead as specified in paragraph (3)(d) of this section is greater than ten micrograms per liter (10 µg/L).

~~(a)~~(b) The lead action level is exceeded if the ~~concentration of lead in more than 10 percent of tap water samples collected during any monitoring period conducted in accordance with Section H below is greater than 0.015 mg/L (i.e., if the "90th percentile" lead level is greater than 0.015 mg/L).~~ 90th percentile concentration of lead as specified in paragraph (3)(d) of this section is greater than fifteen micrograms per liter (15 ug/L).

~~(b)~~(c) The copper action level is exceeded if the ~~concentration of copper in more than 10 percent of tap water samples collected during any monitoring period conducted in accordance with Section H below is greater than 1.3 mg/L (i.e., if the "90th percentile" copper level is greater than 1.3 mg/L).~~ 90th percentile concentration of copper as specified in paragraph (3)(d) of this section is greater than 1.3 mg/L.

~~(c)~~(d) ~~The 90th percentile lead and copper levels shall be computed as follows:~~ For purposes of R.61-58.11 the 90th percentile concentration shall be computed as follows:

(i) For systems that do not have lead service line sites and only have sites identified as Tier 3, Tier 4, or Tier 5 under R.61-58.11.H(1).

~~(i)~~(A) The results of all lead or copper samples taken during a ~~monitoring~~tap sampling period shall be placed in ascending order from the sample with the lowest concentration to the sample with the highest concentration. Each sampling result shall be assigned a number, ascending by single integers beginning with the number 1 for the sample with the lowest contaminant level. The number assigned to the sample with the highest contaminant level shall be equal to the total number of samples ~~taken;~~ taken.

~~(ii)~~(B) The number of samples taken during the ~~monitoring~~tap sampling period shall be multiplied by ~~0.9;~~ 0.9.

~~(iii)~~(C) The contaminant concentration in the numbered sample yielded by the calculation in paragraph (3)(d)(i)(B) of this section is the 90th percentile ~~contaminant level; and,~~ concentration.

~~(iv)~~(D) For water systems serving fewer than one hundred (100) people that collect five (5) samples per ~~monitoring~~ tap sampling period, the 90th percentile concentration is ~~computed by taking~~ the average of the highest and second highest concentrations.

~~(v)~~(E) For a water system that has been allowed by the Department to collect fewer than five (5) samples in accordance with R.61-58.11.H(3) ~~Section H(3)~~ or has failed to collect five (5) samples, the sample result with the highest concentration is considered the 90th percentile value.

(ii) For public water systems with lead service lines with sites identified as Tier 1 or Tier 2 under R.61-58.11.H(1) with enough Tier 1 or Tier 2 sites to meet the minimum number of sites listed in R.61-58.11.H(3):

(A) The results of all lead or copper samples taken at Tier 1 or Tier 2 sites during a tap sampling period shall be placed in ascending order from the sample with the lowest concentration to the sample with the highest concentration. Sample results from Tier 3, Tier 4, or Tier 5 sites shall not be included in this calculation. Each sampling result shall be assigned a number, ascending by single integers beginning with the number one (1) for the sample with the lowest contaminant level. The number assigned to the sample with the highest contaminant level shall be equal to the total number of samples taken.

(B) The number of samples taken at Tier 1 or Tier 2 sites during the tap sampling period shall be multiplied by 0.9.

(C) The contaminant concentration in the numbered sample yielded by the calculation in paragraph (3)(d)(ii)(B) of this section is the 90th percentile concentration.

(D) For water systems serving fewer than one hundred (100) people that collect five (5) samples per tap sampling period, the 90th percentile concentration is the average of the highest and second highest concentration.

(E) For a public water system that has been allowed by the Department to collect fewer than five (5) samples in accordance with R.61-58.11.H(3), or has failed to collect five (5) samples, the sample result with the highest concentration is considered the 90th percentile value.

(iii) For systems with lead service lines with sites identified as Tier 1 or Tier 2 under R.61-58.11.H(1) with insufficient number of Tier 1 or Tier 2 sites to meet the minimum number of sites listed in R.61-58.11.H(3):

(A) The results of all lead or copper samples taken at Tier 1 or Tier 2 sites along with the highest results from Tier 3, Tier 4, or Tier 5 sites sufficient to meet the minimum number of sites shall be placed

in ascending order from the sample with the lowest concentration to the sample with the highest concentration. Sample results from any remaining Tier 3, Tier 4, and Tier 5 sites shall not be included in this calculation. Each sampling result shall be assigned a number, ascending by single integers beginning with the number one (1) for the sample with the lowest contaminant level. The number assigned to the sample with the highest contaminant level shall be equal to the total minimum number of sites listed in R.61-58.11.H(3).

(B) The required minimum number of sites listed in R.61-58.11.H(3) shall be multiplied by 0.9.

(C) The contaminant concentration in the numbered sample yielded by the calculation in paragraph (3)(d)(iii)(B) is the 90th percentile concentration.

(D) For water systems serving fewer than one hundred (100) people that collect five (5) samples per tap sampling period, the 90th percentile concentration is the average of the highest and second highest concentration.

(E) For a public water system that has been allowed by the Department to collect fewer than five (5) samples in accordance with R.61-58.11.H(3), or has failed to collect five (5) samples, the sample result with the highest concentration is considered the 90th percentile value.

~~(2)~~(4) Corrosion Control ~~Treatment~~ Requirements

(a) All water systems shall install and operate optimal corrosion control treatment ~~as defined~~in accordance with R.61-58.11.C and R.61-58.11.D, and that meets the definition of optimal corrosion control treatment in R.61-58.B, Definitions.

(b) Any water system that complies with the applicable corrosion control treatment requirements specified by the Department under ~~Sections C and D below~~R.61-58.11.C and R.61-58.11.D, shall be deemed in compliance with the treatment requirement contained in paragraph (~~2~~4)(a) of this section.

(c) Any small or non-transient, non-community water system that complies with the applicable small system compliance flexibility requirements specified by the Department under R.61-58.11.C(1)(c) and R.61-58.11.O is deemed to be in compliance with the treatment requirement in paragraph (4)(a) of this section.

(d) Any water system shall notify the Department in writing pursuant to R.61-58.11.L(1)(c) of any upcoming long-term change in treatment or addition of a new source as described in R.61-58.11.L(1)(c). The Department must review and approve the addition of a new source or long-term change in water treatment before it is implemented by the water system. The Department may require any such water system to conduct additional monitoring or to take other action the Department deems appropriate to ensure that such water system maintains minimal levels of corrosion control in its distribution system.

~~(3)~~(5) Source Water ~~Treatment~~ Requirements ~~– Any system exceeding the lead or copper action level shall implement all applicable source water treatment requirements specified by the Department under Section E below.~~

(a) Any system exceeding the lead or copper action level shall implement all applicable source water treatment requirements specified by the Department under R.61-58.11.E.

(b) Any system that changes their source water or makes long-term treatment changes shall submit written documentation to the Department describing the change in accordance with R.61-58.11.C(1)(c),

R.61-58.11.H(4)(b)(iv), and R.61-58.11.L(1)(c). The Department must review and approve the change before it is implemented by the water system.

~~(4)~~(6) Lead Service Line ~~Replacement Requirements~~Replacements and Inventory - ~~Any system exceeding the lead action level after implementation of applicable corrosion control and source water treatment requirements shall complete the lead service line replacement requirements contained in Section F below.~~ Lead service line replacements must be conducted as follows:

(a) Any water system exceeding the lead action level specified at paragraph (3) of this section must complete mandatory lead service line replacement. Lead service line replacement must be conducted in accordance with R.61-58.11.F(7) and must include public education pursuant to R.61-58.11.G(1) and(2).

(b) Any water system exceeding the lead trigger level specified at paragraph (3) of this section must complete goal-based lead service line replacement pursuant to R.61-58.11.F(6) and public education pursuant to R.61-58.11.G(7) and (8).

(c) All water systems must prepare an inventory of service lines connected to its distribution system, whether or not they are owned or controlled by the water system, to identify those service lines that are made of lead or of unknown material. The inventory must be prepared in accordance with R.61-58.11.F(1).

~~(5)~~(7) Public Education and Notification Requirements – Pursuant to ~~Section G~~ R.61-58.11.G(4), all water systems must provide ~~a consumer notice~~ notification of lead tap water monitoring results to persons served at the sites (taps) that are tested. ~~Any system exceeding the lead action level shall implement the public education requirements.~~ All community water systems must conduct annual outreach to local and state health agencies pursuant to R.61-58.11.G(9). In addition:

(a) Any water system exceeding the lead action level specified at paragraph (3) of this section shall implement the public education requirements in accordance with R.61-58.11.G(1) and (2).

(b) Any water system exceeding the lead trigger level specified at paragraph (3) of this section shall provide notification to all customers with a lead service line in accordance with R.61-58.11.G(7).

(c) Any water system exceeding the lead action level specified at paragraph (3) of this section shall notify the public in accordance with the public notification requirements in R.61-58.6.E.

(d) Any water system with lead service lines, galvanized requiring replacement, or lead status unknown service lines in their inventory as specified in R.61.58.11.F(1) shall inform all consumers with a lead service line, galvanized requiring replacement, or a lead status unknown service line in accordance with R.61-58.11.G(5).

(e) Any water system that fails to reach its goal lead service line replacement rate as required under R.61-58.11.F(6) shall conduct outreach activities in accordance with R.61-58.11.G(8).

~~(6)~~(8) Monitoring and Analytical Requirements - Tap water monitoring for lead and copper, monitoring for water quality parameters, source water monitoring for lead and copper, and analyses of the monitoring results shall be completed in compliance with Sections H, I, J, and K below.

~~(7)~~(9) Reporting Requirements - Systems shall report to the Department any information required by the treatment provisions of this ~~subpart~~section.

~~(8)~~(10) Recordkeeping Requirements - Systems shall maintain records in accordance with ~~Section L~~R.61-58.11.L below.

~~(9)~~(11) Violation of the State Primary Drinking Water Regulations - Failure to comply with the applicable requirements of ~~this regulation shall constitute a violation of~~ R.61-58.11.B through R.61-58.11.O, including requirements established by the Department pursuant to R.61-58.11, Control of Lead and Copper is a violation of the State Primary Drinking Water Regulations for lead and copper.

(12) Testing in Schools and Child Care Facilities - All community water systems must collect samples from all schools and child care facilities within its distribution system in accordance with R.61-58.11.N.

C. Applicability of Corrosion Control Treatment Steps to Small, Medium-Size and Large Water Systems.

(1) ~~Systems shall complete the applicable corrosion control treatment requirements described in Section D by the deadlines established in this section.~~ Corrosion Control Treatment

This section sets forth when a system must complete the corrosion control treatment steps for systems in paragraph (4) or (5) of this section to optimize or re-optimize corrosion control treatment based on size, whether the system has corrosion control treatment, and whether it has exceeded the lead trigger and/or action level and/or the copper action level.

(a) ~~A large system (serving greater than 50,000 persons) shall complete the corrosion control treatment steps specified in paragraph (4) of this section, unless it is deemed to have optimized corrosion control under paragraph (2)(b) or (2)(c) of this section.~~ Large water system (serving greater than 50,000 people).

(i) Large water systems with corrosion control treatment that exceed either the lead trigger level or copper action level shall complete the corrosion control treatment steps specified in paragraph (4) of this section.

(ii) Large water systems without corrosion control treatment with 90th percentile results as calculated in accordance with R.61-58.11.B(3)(d) that exceed either the lead practical quantitation level of 0.005 mg/L or the copper action level shall complete the corrosion control treatment steps specified in paragraph (5) of this section.

(iii) Large water systems with corrosion control treatment with 90th percentile results as calculated in accordance with R.61-58.11.B(3)(d) that exceed the lead practical quantitation level but do not exceed the lead trigger level or the copper action level may be required by the Department to complete the corrosion control treatment steps in paragraph (4) of this section.

(b) ~~A small system (serving 3300 persons or less) and a medium-size system (serving greater than 3,300 and 50,000 persons or less) shall complete the corrosion control treatment steps specified in paragraph (5) of this section, unless it is deemed to have optimized corrosion control under paragraph (2)(a), (2)(b), or (2)(c) of this section.~~ Medium-size water systems (serving greater than 10,000 and 50,000 people or less).

(i) Medium-size water systems with corrosion control treatment that exceed either the lead trigger level or copper action level shall complete the corrosion control treatment steps specified in paragraph (4) of this section.

(ii) Medium-size water systems without corrosion control treatment that exceed either the lead or copper action level shall complete the corrosion control treatment steps specified in paragraph (5) of this section.

(iii) Medium-size water systems without corrosion control treatment that exceed the lead trigger level but do not exceed the lead or copper action levels shall complete the treatment recommendation step specified in paragraph (5)(a) of this section (Step 1). The water system shall complete the remaining steps in paragraph (5) of this section if it subsequently exceeds either the lead or copper action level.

(c) Small water systems (serving 10,000 people or less) and non-transient, non-community water systems.

(i) Small and non-transient, non-community water systems with corrosion control treatment that exceed the lead trigger level or the lead action level but do not exceed the copper action level, shall complete the corrosion control treatment steps specified in paragraph (4) of this section, if corrosion control treatment is approved by the Department as a compliance option under R.61-58.11.O.

(ii) Small and non-transient, non-community water systems with corrosion control treatment that exceed the copper action level shall complete the corrosion control treatment steps specified in paragraph (4) of this section.

(iii) Small and non-transient, non-community water systems without corrosion control treatment that exceed the lead action level shall complete the corrosion control treatment steps specified in paragraph (5) of this section if corrosion control treatment is approved by the Department as a compliance option under R.61-58.11.O.

(iv) Small and non-transient, non-community water systems without corrosion control treatment that exceed the copper action level shall complete the corrosion control treatment steps specified in paragraph (5) of this section.

(2) ~~A system is deemed to have optimized corrosion control and is not required to complete the applicable corrosion control treatment steps identified in this section if the system satisfies one of the following criteria specified in paragraphs (2)(a) through (2)(c) of this section. Any such system deemed to have optimized corrosion control under this paragraph, and which has treatment in place, shall continue to operate and maintain optimal corrosion control treatment and meet any requirements that the Department determines appropriate to ensure optimal corrosion control treatment is maintained.~~ Systems Deemed to have Optimized Corrosion Control.

A system is deemed to have optimal corrosion control treatment (OCCT) or re-optimized OCCT if the system satisfies one of the criteria specified in paragraphs (2)(a) through (c) of this section. Any such system deemed to have OCCT under this paragraph and which has corrosion control treatment in place shall continue to operate and maintain that treatment and meet any additional requirements that the Department determines to be appropriate to ensure optimal corrosion control treatment is maintained.

(a) ~~A small or medium-size water system is deemed to have optimized corrosion control if the system meets the lead and copper action levels during each of two consecutive six-month monitoring periods conducted in accordance with Section H below.~~ A small or medium-size water system without corrosion control treatment is deemed to have optimal corrosion control if the water system does not exceed the lead action level and copper action level during two (2) consecutive six (6)-month tap sampling monitoring periods and thereafter remains at or below the lead trigger level and copper action level in all tap sampling periods conducted in accordance with R.61-58.11.H.

(b) ~~Any water system may be deemed by the Department to have optimized corrosion control treatment if the system demonstrates to the satisfaction of the Department that it has conducted activities equivalent to the corrosion control steps applicable to such system under this section. If the Department makes this determination, it shall provide the system with written notice explaining the basis for its decision and shall specify the water quality control parameters representing optimal corrosion control in accordance with Section D(6) below. Water systems deemed to have optimized corrosion control under this paragraph shall operate in compliance with the Department- designated optimal water quality control parameters in accordance with Section D(7) below and continue to conduct lead and copper tap and water quality parameter sampling in accordance with Sections H(4)(c) and I(4) below, respectively. A system shall provide the Department with the following information in order to support a determination under this paragraph:~~ A small or medium-size water system with corrosion control treatment is deemed to have optimal corrosion control treatment if the water system does not exceed the lead trigger level and copper action level during two (2) consecutive six (6)-month monitoring periods conducted in accordance with R.61-58.11.H and thereafter remains at or below the lead trigger level and copper action level in all tap sampling periods conducted in accordance with R.61-58.11.H. Small or medium-size systems with corrosion control treatment that exceed the lead trigger level but do not exceed the lead and copper action levels during two (2) consecutive six (6)-month monitoring periods and thereafter remains at or below the lead and copper action levels in all tap sampling periods conducted in accordance with R.61-58.11.H are deemed to have re-optimized optimal corrosion control treatment if the system meets the requirements of this section. Where the Department has set optimal water quality parameters (OWQPs) under paragraph (4) or (5) of this section a system will not be eligible to be deemed to have optimized or re-optimized OCCT pursuant to paragraph (2) of this section

~~(i) The results of all test samples collected for each of the water quality parameters in Section D(3)(c) below;~~

~~(ii) a report explaining the test methods used by the water system to evaluate the corrosion control treatments listed in Section D(3)(a), the results of all tests conducted, and the basis for the system's selection of optimal corrosion control treatment;~~

~~(iii) a report explaining how corrosion control has been installed and how it is being maintained to insure minimal lead and copper concentrations at consumers' taps; and,~~

~~(iv) the results of tap water samples collected in accordance with Section H below, at least once every six (6) months for one (1) year after corrosion control has been installed.~~

(c) ~~Any water system is deemed to have optimized corrosion control if it submits results of tap water monitoring conducted in accordance with Section H below, and source water monitoring conducted in accordance with Section J below, that demonstrates for two (2) consecutive six (6) month monitoring periods that the difference between the 90th percentile tap water lead level computed under Section B(1)(c) and the highest source water lead concentration, is less than the Practical Quantitation Level for lead specified in Section K(1)(a).~~ Any water system is deemed to have optimized or re-optimized corrosion control if it submits results of tap water monitoring in accordance with R.61-58.11.H demonstrating that the 90^{th} percentile tap water lead level is less than or equal to the lead practical quantitation level of 0.005 mg/L and does not exceed the copper action level for two (2) consecutive six (6)-month tap sampling monitoring periods, and does not have optimal water quality parameters that were set by the Department under paragraph (4) or (5) of this section. Any such system with 90^{th} percentile tap sample results that thereafter exceeds the lead practical quantitation level or copper action level during any tap sampling period shall not be eligible to be deemed to have optimized OCCT in accordance with this paragraph (2)(c) without first completing the treatment steps specified in paragraph (4) or (5) of this section

(i) ~~Those systems whose highest source water lead level is below the Method Detection Limit may also be deemed to have optimized corrosion control under this paragraph if the 90th percentile tap water lead level is less than or equal to the Practical Quantitation Level for lead for two consecutive 6-month monitoring periods.~~ [Reserved]

(ii) Any water system deemed to have optimized corrosion control in accordance with this paragraph (2)(c) shall continue monitoring for lead and copper at the tap no less frequently than once every three (3) calendar years using the reduced number of sites specified in R. 61-58.11.H(3) ~~Section H(3) below~~ and collecting the samples at times and locations specified in R. 61-58.11.H(4)(d)(v) ~~Section H(4)(d)(iv) below~~. ~~Any such system that has not conducted a round of monitoring pursuant to Section H(4) below, since September 30, 1997, shall complete a round of monitoring pursuant to this paragraph no later than September 30, 2000.~~

(iii) ~~Any water system deemed to have optimized corrosion control pursuant to this paragraph shall notify the Department in writing pursuant to Section L(1)(c) below, of any upcoming long term change in treatment or the addition of a new source as described in that section. The Department must review and approve the addition of a new source or long term change in water treatment before it is implemented by the water system. The Department may require any such system to conduct additional monitoring or to take other action the Department deems appropriate to ensure that such systems maintain minimal levels of corrosion in the distribution system.~~ [Reserved]

(iv) ~~As of July 12, 2001, a system is not deemed to have optimized corrosion control under this paragraph, and shall implement corrosion control treatment pursuant to paragraph (2)(e)(v) of this section unless it meets the copper action level.~~ [Reserved]

(v) ~~Any system triggered into corrosion control because it is no longer deemed to have optimized corrosion control under this paragraph shall implement corrosion control treatment in accordance with the deadlines in paragraph (5) of this section. Any such large system shall adhere to the schedule specified in that paragraph for medium-size systems, with the time periods for completing each step being triggered by the date the system is no longer deemed to have optimized corrosion control under this paragraph.~~ [Reserved]

(3) ~~Any small or medium-size water system that is required to complete the corrosion control steps due to its exceedance of the lead or copper action level may cease completing the treatment steps whenever the system meets both action levels during each of two consecutive monitoring periods conducted pursuant to Section H below, and submits the results to the Department. If any such water system thereafter exceeds the lead or copper action level during any monitoring period, the system (or the Department, as the case may be) shall recommence completion of the applicable treatment steps, beginning with the first treatment step which was not previously completed in its entirety. The Department may require a system to repeat treatment steps previously completed by the system where the Department determines that this is necessary to implement properly the treatment requirements of this section. The Department shall notify the system in writing of such a determination and explain the basis for its decision. The requirement for any small or medium-size system to implement corrosion control treatment steps in accordance with Paragraph (5) of this section (including systems deemed to have optimized corrosion control under Paragraph (2)(a) of this section) is triggered whenever any small or medium-size system exceeds the lead or copper action level.~~ Corrosion Control Steps Completion for Small and Medium-Size Water Systems Without Corrosion Control Treatment.

Any small or medium-sized system without corrosion control treatment required to complete the corrosion control steps in paragraph (5) of this section due to its exceedance of the lead or copper action

level that does not exceed either the lead or copper action levels during each of two (2) consecutive six (6)-month tap sample monitoring periods pursuant to R.61-58.11.H prior to the start of Step 3 in paragraph (5)(c) of this section or Step 5 in paragraph (5)(e) of this section may cease completing the steps and is not required to complete Step 3 or Step 5, respectively, except that medium-sized systems with lead service lines and small systems with lead service lines that choose the corrosion control option pursuant to R. 61-58.11.O must complete a corrosion control treatment study under paragraph (5)(c)(i) of this section. Any system that initiates Step 5 must complete all remaining steps in paragraphs (5)(f) through (h) of this section and is not permitted to cease the steps. Any system that ceases the steps either prior to Step 3 or Step 5 and thereafter exceeds either the lead or copper action level shall not be permitted to cease the steps a second time and shall complete the applicable treatment steps beginning with the first treatment step which was not previously completed in its entirety. The Department may require a water system to repeat treatment steps previously completed by the water system when the Department determines that this is necessary to implement the treatment requirements of this section. The Department must notify the system in writing of such a determination and explain the basis for its decision.

(4) ~~Treatment Steps and Deadlines for Large Systems - Except as provided in paragraph (2)(b) and (c) of this section, large systems shall complete the following corrosion control treatment steps (described in the referenced portions of Sections D, H, and I below) by the indicated dates:~~ Treatment Steps and Deadlines for Water Systems Re-optimizing Corrosion Control Treatment.

Except as provided in paragraph (2) of this section or R.61-58.11.O, water systems with corrosion control treatment shall complete the following corrosion control treatment steps (described in the referenced portions of R.61-58.11.D, R.61-58.11.H, and R.61-58.11.I by the indicated time periods.

(a) Step 1: ~~The system shall conduct initial monitoring (Section H(4)(a) and Section I(2)) during two consecutive six-month monitoring periods by January 1, 1993.~~

(i) A water system other than those covered in paragraph (4)(a)(ii) of this section shall recommend re-optimized optimal corrosion control treatment (R.61-58.11.D(3)) within six (6) months after the end of the tap sampling period during which it exceeds either the lead trigger level or copper action level. The Department may approve modifications of the existing corrosion control treatment without a study for systems that exceed the lead trigger level, but do not exceed the lead or copper action level. The Department shall specify re-optimized corrosion control treatment within six (6) months of receiving the treatment recommendation. The system shall complete modifications to corrosion control treatment to have re-optimized corrosion control treatment installed within six (6) months of the Department specifying re-optimized corrosion control treatment.

(ii) A water system with lead service lines that exceeds the lead action level must harvest lead pipes from the distribution system and construct flowthrough pipe loops and operate the loops with finished water within one (1) year after the end of the tap sampling period during which it exceeds the lead action level. These water systems must proceed to Step 3 in paragraph (4)(c) of this section and conduct the corrosion control studies for re-optimization under paragraph (4)(c)(i) of this section using the pipe loops.

(b) Step 2: ~~The system shall complete corrosion control studies (Section D.(3) below) by July 1, 1994.~~

(i) Large water systems shall conduct the corrosion control studies for re-optimization under paragraph (4)(c) of this section (Step 3) unless the system is at or below the lead action level and the Department has approved the modification of the existing corrosion control treatment made under paragraph (4)(c)(i) of this section (Step 1).

(ii) Within twelve (12) months after the end of the tap sampling period during which a small or medium-size water system with corrosion control treatment exceeds the lead trigger level or copper action level, the Department may require the water system to perform corrosion control studies for re-optimization (R.61-58.11.D(3)(b) or (c)). If the Department does not require the system to perform such studies, the Department must specify re-optimized corrosion control treatment (R.61-58.11.D(4)(b)) within the timeframes specified in paragraphs (4)(b)(ii)(A) and (B) of this section. The Department must provide its determination to the system in writing.

(A) For medium-size water systems, within twelve (12) months after the end of the tap sampling period during which such water system exceeds the lead trigger level or copper action level.

(B) For small water systems, within eighteen (18) months after the end of the tap sampling period during which such water system exceeds the lead trigger level or copper action level.

(c) Step 3: ~~The Department shall designate optimal corrosion control treatment (Section D(4) below) by January 1, 1995.~~

(i) Any water system with lead service lines that exceeded the lead action level shall complete the corrosion control treatment studies for re-optimization within thirty (30) months after the end of the tap sampling period during which it exceeds the lead action level.

(ii) If the water system is required to perform corrosion control studies under paragraph (4)(b) of this section (Step 2), the water system shall complete the studies (R.61-58.11.D(3)(b)) within eighteen (18) months after the Department requires that such studies be conducted.

(d) Step 4: ~~The system shall install optimal corrosion control treatment (Section D(5) below) by January 1, 1997.~~

(i) The Department shall designate re-optimized corrosion control treatment (R.61-58.11.D(4)(c)) within six (6) months after completion of paragraph (4)(c)(i) of this section (Step 3).

(ii) If the water system has performed corrosion control studies under paragraph (4)(b) of this section (Step 2), the Department shall designate re-optimized corrosion control treatment (R.61-58.11.D(4)(b) or (d)) within six (6) months after completion of paragraph (4)(c)(ii) of this section (Step 3).

(e) Step 5: ~~The system shall complete follow-up sampling (Section H(4)(b) and Section I(3) below) by January 1, 1998.~~

(i) Large water systems shall complete modifications to corrosion control treatment to have reoptimized corrosion control treatment installed within twelve (12) months after completion of paragraph (4)(d)(i) of this section (Step 4).

(ii) Small or medium-size water systems shall install re-optimized corrosion control treatment (R.61-58.11.D(5)(a)) within twelve (12) months after completion of paragraph (4)(d)(ii) of this section (Step 4).

(f) Step 6: ~~The Department shall review installation of treatment and designate optimal water quality control parameters (Section D(6) below) by July 1, 1998.~~ Water systems must complete follow-up sampling (R.61-58.11.H(4)(b) and R.61-58.11.I(3)) within twelve (12) months after completion of paragraph (4)(e)(i) or (ii) of this section (Step 5).

(g) Step 7: ~~The system shall operate in compliance with the Department specified optimal water quality control parameters (Section D(7) below) and continue to conduct tap sampling (Section H(4)(c) and Section (I)(4) below).~~ The Department must review the water system's installation of treatment and designate optimal water quality control parameters (R.61-58.11.D(6)(a)) within six (6) months of completion of paragraph (4)(f) of this section (Step 6).

(h) Step 8: The water system must operate in compliance with the Department-designated optimal water quality control parameters (R.61-58.11.D(7)) and continue to conduct tap sampling (R.61-58.11.H(4)(c)) and water quality parameter monitoring under R.61-58.11.I(4).

(5) Treatment Steps and Deadlines for Systems Without Corrosion Control Treatment. ~~Small and Medium-Size Systems - Except as provided in paragraph (2) of this section, small and medium-size systems shall complete the following corrosion control treatment steps (described in the referenced portions of Sections D, H and I below) by the indicated time periods:~~

Except as provided in paragraph (2) of this section or R.61-58.11.O, water systems without corrosion control treatment must complete the following corrosion control treatment steps (described in the referenced portions of R.61-58.11.D, R.61-58.11.H, and R.61-58.11.I) by the indicated time periods.

(a) Step 1: ~~The system shall conduct initial tap sampling (Section H(4)(a) and Section I(2) below) until the system either exceeds the lead or copper action level or becomes eligible for reduced monitoring under Section (H)(4)(d) below. A system exceeding the lead or copper action level shall recommend optimal corrosion control treatment (Section D(1) below) within six (6) months after the end of the monitoring period during which it exceeds one of the action levels.~~

(i) A water system other than those covered in paragraph (5)(a)(ii) or (iii) of this section must recommend optimal corrosion control treatment (R.61-58.11.D(1)(a), (b), (c), or (d)) within six (6) months after the end of the tap sampling period during which it exceeds either the lead trigger level or copper action level.

(ii) A water system with lead service lines that exceeds the lead action level must harvest lead pipes from the distribution system and construct flowthrough pipe loops and operate the loops with finished water within one (1) year after the end of the tap sampling period during which it exceeds the lead action level. These water systems must proceed to Step 3 in paragraph (5)(c) of this section and conduct the corrosion control studies for optimization under paragraph (5)(c)(i) of this section using the pipe loops.

(iii) Large water systems under paragraph (1)(a)(ii) of this section must conduct the corrosion control studies for optimization under paragraph (5)(c) of this section (Step 3).

(b) Step 2: Within twelve (12) months after the end of the ~~monitoring~~ tap sampling period during which a system exceeds the lead or copper action level, if not otherwise required by this rule, the Department may require the water system to perform corrosion control studies (~~Section D(2)~~ R. 61-58.11.D(2) below). The Department must notify the system in writing of this requirement. If the Department does not require the system to perform such studies, the Department ~~shall~~ must specify optimal corrosion control treatment (~~Section D(4)~~R.61-58.11.D(4)) within ~~the following time frames:~~ the timeframes established in paragraphs (5)(b)(i) and (ii) of this section. The Department must provide its determination to the system in writing.

(i) For medium-size systems, within eighteen (18) months after the end of the ~~monitoring~~ tap sampling monitoring period during which such water system exceeds the lead trigger level or copper action level~~; and~~,.

(ii) For small systems, within twenty-four (24) months after the end of the ~~monitoring~~ tap sampling monitoring period during which such water system exceeds the lead trigger level or copper action level.

(c) Step 3: ~~If the Department requires a system to perform corrosion control studies under Step 2, the system shall complete the studies (Section D(3) below) within eighteen (18) months after the Department requires that such studies be conducted.~~

(i) Large water systems with or without lead service lines and medium or small systems with lead service lines that exceed the lead action level shall complete the corrosion control treatment studies for optimization within thirty (30) months after the end of the tap sampling period during which it exceeds the lead action level.

(ii) If the Department requires a water system to perform corrosion control studies under paragraph (5)(b) of this section (Step 2), the water system must complete the studies R.61-58.11.D(3)(a) within eighteen (18) months after the Department notifies the system in writing that such studies must be conducted.

(d) Step 4: ~~If the system has performed corrosion control studies under Step 2, the Department shall designate optimal corrosion control treatment (Section D(4) below) within six (6) months after completion of Step 3.~~

(i) The Department shall designate re-optimized corrosion control treatment (R.61-58.11.D(4)(c)) within six (6) months after completion of paragraph (4)(c)(i) of this section (Step 3).

(ii) If the water system has performed corrosion control studies under paragraph (5)(b) of this section (Step 2), the Department must designate optimal corrosion control treatment (R.61-58.11.D(4)(a)) within six (6) months after completion of paragraph (5)(c) of this section (Step 3).

(e) Step 5: ~~The system shall install o~~/~~ptimal corrosion control treatment (Section D(5) below) within twenty-four (24) months after the Department designates such treatment.~~ The water system must install optimal corrosion control treatment (R.61-58.11.D(5)(a)) within twenty-four (24) months after the Department designates optimal corrosion control treatment under paragraph (5)(b) or (d) of this section (Step 2 or Step 4).

(f) Step 6: The water system shall complete follow-up sampling (~~Section~~ R.61-58.11.H(4)(b) and ~~Section~~ R.61-58.11.I(3) below) within ~~36~~ twelve (12) months after ~~the Department designates optimal corrosion control treatment.~~ completion of paragraph (5)(e) of this section (Step 5).

(g) Step 7: The Department ~~shall~~ must review the system's installation of treatment and designate optimal water quality control parameters (~~Section~~ R. 61-58.11.D(6) below) within six (6) months ~~after~~ of completion of paragraph (5)(f) of this section (Step 6).

(h) Step 8: The water system ~~shall~~ must operate in compliance with the Department-designated optimal water quality control parameters (~~Section~~ R. 61-58.11.D(7) below) and continue to conduct tap sampling (~~Section~~ R. 61-58.11.H(4)(c) and ~~Section I(4) below)~~and water quality parameter monitoring under R.61-58.11.I(4)).

(6) Treatment Steps and Deadlines for Small Community Water Systems and Non-Transient Non-Community Water Systems Electing Corrosion Control Treatment (CCT) as a Compliance Option Under R.51-58.11.O, or as Required by the Department.

Water systems selecting the corrosion control small system compliance flexibility option must complete the following steps by the indicated time periods.

(a) Step 1: A water system recommends corrosion control treatment as a small system compliance flexibility option under R.61-58.11.O(1)(b) within six (6) months after the end of the tap sampling period during which it exceeds either the lead trigger level or the lead action level.

(b) Step 2: The Department approves in writing the recommendation of corrosion control treatment as a small system compliance flexibility option or designates an alternative option in accordance with R.61-58.11.O(1) within six (6) months of the recommendation by the water system in paragraph (6)(a) of this section (Step 1). Water systems required by the Department to optimize or re-optimize corrosion control treatment must follow the schedules in paragraph (4) or (5) of this section, beginning with Step 3 in paragraph (4)(c) or (5)(c) of this section unless the Department specifies optimal corrosion control treatment pursuant to either paragraph (4)(b)(ii) or (5)(b)(ii) of this section, as applicable.

D. Description of Corrosion Control Treatment Requirements.

~~Each system shall complete the corrosion control treatment requirements described below which are applicable to such system under Section C above.~~ This section sets forth the requirements applicable to systems and states in the designation of optimal corrosion control treatment (OCCT) for a system that is optimizing or re-optimizing corrosion control treatment. Each system must complete the corrosion control treatment requirements in this section as applicable to such system under R.61-58.11.C.

(1) System Recommendation Regarding Corrosion Control ~~treatment - Based upon the results of lead and copper tap monitoring and water quality parameter monitoring, small and medium-size water systems exceeding the lead or copper action level shall recommend installation of one or more of the corrosion control treatments listed in paragraph (3)(a) of this section which the system believes constitutes optimal corrosion control for that system. The Department may require the system to conduct additional water quality parameter monitoring in accordance with Section I(2) to assist the Department in reviewing the system's recommendation.~~ Treatment for Systems that do not Contain Lead Service Lines and Systems with Lead Service Lines that do not Exceed the Lead Action Level.

(a) Any system under this paragraph (1) without corrosion control treatment that is required to recommend a treatment option in accordance with R.61-58.11.C(5) must, based on the results of lead and copper tap sampling and water quality parameter monitoring, recommend designation of one or more of the corrosion control treatments listed in paragraph (3)(a)(i) of this section. Small community water systems and non-transient, non-community water systems that exceed the copper action level must comply with this paragraph (1)(a). The Department may require the system to conduct additional water quality parameter monitoring to assist the Department in reviewing the system's recommendation.

(b) Any small community water system or non-transient, non-community water system in this paragraph (1) without corrosion control treatment that chooses to pursue a small water system compliance flexibility option and is required to recommend an option in accordance with R.61-58.11.C(6) must, based on the results of lead tap sampling and water quality parameter monitoring, recommend designation of one of the options listed in R.61-58.11.O. Systems with no lead service lines that exceed the lead action level and select corrosion control under R.61-58.11.O(1)(b) must recommend designation of one or more of the corrosion control treatments listed in paragraph (3)(a) of this section as the optimal corrosion control treatment for that system.

(c) Any system under this paragraph (1) that exceeds the lead action level and selects corrosion control under R.61-58.11.O(1)(b) must recommend designation of one or more of the corrosion control treatments listed in paragraph (3)(a)(i) of this section as the optimal corrosion control treatment for that system. A corrosion control study under paragraph (3) of this section is not required for medium and small systems that exceed the lead trigger level but do not exceed the lead and copper action levels, unless required by the Department.

(d) Any small community water system or non-transient, non-community water system with corrosion control treatment that exceeds the lead action level and selects corrosion control under R.61-58.11.O(1)(b) must recommend designation of one or more of the corrosion control treatments listed in paragraph (3)(b) of this section as the optimal corrosion control treatment for that system.

(e) The Department may waive the requirement for a system to recommend OCCT if the Department requires the system, in writing, to complete a corrosion control study within three (3) months after the end of the tap sampling period during which the exceedance occurred. Such systems shall proceed directly to paragraph (3) of this section and complete a corrosion control study.

(2) Department Decision to Require Studies ~~of Corrosion Control Treatment (applicable to small and medium-size systems) - The Department may require any small or medium-size system that exceeds the lead or copper action level to perform corrosion control studies under paragraph (3) of this section to identify optimal corrosion control treatment for the system.~~to Identify Initial Optimal Corrosion Control Treatment and Re-optimized Optimal Corrosion Control Treatment Except for Large Systems and Small and Medium Systems with Lead Service Lines that Exceed the Lead Action Level.

Corrosion control treatment studies are always required for large systems that exceed the lead action level, large water systems without corrosion control treatment with 90th percentile results that exceed either the lead practical quantitation level of 0.005 mg/L or the copper action level, medium-size systems with lead service lines that exceed the lead action level, and small systems with lead service lines that exceed the lead action level and select the corrosion control treatment option under R.61-58.11.O(1).

(a) The Department may require any small or medium-size system without corrosion control that exceeds either the lead or copper action level to perform corrosion control treatment studies under paragraph (3)(a) of this section to identify optimal corrosion control treatment for the system.

(b) The Department may require any small or medium-size system without corrosion control that exceeds the lead trigger level but not the lead or copper action level to perform corrosion control treatment studies under paragraph (3)(a) of this section to identify optimal corrosion control treatment for the system. This corrosion control treatment shall be installed if the lead or copper action level is subsequently exceeded.

(c) The Department may require any small or medium-size water systems with corrosion control treatment exceeding either the lead trigger level or copper action level to perform corrosion control treatment studies under paragraph (3)(b) of this section to identify re-optimized optimal corrosion control treatment for the system (i.e., optimal corrosion control treatment after a re-optimization evaluation).

(3) Performance of Corrosion Control Studies

(a) ~~Any public water system performing corrosion control studies shall evaluate the effectiveness of each of the following treatments, and, if appropriate, combinations of the following treatments to identify the optimal corrosion control treatment for that system:~~ Water systems without corrosion control treatment that are required to conduct corrosion control studies must complete the following:

(i) ~~Alkalinity and pH adjustment;~~ Any water system without corrosion control treatment must evaluate the effectiveness of each of the following treatments, and if appropriate, combinations of the following treatments to identify the optimal corrosion control treatment for the system:

(A) Alkalinity and pH adjustment;

(B) The addition of an orthophosphate- or silicate-based corrosion inhibitor at a concentration sufficient to maintain an effective corrosion inhibitor residual concentration in all test samples;

(C) The addition of an orthophosphate-based corrosion inhibitor at a concentration sufficient to maintain an orthophosphate residual concentration of one milligram per liter (1 mg/L) (as PO_4) in all test samples; and

(D) The addition of an orthophosphate-based corrosion inhibitor at a concentration sufficient to maintain an orthophosphate residual concentration of three milligrams per liter (3 mg/L) (as PO_4) in all test samples.

(ii) ~~Calcium hardness adjustment; and,~~ The water system must evaluate each of the corrosion control treatments using either pipe rig/loop tests, metal coupon tests, partial-system tests, or analyses based on documented analogous treatments with other systems of similar size, water chemistry, and distribution system configurations. Large and medium systems, and small community water systems and non-transient, non-community water systems that select the corrosion control treatment option under R.61-58.11.O with lead service lines that exceed the lead action level must conduct pipe rig/loop studies using harvested lead service lines from their distribution systems to assess the effectiveness of corrosion control treatment options on the existing pipe scale. For these systems, metal coupon tests can be used as a screen to reduce the number of options that are evaluated using pipe rig/loops to the current conditions and two (2) options.

(iii) ~~The addition of a phosphate or silicate based corrosion inhibitor at a concentration sufficient to maintain an effective residual concentration in all test tap samples.~~ The water system must measure the following water quality parameters in any tests conducted under this paragraph (3)(a)(iii) before and after evaluating the corrosion control treatments listed in paragraphs (3)(a)(i) and (ii) of this section:

(A) Lead;

(B) Copper;

(C) pH;

(D) Alkalinity;

(E) Orthophosphate as PO_4 (when an orthophosphate-based inhibitor is used); and

(F) Silicate (when a silicate-based inhibitor is used).

(iv) The water system must identify all chemical or physical constraints that limit or prohibit the use of a particular corrosion control treatment and document such constraints with one of the following:

(A) Data and documentation showing that a particular corrosion control treatment has adversely affected other drinking water treatment processes when used by another water system with comparable water quality characteristics. Systems using coupon studies to screen and/or pipe loop/rig studies to evaluate

treatment options must not exclude treatment strategies from the studies based on the constraints identified in this section.

(B) Data and documentation demonstrating that the water system has previously attempted to evaluate a particular corrosion control treatment and has found that the treatment is ineffective or adversely affects other drinking water quality treatment processes. Systems using coupon studies to screen and/or pipe loop/rig studies to evaluate treatment options must not exclude treatment strategies from the studies based on the constraints identified in this section unless the treatment was found to be ineffective in a previous pipe loop/rig study.

(v) The water system must evaluate the effect of the chemicals used for corrosion control treatment on other drinking water quality treatment processes. Systems using coupon studies to screen and/or pipe loop/rig studies to evaluate treatment options shall not exclude treatment strategies from the studies based on the effects identified in this section.

(vi) On the basis of an analysis of the data generated during each evaluation, the water system must recommend to the Department in writing the treatment option that the corrosion control studies indicate constitutes optimal corrosion control treatment for that system as defined in R.61-58.B. The water system must provide a rationale for its recommendation along with all supporting documentation specified in paragraphs (3)(b)(i) through (v) of this section.

(b) ~~The water system shall evaluate each of the corrosion control treatments using either pipe rig/loop tests, metal coupon tests, partial system tests, or analyses based on documented analogous treatments with other systems of similar size, water chemistry and distribution system configuration.~~ Systems with corrosion control treatment that are required to conduct corrosion control studies to determine re-optimized OCCT must complete the following:

(i) The water system must evaluate the effectiveness of the following treatments, and if appropriate, combinations of the following treatments to identify the re-optimized optimal corrosion control treatment for the system:

(A) Alkalinity and/or pH adjustment, or re-adjustment;

(B) The addition of an orthophosphate- or silicate-based corrosion inhibitor at a concentration sufficient to maintain an effective corrosion inhibitor residual concentration in all test samples if no such inhibitor is utilized;

(C) The addition of an orthophosphate-based corrosion inhibitor at a concentration sufficient to maintain an orthophosphate residual concentration of one milligram per liter (1 mg/L) (PO_4) in all test samples unless the current inhibitor process already meets this residual; and

(D) The addition of an orthophosphate-based corrosion inhibitor at a concentration sufficient to maintain an orthophosphate residual concentration of three milligrams per liter (3 mg/L) (PO_4) in all test samples unless the current inhibitor process already meets this residual.

(ii) The water system must evaluate each of the corrosion control treatments using either pipe rig/loop tests, metal coupon tests, partial-system tests, or analyses based on documented analogous treatments with other systems of similar size, water chemistry, and distribution system configurations. If the water system has lead service lines and exceeds the lead action level, it must conduct pipe rig/loop studies using harvested lead service lines from their distribution systems to assess the effectiveness of corrosion control treatment options on the existing pipe scale. For these systems, metal coupon tests can be

used as a screen to reduce the number of options that are evaluated using pipe rig/loops to the current conditions and two (2) options.

(iii) The water system must measure the following water quality parameters in any tests conducted under this paragraph (3)(b)(iii) before and after evaluating the corrosion control treatments listed in paragraphs (3)(b)(i) and (ii) of this section:

(A) Lead;

(B) Copper;

(C) pH;

(D) Alkalinity;

(E) Orthophosphate as PO_4 (when an orthophosphate-based inhibitor is used); and

(F) Silicate (when a silicate-based inhibitor is used).

(iv) The water system must identify all chemical or physical constraints that limit or prohibit the use of a particular corrosion control treatment and document such constraints with one of the following:

(A) Data and documentation showing that a particular corrosion control treatment has adversely affected other drinking water treatment processes when used by another water system with comparable water quality characteristics. Systems using coupon studies to screen and/or pipe loop/rig studies to evaluate treatment options must not exclude treatment strategies from the studies based on the constraints identified in this section.

(B) Data and documentation demonstrating that the water system has previously attempted to evaluate a particular corrosion control treatment and has found that the treatment is ineffective or adversely affects other drinking water quality treatment processes. Systems using coupon studies to screen and/or pipe loop/rig studies to evaluate treatment options shall not exclude treatment strategies from the studies based on the constraints identified in this section unless the treatment was found to be ineffective in a previous pipe loop/rig study.

(v) The water system must evaluate the effect of the chemicals used for corrosion control treatment on other drinking water quality treatment processes. Systems using coupon studies to screen and/or pipe loop/rig studies to evaluate treatment options shall not exclude treatment strategies from the studies based on the effects identified in this section.

(vi) On the basis of an analysis of the data generated during each evaluation, the water system must recommend to the Department in writing the treatment option that the corrosion control studies indicate constitutes optimal corrosion control treatment for that system as defined in R.61-58.B. The water system must provide a rationale for its recommendation along with all supporting documentation specified in paragraph (3)(a)(i) through (v) of this section.

~~(c) The water system shall measure the following water quality parameters in any tests conducted under this paragraph before and after evaluating the corrosion control treatments listed above:~~

~~(i) Lead;~~

~~(ii) Copper;~~

~~(iii) pH;~~

~~(iv) Alkalinity;~~

~~(v) Calcium;~~

~~(vi) Conductivity;~~

~~(vii) Orthophosphate (when an inhibitor containing a phosphate compound is used);~~

~~(viii) Silicate (when an inhibitor containing a silicate compound is used); and,~~

~~(ix) Water temperature.~~

~~(d) The water system shall identify all chemical or physical constraints that limit or prohibit the use of a particular corrosion control treatment and document such constraints with at least one of the following:~~

~~(i) Data and documentation showing that a particular corrosion control treatment has adversely affected other water treatment processes when used by another water system with comparable water quality characteristics; and/or,~~

~~(ii) Data and documentation demonstrating that the water system has previously attempted to evaluate a particular corrosion control treatment and has found that the treatment is ineffective or adversely affects other water quality treatment processes.~~

~~(e) The water system shall evaluate the effect of the chemicals used for corrosion control treatment on other water quality treatment processes.~~

~~(f) On the basis of an analysis of the data generated during each evaluation, the water system shall recommend to the Department in writing the treatment option that the corrosion control studies indicate constitutes optimal corrosion control treatment for that system. The water system shall provide a rationale for its recommendation along with all supporting documentation specified in paragraphs 3(a) through (e) of this section.~~

(4) Department Designation of ~~Optimal~~ Optimized Optimal Corrosion Control Treatment and Re-optimized Optimal Corrosion Control Treatment.

When designating optimal corrosion control treatment, the Department must consider the effects that additional corrosion control treatment will have on water quality parameters and on other drinking water quality treatment processes. The Department must notify the water system of its designation of optimal corrosion control treatment in writing and explain the basis for this determination. If the Department requests additional information to aid its review, the water system must provide the information.

(a) ~~Based upon consideration of available information including, where applicable, studies performed under paragraph (3) of this section and a system's recommended treatment alternative, the Department shall either approve the corrosion control treatment option recommended by the system, or designate alternative corrosion control treatment(s) from among those listed in paragraph (3)(a) of this section. When designating optimal treatment the Department shall consider the effects that additional~~

~~corrosion control treatment will have on water quality parameters and on other water quality treatment processes.~~ Designation of OCCT for systems without corrosion control treatment.

Based upon considerations of available information including, where applicable, studies conducted under paragraph (3)(a) of this section and/or a system's recommended corrosion control treatment option, the Department must either approve the corrosion control treatment option recommended by the system or designate alternative corrosion control treatment(s) from among those listed in paragraph (3)(a)(i) of this section or, where applicable, an alternate small water system compliance flexibility option under R.61-58.11.O(1).

(b) ~~The Department shall notify the system of its decision on optimal corrosion control treatment in writing and explain the basis for this determination. If the Department requests additional information to aid its review, the water system shall provide the information.~~ Designation of re-optimized OCCT for systems with corrosion control treatment.

Based upon considerations of available information including, where applicable, studies conducted under paragraph (3)(b) of this section and/or a system's recommended treatment alternative, the Department must either approve the corrosion control treatment option recommended by the water system or designate alternative corrosion control treatment(s) from among those listed in paragraph (3)(b)(i) of this section or, where applicable, an alternate small water system compliance flexibility option under R.61-58.11.O.

(5) Installation of Optimal Corrosion Control Treatment and Re-optimization of Corrosion Control Treatment. ~~Each system shall properly install and operate throughout its distribution system the optimal corrosion control treatment designated by the Department under paragraph (4) of this section.~~

Each system shall properly install and operate throughout its distribution system the optimal corrosion control treatment designated by the Department under paragraph (4) of this section.

(6) Department Review of Treatment and Specification of Optimal Water Quality Control Parameters for Optimal Corrosion Control Treatment and Reoptimized Corrosion Control Treatment. ~~The Department shall evaluate the results of all lead and copper tap samples and water quality parameter samples submitted by the water system and determine whether the system has properly installed and operated the optimal corrosion control treatment designated by the Department in paragraph (4) of this section. Upon reviewing the results of tap water and water quality parameter monitoring by the system, both before and after the system installs optimal corrosion control treatment, the Department shall designate:~~

The Department must evaluate the results of all lead and copper tap sampling and water quality parameter sampling submitted by the water system and determine whether the water system has properly installed and operated the optimal corrosion control treatment designated by the Department in paragraph (4)(a) or (b) of this section, respectively. Upon reviewing the results of tap water and water quality parameter monitoring by the water system, both before and after the water system installs optimal corrosion control treatment, the Department must designate:

(a) A minimum value or a range of values for pH measured at each entry point to the distribution system~~;~~.

(b) A minimum pH value, measured in all tap samples. Such a value shall be equal to or greater than 7.0, unless the Department determines that meeting a pH level of 7.0 is not technologically feasible or is not necessary for the system to optimize corrosion control~~;~~.

(c) If a corrosion inhibitor is used, a minimum concentration or a range of concentrations for the ~~inhibitor,~~ orthophosphate (as PO_4) or silicate measured at each entry point to the distribution ~~system and in all tap samples, that the Department determines is necessary to form a passivating film on the interior walls of the pipes of the distribution system;~~.

(d) ~~If alkalinity is adjusted as part of optimal corrosion control treatment, a minimum concentration or a range of concentrations for alkalinity, measured at each entry point to the distribution system and in all tap samples; and,~~ If a corrosion inhibitor is used, a minimum orthophosphate or silicate concentration measured in all tap samples that the Department determines is necessary to form a passivating film on the interior walls of the pipes of the distribution system. When orthophosphate is used, such an orthophosphate concentration shall be equal to or greater than 0.5 mg/L (as PO_4) for OCCT designations under paragraph (4)(a) of this section and 1.0 mg/L for OCCT designations under paragraph (4)(b) of this section, unless the Department determines that meeting the applicable minimum orthophosphate residual is not technologically feasible or is not necessary for optimal corrosion control treatment.

(e) ~~If calcium carbonate stabilization is used as part of corrosion control, a minimum concentration or a range of concentrations for calcium, measured in all tap samples.~~ If alkalinity is adjusted as part of optimal corrosion control treatment, a minimum concentration or a range of concentrations for alkalinity, measured at each entry point to the distribution system and in all tap samples.

(f) The values for the applicable water quality control parameters, previously listed in this section, shall be those that the Department determines to reflect optimal corrosion control treatment for the water system. The Department may designate values for additional water quality control parameters determined by the Department to reflect optimal corrosion control treatment for the water system. The Department must notify the system in writing of these determinations and explain the basis for its decisions.

~~The values for the applicable water quality control parameters listed above shall be those that the Department determines to reflect optimal corrosion control treatment for the system. The Department may designate values for additional water quality control parameters determined by the Department to reflect optimal corrosion control for the system. The Department shall notify the system in writing of these determinations and explain the basis for its decisions.~~

(7) Continued Operation and Monitoring for Optimal Corrosion Control Treatment and Re-optimized Optimal Corrosion Control Treatment. ~~All systems shall maintain water quality parameter values at or above minimum values or within ranges designated by the Department under paragraph (6) of this section in each sample collected under Section I(4) below. If the water quality parameter value of any sample is below the minimum value or outside the range designated by the Department, then the system is out of compliance with this paragraph. As specified in Section (I)(4) below, the system may take a confirmation sample for any water quality parameter value no later than 3 days after the first sample. If a confirmation sample is taken, the result must be averaged with the first sampling result and the average must be used for any compliance determinations under this paragraph. All systems optimizing corrosion control shall continue to operate and maintain optimal corrosion control treatment, including maintaining water quality parameters at or above minimum values or within ranges designated by the Department under paragraph (6) of this section, in accordance with this paragraph for all samples collected under Section I(4) (6) below. Compliance with the requirements of this paragraph shall be determined every six months, as specified under Section I(4) below. A water system is out of compliance with the requirements of this paragraph for a six month period if it has excursions for any Department specified parameter on more than nine days during the period. An excursion occurs whenever the daily value for one or more of the water quality parameters measured at a sampling location is below the minimum value or outside the range designated by the Department. Daily values are calculated as follows. The Department has discretion to delete results of obvious sampling errors from this calculation.~~

All systems optimizing or re-optimizing corrosion control must continue to operate and maintain optimal corrosion control treatment, including maintaining water quality parameters at or above minimum values or within ranges designated by the Department under paragraph (6) of this section, in accordance with this paragraph (7) for all samples collected under R.61-58.11.I(4) through (6). The requirements of this paragraph (7) apply to all systems, including consecutive systems that distribute water that has been treated to control corrosion by another system, and any water system with corrosion control treatment, optimal corrosion control treatment, or re-optimized OCCT that is not required to monitor water quality parameters under R.61-58.11.I. Compliance with the requirements of this paragraph (7) shall be determined every six (6) months, as specified under R.61-58.11.I(4). A water system is out of compliance with the requirements of this paragraph (7) for a six (6)-month period if it has excursions for any Department-specified parameter on more than nine (9) days, cumulatively, during the period. An excursion occurs whenever the daily value for one or more of the water quality parameters measured at a sampling location is below the minimum value or outside the range designated by the Department. Daily values are calculated as set out in paragraphs (7)(a) through (c) of this section. The Department has the discretion to not include results of obvious sampling errors from this calculation. Sampling errors must still be recorded even when not included in calculations.

(a) On days when more than one (1) measurement for the water quality parameter is collected at the sampling location, the daily value ~~shall~~ must be the average of all results collected during the day regardless of whether they are collected through continuous monitoring, grab sampling, or a combination of both. If EPA has approved an alternative formula under 40 CFR 142.16(d)(1)(ii) in the Department's application for a program revision submitted pursuant to 40 CFR 142.12, the Department's formula shall be used to aggregate multiple measurements taken at a sampling point for the water quality parameters in lieu of the formula in this paragraph (7)(a).

(b) On days when only one (1) measurement for the water quality parameter is collected at the sampling location, the daily value shall be the result of that measurement.

(c) On days when no measurement is collected for the water quality parameter at the sampling location, the daily value shall be the daily value calculated on the most recent day on which the water quality parameter was measured at the ~~sample site~~ sampling location.

(8) Modification of Department Treatment Decisions for Optimal Corrosion Control and Re-optimized Corrosion Control. ~~Upon its own initiative or in response to a request by a water system or other interested party, a Department may modify its determination of the optimal corrosion control treatment under paragraph (4) of this section or optimal water quality control parameters under paragraph (6) of this section. A request for modification by a system or other interested party shall be in writing, explain why the modification is appropriate, and provide supporting documentation. The Department may modify its determination where it concludes that such change is necessary to ensure that the system continues to optimize corrosion control treatment. A revised determination shall be made in writing, set forth the new treatment requirements, explain the basis for the Department's decision, and provide an implementation schedule for completing the treatment modifications.~~

Upon its own initiative or in response to a request by a water system or other interested party, the Department may modify its determination of the optimal corrosion control treatment under paragraph (4) of this section, or optimal water quality control parameters under paragraph (6) of this section. A request for modification by a system or other interested party shall be in writing, explaining why the modification is appropriate, and providing supporting documentation. The Department may modify its determination where it concludes that such change is necessary to ensure that the water system continues to optimize corrosion control treatment. A revised determination must be made in writing, set forth the new treatment

requirements and/or water quality parameters, explain the basis for the Department's decision, and provide an implementation schedule for completing the treatment modifications for re-optimized corrosion control treatment.

(9) Treatment Decisions by EPA in lieu of the Department on Optimal Corrosion Control Treatment and Re-optimized Corrosion Control Treatment.

Pursuant to the procedures in 40 CFR 142.19, EPA Regional Administrator may review optimal corrosion control treatment determinations made by the Department under paragraph (4)(a) or (b), (6), or (8) of this section and issue Federal treatment determinations consistent with the requirements of paragraph (4)(a) or (b), (6), or (8) of this section where the Regional Administrator finds that:

(a) A Department has failed to issue a treatment determination by the applicable deadlines contained in R.61-58.11.C;

(b) A Department has abused its discretion in a substantial number of cases or in cases affecting a substantial population; or

(c) The technical aspects of a Department's determination would be indefensible in a Federal enforcement action taken against a water system.

(10) Find-and-fix Assessment for Tap Sample Sites that Exceed the Lead Action Level.

The water system shall conduct the following steps, when a tap sample site exceeds the lead action level under monitoring conducted under R.61-58.11.H.

(a) Step 1: Corrosion Control Treatment Assessment. The water system must sample at a new water quality parameter site that is on the same size water main in the same pressure zone and located within a half mile of the location with the action level exceedance within five (5) days of receiving the sample results. Small water systems without corrosion control treatment may have up to fourteen (14) days to collect the samples. The water system must measure the following parameters:

(i) pH;

(ii) Alkalinity;

(iii) Orthophosphate (as PO_4), when an inhibitor containing an orthophosphate compound is used;

(iv) Silica, when an inhibitor containing a silicate compound is used; and

(v) Water systems with an existing water quality parameter location that meets the requirements of this section can conduct this sampling at that location.

(vi) All water systems required to meet optimal water quality control parameters but that do not have an existing water quality parameter location that meets the requirement of this section must add new sites to the minimum number of sites as described in R.61-58.11.I(7). Sites must be added until a system has twice the minimum number of sites listed in Table 1 to R.61-58.11.I(1)(b). When a system exceeds this upper threshold for the number of sites, the Department has discretion to determine if the newer site can better assess the effectiveness of the corrosion control treatment and to remove existing sites during sanitary survey evaluation of OCCT.

(b) Step 2: Site Assessment. Water systems shall collect a follow-up sample at any tap sample site that exceeds the action level within thirty (30) days of receiving the sample results. These follow-up samples may use different sample volumes or different sample collection procedures to assess the source of elevated lead levels. Samples collected under this section must be submitted to the Department but shall not be included in the 90th percentile calculation for compliance monitoring under R.61-58.11.H. If the water system is unable to collect a follow-up sample at a site, the water system must provide documentation to the Department, explaining why it was unable to collect a follow-up sample.

(c) Step 3: Water systems shall evaluate the results of the monitoring conducted under this paragraph (10)(c) to determine if either localized or centralized adjustment of the optimal corrosion control treatment or other distribution system actions are necessary and submit the recommendation to the Department within six months after the end of the tap sampling period in which the site(s) exceeded the lead action level. Corrosion control treatment modification may not be necessary to address every exceedance. Other distribution system actions may include flushing to reduce water age. Water systems must note the cause of the elevated lead level, if known from the site assessment, in their recommendation to the Department as site-specific issues can be an important factor in why the system is not recommending any adjustment of corrosion control treatment or other distribution system actions. Systems in the process of optimizing or reoptimizing optimal corrosion control treatment under paragraphs (1) through (6) of this section do not need to submit a treatment recommendation for find-and-fix.

(d) Step 4: The Department shall approve the treatment recommendation or specify a different approach within six (6) months of completion of Step 3 as described in paragraph (10)(c) of this section.

(e) Step 5: If the Department-approved treatment recommendation requires the water system to adjust the optimal corrosion control treatment process, the water system must complete modifications to its corrosion control treatment within twelve (12) months after completion of Step 4 as described in paragraph (10)(d) of this section. Systems without corrosion control treatment required to install optimal corrosion control treatment must follow the schedule in R.61-58.11.C(5).

(f) Step 6: Water systems adjusting its optimal corrosion control treatment must complete follow-up sampling (R.61-58.11.H(4)(b) and R.61-58.11.I(3)) within twelve (12) months after completion of Step 5 as described in paragraph (10)(e) of this section.

(g) Step 7: For water systems adjusting its optimal corrosion control treatment, the Department must review the water system's modification of corrosion control treatment and designate optimal water quality control parameters (R.61-58.11.D(6)(a)) within six (6) months of completion of Step 6 as described in paragraph (10)(f) of this section.

(h) Step 8. For a water system adjusting its optimal corrosion control treatment, the water system must operate in compliance with the Department-designated optimal water quality control parameters (R.61-58.11.D(7)) and continue to conduct tap sampling (R.61-58.11.H(4)(c) and R.61-58.11.I(4)).

E. Source Water Treatment Requirements.

Systems shall complete the applicable source water monitoring and treatment requirements (described in the referenced portions of paragraph (2) of this section, and in R. 61-58.11.H and R. 61-58.11.J ~~Sections H and J~~ by the following deadlines.

(1) Deadlines for Completing Source Water Treatment Steps

(a) Step 1: A system exceeding the lead or copper action level shall complete lead and copper source water monitoring (R. 61-58.11.J(2)~~Section J(2)~~ below) and make a treatment recommendation to the Department (paragraph (2)(a) of this section) no later than one hundred eighty (180) days after the end of the monitoring period during which the lead or copper action level was exceeded.

(b) Step 2: The Department shall make a determination regarding source water treatment (paragraph (2)(b) of this section) within six (6) months after submission of monitoring results under Step 1.

(c) Step 3: If the Department requires installation of source water treatment, the system shall install the treatment (paragraph (2)(c) of this section) within twenty-four (24) months after completion of Step 2.

(d) Step 4: The system shall complete follow-up tap water monitoring (R. 61-58.11.H(4)(b)~~Section H(4)(b)~~ below) and source water monitoring (R. 61-58.11.J(3)~~Section J(3)~~ below) within thirty-six (36) months after completion of Step 2.

(e) Step 5: The Department shall review the system's installation and operation of source water treatment and specify maximum permissible source water levels (paragraph (2)(d) of the section) within six (6) months after completion of Step 4.

(f) Step 6: The system shall operate in compliance with the Department-specified maximum permissible lead and copper source water levels (paragraph (2)(d) of this section) and continue source water monitoring (R. 61-58.11.J(4) ~~Section J(4)~~ below).

(2) Description of Source Water Treatment Requirements

(a) System Treatment Recommendation - Any system which exceeds the lead or copper action level shall recommend in writing to the Department the installation and operation of one of the source water treatments listed in paragraph (2)(b) of this section. A system may recommend that no treatment be installed based upon a demonstration that source water treatment is not necessary to minimize lead and copper levels at users' taps.

(b) Department Determination Regarding Source Water Treatment - The Department shall complete an evaluation of the results of all source water samples submitted by the water system to determine whether source water treatment is necessary to minimize lead or copper levels in water delivered to users' taps. If the Department determines that treatment is needed, the Department shall either require installation and operation of the source water treatment recommended by the system (if any) or require the installation and operation of another source water treatment from among the following: ion exchange, reverse osmosis, lime softening or coagulation/filtration. If the Department requests additional information to aid in its review, the water system shall provide the information by the date specified by the Department in its request. The Department shall notify the system in writing of its determination and set forth the basis for its decision.

(c) Installation of Source Water Treatment - Each system shall properly install and operate the source water treatment designated by the Department under paragraph (2)(b) of this section.

(d) Department Review of Source Water Treatment and Specification of Maximum Permissible Source Water Levels - The Department shall review the source water samples taken by the water system both before and after the system installs source water treatment, and determine whether the system has properly installed and operated the source water treatment designated by the Department. Based upon its review, the Department shall designate the maximum permissible lead and copper concentrations for finished water entering the distribution system. Such levels shall reflect the contaminant removal capability

of the treatment properly operated and maintained. The Department shall notify the system in writing and explain the basis for its decision.

(e) Continued Operation and Maintenance - Each water system shall maintain lead and copper levels below the maximum permissible concentrations designated by the Department at each sampling point monitored in accordance with R. 61-58.11.J ~~Section J~~. The system is out of compliance with this paragraph if the level of lead or copper at any sampling point is greater than the maximum permissible concentration designated by the Department.

(f) Modification of Department Treatment Decisions - Upon its own initiative or in response to a request by a water system or other interested party, the Department may modify its determination of the source water treatment under paragraph (2)(b) of this section, or maximum permissible lead and copper concentrations for finished water entering the distribution system under paragraph (2)(d) of this section. A request for modification by a system or other interested party shall be in writing, explain why the modification is appropriate, and provide supporting documentation. The Department may modify its determination where it concludes that such change is necessary to ensure that the system continues to minimize lead and copper concentrations in source water. A revised determination shall be made in writing, set forth the new treatment requirements, explain the basis for the Department's decision, and provide an implementation schedule for completing the treatment modifications.

. F. Lead Service Line Inventory and Replacement Requirements.

(1) ~~Systems that fail to meet the lead action level in tap samples taken pursuant to Section H(4)(b), after installing corrosion control and/or source water treatment (whichever sampling occurs later), shall replace lead service lines in accordance with the requirements of this section. If a system is in violation of Section C or Section E for failure to install source water or corrosion control treatment, the Department may require the system to commence lead service line replacement under this section after the date by which the system was required to conduct monitoring under Section H(4)(b) below, has passed.~~ Lead Service Line Inventory.

All water systems must develop an inventory to identify the materials of service lines connected to the public water distribution system. The inventory must meet the following requirements:

(a) All water systems must develop an initial inventory by January 16, 2024, and submit it to the primacy agency in accordance with R.61-58.11.L(5).

(b) The inventory must include all service lines connected to the public water distribution system regardless of ownership status (e.g., where service line ownership is shared, the inventory would include both the portion of the service line owned by the water system and the customer-owned portion of the service line).

(c) A water system must use any information on lead and galvanized iron or steel that it has identified pursuant to R.61-58.5.V when conducting the inventory of service lines in its distribution system for the initial inventory under paragraph (1)(a) of this section. The water system must also review the sources of information listed in paragraphs (1)(c)(i) through (iv) of this section to identify service line materials for the initial inventory. The water system may use other sources of information not listed in paragraphs (1)(c)(i) through (iv) of this section if approved by the Department.

(i) All construction and plumbing codes, permits, and existing records or other documentation which indicates the service line materials used to connect structures to the distribution system.

(ii) All water system records, including distribution system maps and drawings, historical records on each service connection, meter installation records, historical capital improvement or master plans, and standard operating procedures.

(iii) All inspections and records of the distribution system that indicate the material composition of the service connections that connect a structure to the distribution system.

(iv) Any resource, information, or identification method provided or required by the Department to assess service line materials.

(d) Each service line, or portion of the service line where ownership is split, must be categorized in the following manner:

(i) ''Lead'' where the service line is made of lead.

(ii) ''Galvanized Requiring Replacement'' where a galvanized service line is or was at any time downstream of a lead service line or is currently downstream of a ''Lead Status Unknown'' service line. If the water system is unable to demonstrate that the galvanized service line was never downstream of a lead service line, it must presume there was an upstream lead service line.

(iii) ''Non-lead'' where the service line is determined through an evidence-based record, method, or technique not to be lead or galvanized requiring replacement. The water system may classify the actual material of the service line (i.e., plastic or copper) as an alternative to classifying it as ''Non-lead.''

(iv) ''Lead Status Unknown'' where the service line material is not known to be lead, galvanized requiring replacement, or a non-lead service line, such as where there is no documented evidence supporting material classification. The water system may classify the line as ''Unknown'' as an alternative to classifying it as ''Lead Status Unknown,'' however, all requirements that apply to ''Lead Status Unknown'' service lines must also apply to those classified as ''Unknown.'' Water systems may elect to provide more information regarding their unknown lines as long as the inventory clearly distinguishes unknown service lines from those where the material has been verified through records or inspection.

(e) Water systems shall identify and track service line materials in the inventory as they are encountered in the course of its normal operations (e.g., checking service line materials when reading water meters or performing maintenance activities).

(f) Water systems must update the inventory based on all applicable sources described in paragraphs (1)(c) and (e) of this section and any lead service line replacements or service line material inspections that may have been conducted. The water system may use other sources of information if approved by the Department and must use other sources of information provided or required by the Department. Water systems must submit the updated inventory to the Department in accordance with R.61-58.11.L(5). The inventory updates must be reflected in the publicly accessible inventory no less frequently than when required to be submitted to the Department.

(i) Water systems whose inventories contain only non-lead service lines are not required to provide inventory updates to the Department or to the public. If, in the future, such a water system finds a lead service line within its system, it must prepare an updated inventory in accordance with paragraph (1) of this section on a schedule established by the Department.

(ii) [Reserved]

(g) To calculate the number of service line replacements applicable to paragraphs (6) and (7) of this section, the replacement rate must be applied to the sum of known lead and galvanized requiring replacement service lines when the system first exceeds the trigger or action level plus the number of lead status unknown service lines in the beginning of each year of a system's annual goal or mandatory lead service line replacement program.

(i) Each service line shall count only once for purposes of calculating the required number of service line replacements, even where the ownership of the service line is split and both the customer-owned and system-owned portions require replacement.

(ii) The number of service lines requiring replacement must be updated annually to subtract the number of lead status unknown service lines that were discovered to be non-lead and to add the number of non-lead service lines that were discovered to be a lead or galvanized requiring replacement service line.

(iii) Verification of a lead status unknown service line as non-lead in the inventory does not count as a service line replacement.

(h) The service line materials inventory must be publicly accessible.

(i) The inventory must include a location identifier, such as a street address, block, intersection, or landmark, associated with each lead service line and galvanized requiring replacement service line. Water systems may, but are not required to, include a locational identifier for lead status unknown service lines or list the exact address of each service line.

(ii) Water systems serving greater than 50,000 persons must make the publicly accessible inventory available online.

(i) When a water system has no lead, galvanized requiring replacement, or lead status unknown service lines (regardless of ownership) in its inventory, it may comply with the requirements in paragraph (1)(h) of this section using a written statement, in lieu of the inventory, declaring that the distribution system has no lead service lines or galvanized requiring replacement service lines. The statement must include a general description of all applicable sources described in paragraphs (1)(c), (e), and (f) of this section used to make this determination.

(j) Instructions to access the service line inventory (including inventories consisting only of a statement in accordance with paragraph (1)(i) of this section) must be included in Consumer Confidence Report in accordance with R.61-58.12.C(4)(d)(xi).

(2) Lead Service Line Replacement Plan.

All water systems with one (1) or more lead, galvanized requiring replacement, or lead status unknown service lines in their distribution system must, by January 16, 2024, submit a lead service line replacement plan to the Department in accordance with R.61-58.11.L(5). The lead service line replacement plan must be sufficiently detailed to ensure a system is able to comply with the lead service line replacement requirements in accordance with this section. The plan must include a description of:

(a) ~~A water system shall replace annually at least seven (7) percent of the initial number of lead service lines in its distribution system. The initial number of lead service lines is the number of lead lines in place at the time the replacement program begins. The system shall identify the initial number of lead service lines in its distribution system, including an identification of the portions(s) owned by the system, based on a materials evaluation, including the evaluation required under Section H(1) below and relevant legal~~

~~authorities (e.g. contracts, local ordinances) regarding the portion owned by the system. The first year of lead service line replacement shall begin on the first day following the end of the monitoring period in which the action level was exceeded under paragraph (1) of this section. If monitoring is required annually or less frequently, the end of the monitoring period is September 30 of the calendar year in which the sampling occurs. If the Department has established an alternate monitoring period, then the end of the monitoring period will be the last day of that period.~~ A strategy for determining the composition of lead status unknown service lines in its inventory;

(b) ~~Any water system resuming a lead service line replacement program after the cessation of its lead service line replacement program as allowed by paragraph (6) of this section shall update its inventory of lead service lines to include those sites that were previously determined not to require replacement through the sampling provision under paragraph (3) of this section. The system will then divide the updated number of remaining lead service lines by the number of remaining years in the program to determine the number of lines that must be replaced per year (seven (7) percent lead service line replacement is based on a fifteen (15) year replacement program, so, for example, systems resuming lead service line replacement after previously conducting two years of replacement would divide the updated inventory by thirteen (13)). For those systems that have completed a fifteen (15) year lead service line replacement program, the Department will determine a schedule for replacing or retesting lines that were previously tested out under the replacement program when the system re exceeded the action level.~~ A procedure for conducting full lead service line replacement;

(c) A strategy for informing customers before a full or partial lead service line replacement;

(d) For systems that serve more than 10,000 persons, a lead service line replacement goal rate recommended by the system in the event of a lead trigger level exceedance;

(e) A procedure for customers to flush service lines and premise plumbing of particulate lead;

(f) A lead service line replacement prioritization strategy based on factors including, but not limited to, the targeting of known lead service lines, lead service line replacement for disadvantaged consumers and populations most sensitive to the effects of lead; and

(g) A funding strategy for conducting lead service line replacements which considers ways to accommodate customers that are unable to pay to replace the portion they own.

(3) ~~A system is not required to replace an individual lead service line if the lead concentration in all service line samples from that line, taken pursuant to Section H(2)(c), is less than or equal to 0.015 mg/L.~~ Operating Procedures for Replacing Lead Goosenecks, Pigtails, or Connectors.

(a) The water system must replace any lead gooseneck, pigtail, or connector it owns when encountered during planned or unplanned water system infrastructure work.

(b) The water system must offer to replace a customer-owned lead gooseneck, pigtail, or connector; however, the water system is not required to bear the cost of replacement of the customer-owned parts.

(c) The water system is not required to replace a customer-owned lead gooseneck, pigtail, or connector if the customer objects to its replacement.

(d) The replacement of a lead gooseneck, pigtail, or connector does not count for the purposes of meeting the requirements for goal-based or mandatory lead service line replacements, in accordance with paragraphs (6) and (7) of this section, respectively.

(e) Upon replacement of any gooseneck, pigtail, or connector that is attached to a lead service line, the water system must follow risk mitigation procedures specified in R.61-58.11.G(6)(b).

(f) The requirements of paragraphs (3)(a), (b), (c), and (e) of this section do not apply if state law includes lead connectors in the definition of lead service lines, prohibits partial lead service line replacements, and requires systems to remove all lead service lines irrespective of a system's 90th percentile lead level.

(4) ~~A water system shall replace that portion of the lead service line that it owns. In cases where the system does not own the entire lead service line, the system shall notify the owner of the line, or the owner's authorized agent, that the system will replace the portion of the service line that it owns and shall offer to replace the owner's portion of the line. A system is not required to bear the cost of replacing the privately-owned portion of the line, nor is it required to replace the privately-owned portion where the owner chooses not to pay the cost of replacing the privately-owned portion of the line, or where replacing the privately-owned portion would be precluded by State, local or common law. A water system that does not replace the entire length of the service line also shall complete the following tasks.~~ Requirements for Conducting Lead Service Line Replacement that may Result in Partial Replacement.

(a) ~~At least forty-five (45) days prior to commencing with the partial replacement of a lead service line, the water system shall provide notice to the resident(s) of all buildings served by the line explaining that they may experience a temporary increase of lead levels in their drinking water, along with guidance on measures consumers can take to minimize their exposure to lead. The Department may allow the water system to provide notice under the previous sentence less than forty-five (45) days prior to commencing partial lead service line replacement where such replacement is in conjunction with emergency repairs. In addition, the water system shall inform the resident(s) served by the line that the system will, at the system's expense, collect a sample from each partially-replaced lead service line that is representative of the water in the service line for analysis of lead content, as prescribed under Section H(2)(e) below, within seventy-two (72) hours after the completion of the partial replacement of the service line. The system shall collect the sample and report the results of the analysis to the owner and the resident(s) served by the line within three (3) business days of receiving the results. Mailed notices post-marked within three (3) business days of receiving the results shall be considered "on-time."~~ Any water system that plans to partially replace a lead service line (e.g., replace only the portion of a lead service line that it owns) in coordination with planned infrastructure work must provide notice to the owner of the affected service line, or the owner's authorized agent, as well as non-owner resident(s) served by the affected service line at least forty-five (45) days prior to the replacement. The notice must explain that the system will replace the portion of the line it owns and offer to replace the portion of the service line not owned by the water system. The water system is not required to bear the cost of replacement of the portion of the affected service line not owned by the water system.

(i) Before the affected service line is returned to service, the water system must provide notification meeting the content requirements of R.61-58.11.G(1) explaining that consumers may experience a temporary increase of lead levels in their drinking water due to the replacement, information about the health effects of lead, and actions consumers can take to minimize their exposure to lead in drinking water. In instances where multi-family dwellings are served by the affected service line to be partially replaced, the water system may elect to post the information at a conspicuous location instead of providing individual notification to all residents.

(ii) The water system must provide information about service line flushing in accordance with the procedure developed in paragraph (2)(e) of this section before the affected service line is returned to service.

(iii) The water system must provide the consumer with a pitcher filter or point-of-use device certified by an American National Standards Institute accredited certifier to reduce lead, six (6) months of replacement cartridges, and instructions for use before the affected service line is returned to service. If the affected service line serves more than one (1) residence or non-residential unit (e.g., a multi-unit building), the water system must provide a filter, six (6) months of replacement cartridges, and use instructions to every residence in the building.

(iv) The water system must offer to collect a follow-up tap sample between three (3) months and six (6) months after completion of any partial replacement of a lead service line. The water system must provide the results of the sample in accordance with R.61-58.11.G(4).

(b) ~~The water system shall provide the information required by paragraph (4)(a) of this section to the residents of individual dwellings by mail or by other methods approved by the Department. In instances where multi-family dwellings are served by the line, the water system shall have the option to post the information at a conspicuous location.~~ Any water system that replaces the portion of the lead service line it owns due to an emergency repair, must provide notice and risk mitigation measures to the persons served by the affected service line in accordance with paragraphs (4)(a)(i) through (iii) of this section before the affected service line is returned to service.

(c) When a water system is notified by the customer that the customer's portion of the lead service line will be replaced, the water system must make a good faith effort to coordinate simultaneous replacement of its portion of the service line. If simultaneous replacement cannot be conducted, the water system must replace its portion as soon as practicable but no later than forty-five (45) days from the date the customer replaces its portion of the lead service line. The water system must provide notification and risk mitigation measure in accordance with paragraphs (4)(a)(i) through (iii) of this section. If the water system fails to replace its portion of the lead service line within forty-five (45) days from the date the customer replaces the customer's portion of the lead service line, the water system must notify the Department within thirty (30) days of failing to meet the deadline in accordance with R.61-58.11.L(5) and complete the replacement no later than one hundred eighty (180) days of the date the customer replaces its portion.

(d) When a water system is notified or otherwise learns that replacement of a customer-owned lead service line has occurred within the previous six (6) months and left in place a system-owned lead service line, the water system must replace its portion within forty-five (45) days from the day of becoming aware of the customer replacement. The water system must provide notification and risk mitigation measures in accordance with paragraphs (4)(a)(i) through (iii) of this section within twenty-four (24) hours of becoming aware of the customer replacement. If the water system fails to replace its portion of the affected service line within forty-five (45) days of becoming aware of the customer replacement, it must notify the Department within thirty (30) days of failing to meet the deadline in accordance with R.61-58.11.L(5). The water system must complete the replacement no later than one hundred eighty (180) days after the date the customer replaces its portion.

(e) When a water system is notified or otherwise learns of a replacement of a customer-owned lead service line which has occurred more than six (6) months in the past, the water system is not required to complete the lead service line replacement of the system-owned portion under this paragraph (4)(e), however the system-owned portion must still be included in the calculation of a lead service line replacement rate under paragraph (1)(g) of this section.

(5) ~~The Department shall require a system to replace lead service lines on a shorter schedule than that required by this section, taking into account the number of lead service lines in the system, where such a shorter replacement schedule is feasible. The Department shall make this determination in writing and~~

~~notify the system of its finding within 6 months after the system is triggered into lead service line replacement based on monitoring referenced in paragraph (1) of this section.~~ Requirements for Conducting Full Lead Service Line Replacement.

Any water system that conducts a full lead service line replacement must provide notice to the owner of the affected service line, or the owner's authorized agent, as well as non-owner resident(s) served by the affected service line within twenty-four (24) hours of completion of the replacement. The water system is not required to bear the cost of replacement of the portion of the lead service line not owned by the water system.

(a) The notification must meet the content requirements of R.61-58.11.G(1) explaining that consumers may experience a temporary increase of lead levels in their drinking water due to the replacement, information about the health effects of lead, and actions consumers can take to minimize their exposure to lead in drinking water. In instances where multi-family dwellings are served by the lead service line to be replaced, the water system may elect to post the information at a conspicuous location instead of providing individual notification to all residents.

(b) The water system must provide information about service line flushing in accordance with the procedure developed under paragraph (2)(e) of this section before the replaced service line is returned to service.

(c) The water system must provide the consumer with a pitcher filter or point-of-use device certified by an American National Standards Institute accredited certifier to reduce lead, six (6) months of replacement cartridges, and instructions for use before the replaced service line is returned to service. If the lead service line serves more than one (1) residence or non-residential unit (e.g., a multi-unit building), the water system must provide a filter, six (6) months of replacement cartridges, and use instructions to every residence in the building.

(d) The water system must offer to the consumer to take a follow-up tap sample between three (3) months and six (6) months after completion of any full replacement of a lead service line. The water system must provide the results of the sample to the consumer in accordance with paragraph (4) of this section.

(6) ~~Any system may cease replacing lead service lines whenever first draw samples collected pursuant to Section H(2)(b) below, meet the lead action level during each of two consecutive monitoring periods and the system submits the results to the Department. If the first draw tap samples collected in any such system thereafter exceeds the lead action level, the system shall recommence replacing lead service lines pursuant to paragraph (2) of this section.~~ Goal-based Full Lead Service Line Replacement for Water Systems Whose 90th Percentile Lead Level is Above the Trigger Level but at or Below the Lead Action Level.

Water systems that serve more than 10,000 persons whose 90th percentile lead level from tap samples taken pursuant to R.61-58.11.H is above the lead trigger level but at or below the lead action level must conduct goal-based full lead service line replacement at a rate approved by the Department.

(a) The water system must calculate the number of full lead service line replacements it must conduct annually in accordance with paragraph (1)(g) of this section.

(b) Replacement of lead service lines must be conducted in accordance with the requirements of paragraph (4) or (5) of this section.

(c) Only full lead service line replacements count towards a water system's annual replacement goal. Partial lead service line replacements do not count towards the goal.

(d) The water system must provide information to customers with lead, galvanized requiring replacement, or lead status unknown service lines as required in R.61-58.11.G(7).

(e) Any water system that fails to meet its lead service line replacement goal must:

(i) Conduct public outreach activities pursuant to R.61-58.11.G(8) until either the water system meets its replacement goal, or tap sampling shows the 90th percentile of lead is at or below the trigger level for two (2) consecutive one (1)-year monitoring periods.

(ii) Recommence its goal-based lead service line replacement program pursuant to this paragraph (6)(e)(ii) if the 90th percentile lead level anytime thereafter exceeds the lead trigger level but is at or below the lead action level.

(f) The first year of lead service line replacement shall begin on the first day following the end of the tap sampling period in which the lead trigger level was exceeded. If sampling is required annually or less frequently, the end of the tap sampling monitoring period is September 30 of the calendar year in which the sampling occurs. If the Department has established an alternate monitoring period, then the end of the monitoring period will be the last day of that period.

(7) ~~To demonstrate compliance with paragraphs (1) through (4) of this section, a system shall report to the Department the information specified in Section L(5) below.~~ Mandatory Full Lead Service Line Replacement for Water Systems Whose 90th Percentile Lead Level Exceeds the Lead Action Level.

Water systems serving more than 10,000 persons that exceed the lead action level in tap samples taken pursuant to R.61-58.11.H must conduct mandatory full lead service line replacement at an average annual rate of at least three percent (3%), calculated on a two (2)-year rolling basis.

(a) The average annual number of full lead service line replacements must be calculated in accordance with paragraph (1)(g) of this section.

(b) Lead service line replacement must be conducted in accordance with the requirements of paragraphs (4) and (5) of this section.

(c) Only full lead service line replacement count towards a water system's mandatory replacement rate of at least three percent (3%) annually. Partial lead service line replacements do not count towards the mandatory replacement rate.

(d) Water systems must provide information to customers with lead, galvanized requiring replacement, or lead status unknown service lines consistent with R.61-58.11.G(7).

(e) Community water systems serving 10,000 or fewer persons and non-transient, non-community water systems for which the Department has approved or designated lead service line replacement as a compliance option must conduct lead service line replacement as described in R.61-58.11.O(1)(a). Replacement of lead service lines must be conducted in accordance with the requirements of paragraphs (4) and (5) of this section.

(f) A water system may cease mandatory lead service line replacement when it has conducted a cumulative percentage of replacements greater than or equal to three percent (3%), or other percentage specified in paragraph (7)(i) of this section, of the service lines specified in paragraph (1)(g) of this section multiplied by the number of years that elapsed from when the system most recently began mandatory lead

service line replacement and the date on which the system's 90th percentile lead level, in accordance with R.61-58.11.B(3)(d), has been calculated to be at or below the lead action level during each of four (4) consecutive six (6)-month tap sampling monitoring periods. If tap samples collected in any such system thereafter exceed the lead action level, the system shall recommence mandatory lead service line replacement at the same two (2)-year rolling average rate, unless the Department has designated an alternate replacement rate under paragraph (7)(i) of this section.

(g) The water system may also cease mandatory lead service line replacement if the system has no remaining lead status unknown service lines in its inventory and obtains refusals to conduct full lead service line replacement or non-responses from every remaining customer in its distribution system served by either a full or partial lead service line, or a galvanized requiring replacement service line. For purposes of this paragraph (7)(g) and in accordance with R.61-58.11.L(5), a water system must provide documentation to the Department of customer refusals including a refusal signed by the customer, documentation of a verbal statement made by the customer refusing replacement, or documentation of no response from the customer after the water system made a minimum of two (2) good faith attempts to reach the customer regarding full lead service line replacement. If the water system's 90th percentile exceeds the lead action level again, it must contact all customers served by a full or partial lead service line or a galvanized requiring replacement service line with an offer to replace the customer-owned portion. Nothing in this paragraph (7)(g) requires the water system to bear the cost of replacement of the customer-owned lead service line.

(h) The first year of lead service line replacement shall begin on the first day following the end of the tap sampling period in which lead action level was exceeded.

(i) The Department shall require a system to replace lead service lines on a shorter schedule than that required by this section, taking into account the number of lead service lines in the system, where the Department determines a shorter replacement schedule is feasible. The Department shall make this determination in writing and notify the system of its finding within six (6) months after the system is required to begin lead service line replacement under paragraph (7) of this section.

(8) Reporting to Demonstrate Compliance to Department.

To demonstrate compliance with paragraphs (1) through (7) of this section, a system shall report to the Department the information specified in R.61-58.11.L(5).

G. Public Education and Supplemental Monitoring and Mitigation Requirements.

All water systems must deliver a consumer notice of lead tap water monitoring results to persons served by the water system at sites that are ~~tested~~ sampled, as specified in paragraph (4) of this section. ~~A water system that exceeds the lead action level based on tap water samples collected in accordance with Section H shall deliver the public education materials contained in paragraph (1) this section in accordance with the requirements in paragraph (2) of this section. Water systems that exceed the lead action level must sample the tap water of any customer who requests it in accordance with paragraph (3) of this section.~~ A water system with lead, galvanized requiring replacement, or lead status unknown service lines must deliver public education materials to persons with a lead, galvanized requiring replacement, or lead status unknown service line as specified in paragraphs (5) through (7) of this section. All community water systems must conduct annual outreach to local and state health agencies as outlined in paragraph (9) of this section. A community water system serving more than 10,000 persons that fails to meet its annual lead service line replacement goal as required under R.61-58.11.F(6) shall conduct outreach activities as specified in paragraph (8) of this section. A water system that exceeds the lead action level based on tap water samples collected in accordance with R.61-58.11.H shall deliver the public education materials contained in paragraph (1) of this section and in accordance with the requirements in paragraph (2) of this section. Water

systems that exceed the lead action level shall offer to sample the tap water of any customer who requests it in accordance with paragraph (3) of this section. All small community water systems and non-transient, non-community water systems that elect to implement point-of-use (POU) devices under R.61-58.11.O must provide public education materials to inform users how to properly use POU devices in accordance with paragraph (10) of this section.

(1) Content ~~of written public education materials~~of Written Public Education Materials.

(a) Community water systems and ~~N~~non-transient, non-community water systems. Water systems must include the following elements in printed material (e.g., brochures and pamphlets) in the same order as listed ~~below~~ in paragraphs (1)(a)(i) through (vii) of this section. In addition, language in paragraphs (1)(a)(i), ~~through~~ (ii), and ~~(1)(a)~~(vi) of this section must be included in the materials, exactly as written, except for the text in brackets in ~~these~~ paragraphs (1)(a)(i), (ii), and (vi) of this section for which the water system must include system-specific information. Any additional information presented by a water system must be consistent with the information ~~below~~ in paragraphs (1)(a)(i) through (vii) of this section and be in plain language that can be understood by the general public. Water systems must submit all written public education materials to the Department prior to delivery. The Department may require the system to obtain approval of the content of written public materials prior to delivery. Water systems may change the mandatory language in paragraphs (1)(a)(i) and (ii) of this section only with Department approval.

(i) IMPORTANT INFORMATION ABOUT LEAD IN YOUR DRINKING WATER. [INSERT NAME OF WATER SYSTEM] found elevated levels of lead in drinking water in some homes/buildings. Lead can cause serious health problems, especially for pregnant women and young children. Please read this information closely to see what you can do to reduce lead in your drinking water.

(ii) Health effects of lead. ~~Lead can cause serious health problems if too much enters your body from drinking water or other sources. It can cause damage to the brain and kidneys, and can interfere with the production of red blood cells that carry oxygen to all parts of your body. The greatest risk of lead exposure is to infants, young children, and pregnant women. Scientists have linked the effects of lead on the brain with lowered IQ in children. Adults with kidney problems and high blood pressure can be affected by low levels of lead more than healthy adults. Lead is stored in the bones, and it can be released later in life. During pregnancy, the child receives lead from the mother's bones, which may affect brain development.~~ Exposure to lead in drinking water can cause serious health effects in all age groups. Infants and children can have decreases in IQ and attention span. Lead exposure can lead to new learning and behavior problems or exacerbate existing learning and behavior problems. The children of women who are exposed to lead before or during pregnancy can have increased risk of these adverse health effects. Adults can have increased risks of heart disease, high blood pressure, kidney, or nervous system problems.

(iii) Sources of Lead.

(A) Explain what lead is.

(B) Explain possible sources of lead in drinking water and how lead enters drinking water. Include information on homes/building plumbing materials and service lines that may contain lead.

(C) Discuss other important sources of lead exposure in addition to drinking water (e.g., paint).

(iv) Discuss the steps the consumer can take to reduce their exposure to lead in drinking water.

(A) Encourage running the water to flush out the lead.

(B) Explain concerns with using hot water from the tap and specifically caution against the use of hot water for preparing baby formula.

(C) Explain that boiling water does not reduce lead levels.

(D) Discuss other options consumers can take to reduce exposure to lead in drinking water, such as alternative sources or treatment of water.

(E) Suggest that parents have their child's blood tested for lead.

(v) Explain why there are elevated levels of lead in the system's drinking water (if known) and what the water system is doing to reduce the lead levels in homes/buildings in this area..

(vi) For more information, call us at [INSERT YOUR NUMBER] [(IF APPLICABLE), or visit our Web site at [INSERT YOUR WEB SITE HERE]]. For more information on reducing lead exposure around your home/building and the health effects of lead, visit EPA's website at http://www.epa.gov/lead or contact your health care provider.

(vii) Information on lead service lines. For systems with lead service lines, discuss opportunities to replace lead service lines and explain how to access the service line inventory so the consumer can find out if they have a lead service line. Include information on programs that provide financing solutions to assist property owners with replacement of their portion of a lead service line, and a statement that the water system is required to replace its portion of a lead service line when the property owner notifies them they are replacing their portion of the lead service line.

(b) Community water systems. In addition to including the elements specified in paragraph (1)(a) of this section, community water systems must:

(i) Tell consumers how to get their water tested.

(ii) Discuss lead in plumbing components and the difference between low lead and lead free.

(2) Delivery of public education materials:

(a) For public water systems serving a large proportion of non-English speaking consumers, as determined by the Department, the public education material must contain information in the appropriate language(s) regarding the importance of the notice or contain a telephone number or address where persons served may contact the water system to obtain a translated copy of the public education materials or to request assistance in the appropriate language.

(b) A community water system that exceeds the lead action level on the basis of tap water samples collected in accordance with ~~Section H~~ R.61-58.11.H and that is not already conducting public education tasks under this section, must conduct the public education tasks under this section within 60 days after the end of the ~~monitoring~~ tap sampling period in which the exceedance occurred:

(i) Deliver printed materials meeting the content requirements of paragraph (1) of this section to all bill paying customers.

(ii) (A) Contact customers who are most at risk by delivering education materials that meet the content requirements of paragraph (1) of this section to local public health agencies even if they are not located within the water system's service area, along with an informational notice that encourages

distribution to all the organization's potentially affected customers or community water system's users. The water system must contact the local public health agencies directly by phone or in person. The local public health agencies may provide a specific list of additional community based organizations serving target populations, which may include organizations outside the service area of the water system. If such lists are provided, systems must deliver education materials that meet the content requirements of paragraph (1) of this section to all organizations on the provided lists.

(B) Contact customers who are most at risk by delivering materials that meet the content requirements of paragraph (1) of this section to the following organizations listed in (2)(b)(ii)(B)(1) through ~~(6) below~~ (7) of this section that are located within the water system's service area, along with an information notice that encourages distribution to all the organization's potentially affected customers or community water system's users:

(1) ~~Public and private schools or school boards.~~Schools, child care facilities, and school boards.

(2) Women, Infants and Children (WIC) and Head Start Programs.

(3) Public and private hospitals and medical clinics.

(4) Pediatricians.

(5) Family planning clinics.

(6) Local welfare agencies.

(7) Obstetricians-Gynecologists and Midwives.

(C) Make a good faith effort to locate the following organizations within the service area and deliver materials that meet the content requirements of paragraph (1) of this section to them, along with an informational notice that encourages distribution to all potentially affected customers or users. The good faith effort to contact at risk customers may include requesting a specific contact list of these organizations from the local public health agencies, even if the agencies are not located within the water system's service area:

(1) Licensed childcare centers.

(2) Public and private preschools.

(3) Obstetricians Gynecologist and Midwives.

(iii) No less often than quarterly, provide information on or in each water bill as long as the system exceeds the action level for lead. The message on the water bill must include the following statement exactly as written except for the text in brackets for which the water system must include system-specific information: [INSERT NAME OF WATER SYSTEM] found high levels of lead in drinking water in some homes. Lead can cause serious health problems. For more information please call [INSERT NAME OF WATER SYSTEM] [or visit (INSERT YOUR WEB SITE HERE)]. The message or delivery mechanism can be modified in consultation with the Department; specifically, the Department may allow a separate mailing of public education materials to customers if the water system cannot place the information on water bills.

(iv) Post materials meeting the content requirements of paragraph (1) of this section on the water system's Web site if the system serves a population of greater than 100,000.

(v) Submit a press release to newspaper, television and radio stations.

(vi) In addition to paragraph 2(b)(i) through (v) of this section, systems must implement at least three activities from one or more categories listed below. The educational content and selection of these activities must be determined in consultation with the Department.

(A) Public Service Announcements.

(B) Paid advertisements.

(C) Public Area Information Displays.

(D) E mails to customers.

(E) Public Meetings.

(F) Household Deliveries.

(G) Targeted Individual Customer Contact.

(H) Direct material distribution to all multi family homes and institutions.

(I) Other methods approved by the Department.

(vii) For systems that are required to conduct monitoring annually or less frequently, the end of the ~~monitoring~~tap sampling period is September 30 of the calendar year in which the sampling occurs, or, if the Department has established an alternate ~~monitoring~~tap sampling period, the last day of that period.

(c) As long as a community water system exceeds the action level, it must repeat the activities pursuant to paragraph (2)(b) of this section as described in paragraphs (2)(c)(i) through (iv) of this section.

(i) A community water system shall repeat the tasks contained in paragraphs (2)(b)(i), (ii) and (vi) of this section every 12 months.

(ii) A community water system shall repeat the tasks contained in paragraph (2)(b)(iii) of this section with each billing cycle.

(iii) A community water system serving a population greater than 100,000 shall post and retain material on a publicly accessible Web site pursuant to paragraph (2)(b)(iv) of this section.

(iv) The community water system shall repeat the task in paragraph (2)(b)(v) of this section twice every twelve (12) months on a schedule agreed upon with the Department. The Department can allow activities in paragraph (2)(b) of this section to extend beyond the sixty (60) day requirement if needed for implementation purposes on a case by case basis; however, this extension must be approved in writing by the Department in advance of the sixty (60) day deadline.

(d) Within sixty (60) days after the end of the ~~monitoring~~ tap sampling period in which the exceedance occurred (unless it already is repeating public education tasks pursuant to paragraph (2)(e) of

this section), a non-transient non-community water system shall deliver the public education materials specified in paragraph ~~(a)~~ (1) of this section as follows:

(i) Post informational posters on lead in drinking water in a public place or common area in each of the buildings served by the system; and:

(ii) Distribute informational pamphlets and/or brochures on lead in drinking water to each person served by the non-transient non-community water system. The Department may allow the system to utilize electronic transmission in lieu of or combined with printed materials as long as it achieves at least the same coverage.

(iii) For systems that are required to conduct monitoring annually or less frequently, the end of the ~~monitoring~~ tap sampling period is September 30 of the calendar year in which the sampling occurs, or, if the Department has established an alternate ~~monitoring~~ tap sampling period, the last day of that period.

(e) A non-transient non-community water system shall repeat the tasks contained in paragraph (2)(d) of this section at least once during each calendar year in which the system exceeds the lead action level. The Department can allow activities in (2)(d) of this section to extend beyond the sixty (60) day requirement if needed for implementation purposes on a case-by-case basis; however, this extension must be approved in writing by the Department in advance of the sixty (60) day deadline.

(f) A water system may discontinue delivery of public education materials if the system ~~has met~~ is at or below the lead action level during the most recent six-month monitoring period conducted pursuant to ~~Section H~~R.61-58.11.H. Such a system shall recommence public education in accordance with this section if it subsequently exceeds the lead action level during any ~~monitoring~~ tap sampling period.

(g) A community water system may apply to the Department, in writing (unless the Department has waived the requirement for prior Department approval), to use only the text specified in paragraph (1)(a) of this section in lieu of the text in paragraphs (1)(a) and (1)(b) of this section and to perform the tasks listed in paragraphs (2)(d) and (2)(e) of this section in lieu of the tasks in paragraphs (2)(b) and (2)(c) of this section if:

(i) The system is a facility, such as a prison or a hospital, where the population served is not capable of or is prevented from making improvements to plumbing or installing point of use treatment devices; and

(ii) The system provides water as part of the cost of services provided and does not separately charge for water consumption.

(h) A community water system serving 3,300 or fewer people may limit certain aspects of their public education programs as follows:

(i) With respect to the requirements of paragraph (2)(b)(vi) of this section, a system serving 3,300 or fewer people must implement at least one of the activities listed in that paragraph.

(ii) With respect to the requirements of paragraph (2)(b)(ii) of this section, a system serving 3,300 or fewer people may limit the distribution of the public education materials required under that paragraph to facilities and organizations served by the system that are most likely to be visited regularly by pregnant women and children.

(iii) With respect to the requirements of paragraph (2)(b)(v) of this section, the Department may waive this requirement for systems serving 3,300 or fewer persons as long as the system distributes notices to every household served by the system.

(3) Supplemental monitoring and notification of results.

A water system that fails to meet the lead action level on the basis of tap samples collected in accordance with ~~Section H~~R.61-58.11.H shall offer to sample the tap water of any customer who requests it. The system is not required to pay for collecting or analyzing the sample, nor is the system required to collect and analyze the sample itself.

(4) Notification of results.

(a) Reporting requirements. All water systems must provide a notice of the individual tap results from lead tap water monitoring carried out under the requirements of ~~Section H~~ R.61-58.11.H to the persons served by the water system at the specific sampling site from which the sample was taken (e.g., the occupants of the ~~residence~~ building where the tap was ~~tested~~ sampled).

(b) Timing of notification. A water system must provide the consumer notice as soon as practical, but no later than ~~thirty (30) days after the system learns of the tap monitoring results~~ the following timeframes.

(i) For individual samples that do not exceed fifteen micrograms per liter (15 µg/L) of lead, no later than thirty (30) days after the water system learns of the tap monitoring results.

(ii) For individual samples that exceed fifteen micrograms per liter (15 µg/L) of lead, as soon as practicable but no later than three (3) calendar days after the water system learns of the tap monitoring results. Water systems that choose to mail the notification must assure those letters are postmarked within three (3) days.

(c) Content. The consumer notice must include the results of lead tap water monitoring for the tap that was tested, an explanation of the health effects of lead, list steps consumers can take to reduce exposure to lead in drinking water and contact information for the water utility. The notice must also provide the maximum contaminant level goal and the action level for lead and the definitions for these two terms from R.61-58.12.C(3).

(d) Delivery. ~~The consumer notice must be provided to persons served at the tap that was tested, either by mail or by another method approved by the Department. For example, upon approval by the Department, a non-transient non-community water system could post the results on a bulletin board in the facility to allow users to review the information. The system must provide the notice to customers at sample taps tested, including consumers who do not receive water bills.~~

(i) For lead tap sample results that do not exceed fifteen micrograms per liter (15 µg/L), the water systems must provide consumer notice to persons served at the tap that was sampled, by mail or by another method approved by the Department. For example, upon approval by the Department, a non-transient, non-community water system could post the results on a bulletin board in the facility to allow users to review the information.

(ii) For lead tap sample results that exceed fifteen micrograms per liter (15 µg/L), the water systems must provide consumer notice to persons served by the tap that was sampled; such notice must be provided electronically or by phone, hand delivery, by mail, or another method approved by the Department.

(5) Notification of Known or Potential Service Line Containing Lead

(a) Notification requirements. All water systems with lead, galvanized requiring replacement, or lead status unknown service lines in their inventory pursuant to R.61-58.11.F(1) must inform all persons served by the water system at the service connection with a lead, galvanized requiring replacement, or lead status unknown service line.

(b) Timing of notification. A water system must provide the initial notification within thirty (30) days of completion of the lead service line inventory required under R.61-58.11.F and repeat the notification on an annual basis until the entire service connection is no longer a lead, galvanized requiring replacement, or lead status unknown service line. For new customers, water systems shall also provide the notice at the time of service initiation.

(c) Content

(i) Persons served by a confirmed lead service line. The notice must include a statement that the person's service line is lead, an explanation of the health effects of lead that meets the requirements of paragraph (1)(a)(ii) of this section, steps persons at the service connection can take to reduce exposure to lead in drinking water, information about opportunities to replace lead service lines as well as programs that provide financing solutions to assist property owners with replacement of their portion of a lead service line, and a statement that the water system is required to replace its portion of a lead service line when the property owner notifies them they are replacing their portion of the lead service line.

(ii) Persons served by a galvanized requiring replacement service line. The notice must include a statement that the person's service line is galvanized requiring replacement, an explanation of the health effects of lead, steps persons at the service connection can take to reduce exposure to lead in drinking water, and information about opportunities for replacement of the service line.

(iii) Persons served by a lead status unknown service line. The notice must include a statement that the person's service line material is unknown but may be lead, an explanation of the health effects of lead that meets the requirements of paragraph (1)(a)(ii) of this section, steps persons at the service connection can take to reduce exposure to lead in drinking water, and information about opportunities to verify the material of the service line.

(d) Delivery. The notice must be provided to persons served by the water system at the service connection with a lead, galvanized requiring replacement, or lead status unknown service line, by mail or by another method approved by the Department.

(6) Notification Due to a Disturbance to a Known or Potential Service Line Containing Lead

(a) Water systems that cause disturbance to a lead, galvanized requiring replacement, or lead status unknown service line that results in the water to an individual service line being shut off or bypassed, such as operating a valve on a service line or meter setter, and without conducting a partial or full lead service line replacement, must provide the persons served by the water system at the service connection with information about the potential for elevated lead levels in drinking water as a result of the disturbance as well as instructions for a flushing procedure to remove particulate lead. The water system must comply with the requirements in this paragraph (6)(a) before the affected service line is returned to service.

(b) If the disturbance of a lead, galvanized requiring replacement, or lead status unknown service line results from the replacement of an inline water meter, a water meter setter, or gooseneck, pigtail, or

connector, the water system must provide the person served by the water system at the service connection with information about the potential for elevated lead levels in drinking water as a result of the disturbance, public education materials that meet the content requirements in paragraph (1) of this section, a pitcher filter or point-of-use device certified by an American National Standards Institute accredited certifier to reduce lead, instructions to use the filter, and six (6) months of filter replacement cartridges. The water system must comply with the requirements of this paragraph (6)(b) before the affected service line is returned to service.

(c) A water system that conducts a partial or full lead service line replacement must follow procedures in accordance with the requirements in R.61-58.11.F(4)(a)(i) through (iv) and (5)(a)(i) through (iv), respectively.

(7) Information for Persons Served by Known or Potential Service Lines Containing Lead When a System Exceeds the Lead Trigger Level

(a) Content. All water systems with lead service lines that exceed the lead trigger level of ten micrograms per liter (10 µg/L) must provide persons served by the water system at the service connection with a lead, galvanized requiring replacement, or lead status unknown service line information regarding the water system's lead service line replacement program and opportunities for replacement of the lead service line.

(b) Timing. Waters systems must send notification within thirty (30) days of the end of the tap sampling period in which the trigger level exceedance occurred. Water systems must repeat the notification annually until the results of sampling conducted under R.61-58.11.H are at or below the lead trigger level.

(c) Delivery. The notice must be provided to persons served at the service connection with a lead, galvanized requiring replacement, or lead status unknown service line, by mail or by another method approved by the Department.

(8) Outreach Activities for Failure to Meet the Lead Service Line Replacement Goal

(a) In the first year after a community water system that serves more than 10,000 persons does not meet its annual lead service line replacement goal as required under R.61-58.11.F(6), it must conduct one (1) outreach activity from the following list in the following year until the water system meets its replacement goal or until tap sampling shows that the 90th percentile for lead is at or below the trigger level of ten micrograms per liter (10 µg/L) for two (2) consecutive tap sampling monitoring periods:

(i) Send certified mail to customers with a lead or galvanized requiring replacement service line to inform them about the water system's goal-based lead service line replacement program and opportunities for replacement of the service line.

(ii) Conduct a townhall meeting.

(iii) Participate in a community event to provide information about its lead service line replacement program and distribute public education materials that meet the content requirements in paragraph (1) of this section.

(iv) Contact customers by phone, text message, email, or door hanger.

(v) Use another method approved by the Department to discuss the lead service line replacement program and opportunities for lead service line replacement.

(b) After the first year following a trigger level exceedance, any water system that thereafter continues to fail to meet its lead service line replacement goal must conduct one (1) activity from paragraph (8)(a) of this section and two (2) additional outreach activities per year from the following list:

(i) Conduct social media campaign.

(ii) Conduct outreach via newspaper, television, or radio.

(iii) Contact organizations representing plumbers and contractors by mail to provide information about lead in drinking water including health effects, sources of lead, and the importance of using leadfree plumbing materials.

(iv) Visit targeted customers to discuss the lead service line replacement program and opportunities for replacement.

(c) The water system may cease outreach activities when tap sampling shows that the 90^{th} percentile for lead is at or below the trigger level of ten micrograms per liter (10 µg/L) for two (2) consecutive tap sampling monitoring periods or when all customer-side lead or galvanized requiring replacement service line owners refuse to participate in the lead service line replacement program. For purposes of this paragraph (8)(c), a refusal includes a signed statement by the customer refusing lead service line replacement, or documentation by the water system of a verbal refusal or of no response after two (2) good faith attempts to reach the customer.

(9) Public Education to Local and State Health Agencies

(a) Find-and-fix results. All community water systems must provide information to local and state health agencies about find-and-fix activities conducted in accordance with R.61-58.11.D(10), including the location of the tap sample site that exceeded fifteen micrograms per liter (15 µg/L), the result of the initial tap sample, the result of the follow-up tap sample, the result of water quality parameter monitoring, and any distribution system management actions or corrosion control treatment adjustments made.

(b) Timing and content. Community water systems must annually send copies of the public education materials provided under paragraph (1) of this section, and of paragraph (8)(a) of this section for actions conducted in the previous calendar year no later than July 1 of the following year.

(c) Delivery. Community water systems shall send public education materials and find-and-fix information to local and state health agencies by mail or by another method approved by the Department.

(10) Public Education Requirements for Small Water System Compliance Flexibility POU Devices

(a) Content. All small community water systems and non-transient non-community water systems that elect to implement POU devices under R.61-58.11.O must provide public education materials to inform users how to properly use POU devices to maximize the units' effectiveness in reducing lead levels in drinking water.

(b) Timing. Water systems shall provide the public education materials at the time of POU device delivery.

(c) Delivery. Water systems shall provide the public education materials in person, by mail, or by another method approved by the Department, to persons at locations where the system has delivered POU devices.

H. Monitoring Requirements for Lead and Copper in Tap Water.

(1) Sample Site Location

(a) By the applicable date for commencement of monitoring under paragraph (4)(a) of this section, each water system shall ~~complete a materials evaluation of its distribution system in order to~~ identify a pool of targeted sampling sites based on the service line inventory conducted in accordance with R.61-58.11.F(1), that ~~meets~~ meet the requirements of this section, and which is sufficiently large enough to ensure that the water system can collect the number of lead and copper tap samples required in paragraph (3) of this section. ~~All sites from which first draw samples are collected shall be selected from this pool of targeted sampling sites.~~ Sampling sites may not include ~~faucets that have point-of-use or point-of-entry treatment devices designed to remove inorganic contaminants.~~ sites with installed point-of-entry (POE) treatment devices and taps used at sampling sites may not have point-of-use (POU) devices designed to remove inorganic contaminants, except for water systems monitoring under R.61-58.11.O(1)(c)(iv) and water systems using these devices for the primary drinking water tap to meet other primary and secondary drinking water standards and all service connections have POEs or POUs to provide localized treatment for compliance with the other drinking water standards. Lead and copper sampling results for systems monitoring under R.61-58.11.O(1)(c)(iv) may not be used for the purposes of meeting the criteria for reduced monitoring specified in paragraph (4)(d) of this section.

(b) A water system ~~shall~~ must use the information on lead, copper, and galvanized iron or steel that it is required ~~to collect under~~ to be identified under R.61-58.5.V~~, Special Corrosivity Characteristics, of this part [special monitoring for corrosivity characteristics]~~ when conducting a materials evaluation and the information on lead service lines that is required to be collected under R.61-58.11.F(1) to identify potential lead service line sampling sites. ~~When an evaluation of the information collected pursuant to R.61-58.5.V, Special Monitoring for Corrosivity Characteristics, is insufficient to locate the requisite number of lead and copper sampling sites that meet the targeting criteria in paragraph (1) of this section, the water system shall review the sources of information listed below in order to identify a sufficient number of sampling sites. In addition, the system shall seek to collect such information where possible in the course of its normal operations (e.g., checking service line materials when reading water meters or performing maintenance activities):~~

~~(i) All plumbing codes, permits, and records in the files of the building department(s) which indicate the plumbing materials that are installed within publicly and privately owned structures connected to the distribution system;~~

~~(ii) All inspections and records of the distribution system that indicate the material composition of the service connections that connect a structure to the distribution system; and~~

~~(iii) All existing water quality information, which includes the results of all prior analyses of the system or individual structures connected to the system, indicating locations that may be particularly susceptible to high lead or copper concentrations.~~

(c) The sampling sites selected for a community water system's sampling pool ~~("Tier 1 sampling sites") shall consist of single family structures that:~~ must consist of single-family structures that are served by a lead service line (‘‘Tier 1 sampling sites’’). When multiple-family residences comprise at least twenty percent (20%) of the structures served by the water system, the system may include these types of structures

in its Tier 1 sampling pool, if served by a lead service line. Sites with lead status unknown service lines must not be used as Tier 1 sampling sites.

~~(i) Contain copper pipes with lead solder installed after 1982 or contain lead pipes; and/or,~~

~~(ii) Are served by a lead service line. When multiple-family residences comprise at least twenty (20) percent of the structures served by a water system, the system may include these types of structures in its sampling pool.~~

(d) ~~Any community water system with insufficient Tier 1 sampling sites shall complete its sampling pool with "Tier 2 sampling sites", consisting of buildings, including multiple-family residences that:~~ A community water system with insufficient Tier 1 sampling sites must complete its sampling pool with ‘‘Tier 2 sampling sites,’’ consisting of buildings, including multiple-family residences that are served by a lead service line. Sites with lead status unknown service lines must not be used as Tier 2 sampling sites.

~~(i) Contain copper pipes with lead solder installed after 1982 or contain lead pipes; and/or,~~

~~(ii) Are served by a lead service line.~~

(e) ~~Any community water system with insufficient Tier 1 and Tier 2 sampling sites shall complete its sampling pool with "tier 3 sampling sites," consisting of single family structures that contain copper pipes with lead solder installed before 1983. A community water system with insufficient Tier 1, Tier 2, and Tier 3 sampling sites shall complete its sampling pool with representative sites throughout the distribution system. For the purpose of this paragraph, a representative site is a site in which the plumbing materials used at that site would be commonly found at other sites served by the water system.~~ A community water system with insufficient Tier 1 and Tier 2 sampling sites must complete its sampling pool with ‘‘Tier 3 sampling sites,’’ consisting of single-family structures that contain galvanized lines identified as being downstream of a lead service line (LSL) currently or in the past, or known to be downstream of a lead gooseneck, pigtail, or connector. Sites with lead status unknown service lines must not be used as Tier 3 sampling sites.

(f) ~~The sampling sites selected for a non-transient non-community water system ("Tier 1 sampling sites") shall consist of buildings that:~~ A community water system with insufficient Tier 1, Tier 2, and Tier 3 sampling sites must complete its sampling pool with ‘‘Tier 4 sampling sites,’’ consisting of single-family structures that contain copper pipes with lead solder installed before the effective date of the state’s applicable lead ban. Sites with lead status unknown service lines must not be used as Tier 4 sampling sites.

~~(i) Contain copper pipes with lead solder installed after 1982 or contain lead pipes; and/or,~~

~~(ii) Are served by a lead service line.~~

(g) ~~A non-transient non-community water system with insufficient tier 1 sites that meet the targeting criteria in paragraph (1)(f) of this section shall complete its sampling pool with sampling sites that contain copper pipes with lead solder installed before 1983. If additional sites are needed to complete the sampling pool, the non-transient non- community water system shall use representative sites throughout the distribution system. For the purpose of this paragraph, a representative site is a site in which the plumbing materials used at that site would be commonly found at other sites served by the water system.~~ A community water system with insufficient Tier 1, Tier 2, Tier 3, and Tier 4 sampling sites must complete its sampling pool with ‘‘Tier 5 sampling sites,’’ consisting of single-family structures or buildings, including multiple family residences that are representative of sites throughout the distribution system. For the purpose of this paragraph (1)(g), a representative site is a site in which the plumbing materials used at that site would be

commonly found at other sites served by the water system. Water systems may use non-residential buildings that are representative of sites throughout the distribution system if and only if there are an insufficient number of single-family or multiple family residential Tier 5 sites available.

(h) ~~Any water system whose distribution system contains lead service lines shall draw 50 percent of the samples it collects during each monitoring period from sites that contain lead pipes, or copper pipes with lead solder, and 50 percent of the samples from sites served by a lead service line. A water system that cannot identify a sufficient number of sampling sites served by a lead service line shall collect first-draw samples from all of the sites identified as being served by such lines.~~ The sampling sites selected for a non-transient, non-community water system must consist of sites that are served by a lead service line (''Tier 1 sampling sites''). Sites with lead status unknown service lines must not be used as Tier 1 sampling sites.

(i) A non-transient, non-community water system with insufficient Tier 1 sites complete its sampling pool with ''Tier 3 sampling sites,'' consisting of sampling sites that contain galvanized lines identified as being downstream of an LSL currently or in the past, or known to be downstream of a lead gooseneck, pigtail, or connector. Sites with lead status unknown service lines must not be used as Tier 3 sampling sites.

(j) A non-transient, non-community water system with insufficient Tier 1 and Tier 3 sampling sites must complete its sampling pool with ''Tier 5 sampling sites,'' consisting of sampling sites that are representative of sites throughout the distribution system. For the purpose of this paragraph (1)(j), a representative site is a site in which the plumbing materials used at that site would be commonly found at other sites served by the water system.

(k) A water system whose distribution system contains lead service lines must collect all samples for monitoring under this section from sites served by a lead service line. A water system that cannot identify a sufficient number of sampling sites served by lead service lines must still collect samples from every site served by a lead service line, and collect the remaining samples in accordance with tiering requirements under paragraphs (1)(e) through (g) or paragraphs (1)(i) through (j) of this section.

(2) Sample Collection Methods

(a) All tap samples for lead and copper collected in accordance with this section, with the exception of ~~lead service line samples collected under Section F(3) above, and samples collected under paragraph (2)(e) of this section,~~ ~~shall~~ fifth liter samples collected under paragraph (2)(c) of this section, and samples collected under paragraphs (2)(e) and (8) of this section, must be first-draw samples. The first-draw sample shall be analyzed for lead and copper in tap sampling periods where both contaminants are required to be monitored. In tap sampling periods where only lead is required to be monitored, the first-draw sample may be analyzed for lead only.

(b) Each first-draw tap sample for lead and copper shall be one ~~(1)~~ liter (1 L) in volume and have stood motionless in the plumbing system of each sampling site for at least six (6) hours. Bottles used to collect first-draw samples must be wide-mouth one-liter sample bottles. First-draw samples from residential housing ~~shall~~ must be collected from the cold water kitchen ~~tap~~ or bathroom sink tap. First-draw samples from a nonresidential building shall be one liter in volume and ~~shall be~~ collected at ~~an interior~~ a tap from which water is typically drawn for consumption. Department-approved ~~Non~~non-first-draw samples collected in lieu of first-draw samples pursuant to paragraph (2)(e) of this section ~~shall~~ must be one liter (1 L) in volume and ~~shall~~ must be collected at an interior tap from which water is typically drawn for consumption. First-draw samples may be collected by the system or the system may allow residents to collect first-draw samples after instructing the residents of the sampling procedures specified in this paragraph (2)(b). Sampling instructions provided to residents must not include instructions for aerator removal and cleaning or flushing of taps prior to the start of the minimum six (6)-hour stagnation period.

To avoid problems of residents handling nitric acid, acidification of first-draw samples may be done up to fourteen (14) days after the sample is collected. After acidification to resolubilize the metals, the sample must stand in the original container for the time specified in the approved EPA method before the sample can be analyzed. If a system allows residents to perform sampling, the system may not challenge, based on alleged errors in sample collection, the accuracy of sampling results.

(c) ~~Each service line sample shall be one liter in volume and have stood motionless in the lead service line for at least six (6) hours. Lead service line samples shall be collected in one of the following three ways:~~

(i) ~~At the tap after flushing the volume of water between the tap and the lead service line. The volume of water shall be calculated based on the interior diameter and length of the pipe between the tap and the lead service line;~~ All tap samples for copper collected at sites with a lead service line shall be the first-draw sample collected using the procedure listed in this paragraph (2)(c). Tap samples for copper are required to be collected and analyzed only in monitoring periods for which copper monitoring is required.

(ii) ~~Tapping directly into the lead service line; or,~~ Systems must collect tap water in five (5) consecutively numbered one-liter (1 L) sample bottles after the water has stood motionless in the plumbing of each sampling site for at least six (6) hours without flushing the tap prior to sample collection. Systems must analyze first-draw samples for copper, when applicable, and fifth liter samples for lead. Bottles used to collect these samples must be wide-mouth one-liter (1 L) sample bottles. Systems must collect first-draw samples in the first sample bottle with each subsequently numbered bottle being filled until the final bottle is filled with the water running constantly during sample collection. Fifth liter sample is the final sample collected in this sequence. System must collect first-draw and fifth liter samples from residential housing from the cold water kitchen or bathroom sink tap. First-draw and fifth liter samples from a nonresidential building must be one liter (1 L) in volume and collected at an interior cold water tap from which water is typically drawn for consumption. First-draw and fifth liter samples may be collected by the system or the system may allow residents to collect first-draw samples and fifth liter samples after instructing the residents on the sampling procedures specified in this paragraph (2)(c)(ii). Sampling instructions provided to customers must not direct the customer to remove the aerator or clean or flush the taps prior to the start of the minimum six (6)-hour stagnation period. To avoid problems of residents handling nitric acid, the system may acidify first-draw samples up to fourteen (14) days after the sample is collected. After acidification to resolubilize the metals, the sample must stand in the original container for the time specified in the approved EPA method before the sample can be analyzed. If a system allows residents to perform sampling, the system may not challenge, based on alleged errors in sample collection, the accuracy of sampling results.

~~(iii) If the sampling site is a building constructed as a single-family residence, allowing the water to run until there is a significant change in temperature which would be indicative of water that has been standing in the lead service line.~~

(d) A water system ~~shall~~ must collect each first-draw tap sample from the same sampling site from which it collected ~~a~~ the previous sample. A water system must collect each fifth liter sample from the same sampling site from which it collected the previous sample. If, ~~for any reason~~ for reasons beyond the control of the water system, the water system cannot gain entry to a sampling site in order to collect a follow-up tap sample, the system may collect the follow-up tap sample from another sampling site in its sampling pool as long as the new site meets the same targeting criteria, and is within reasonable proximity of the original site.

(e) A non-transient, non-community water system, or a community water system that meets the criteria of ~~Section~~ R.61-58.11.G(2)(g) ~~above~~, that does not have enough taps that can supply first-draw

samples or fifth liter samples meeting the six (6)-hour minimum stagnation time, as defined in R.61-58(B), may apply to the Department in writing to substitute non-first-draw samples, first-draw, or fifth liter samples that do not meet the six (6)-hour minimum stagnation time. Such systems must collect as many first-draw or fifth liter samples from ~~appropriate~~ interior taps typically used for consumption as possible and must identify sampling times and locations that would likely result in the longest standing time for the remaining sites. The Department has the discretion to waive the requirement for prior Department approval of ~~non-first-draw sample~~ sites ~~selected by the system,~~ not meeting the six (6)-hour stagnation time either through State regulation or written notification to the system.

(3) Number of Samples - Water systems shall collect at least one (1) sample during each monitoring period specified in paragraph (4) of this section from the number of sites listed in the first column ("standard monitoring") of the table in this paragraph. A system conducting reduced monitoring under paragraph (4)(d) of this section shall collect at least one (1) sample from the number of sites specified in the second column ("reduced monitoring") of the table in this paragraph during each monitoring period specified in paragraph (4)(d) of this section. Such reduced monitoring sites shall be representative of the sites required for standard monitoring. A public water system that has fewer than five drinking water taps, that can be used for human consumption meeting the sample site criteria of paragraph (1) of this section to reach the required number of sample sites listed in paragraph (3) of this section, must collect at least one sample from each tap and then must collect additional samples from those taps on different days during the monitoring period to meet the required number of sites. Alternatively the Department may allow these public water systems to collect a number of samples less than the number of sites specified in paragraph (3) of this section, provided that one hundred (100) percent of all taps that can be used for human consumption are sampled. The Department must approve this reduction of the minimum number of samples in writing based on a request from the system or onsite verification by the Department. The Department may specify sampling locations when a system is conducting reduced monitoring. The table is as follows:

System Size (# People Served)	# of Sites (Standard Monitoring)	# of Sites (Reduced Monitoring)
>100,000	100	50
10,001 to 100,000	60	30
3,301 to 10,000	40	20
501 to 3,300	20	10
101 to 500	10	5
<= 100	5	5

(4) Timing of Monitoring

~~(a) Initial Tap Sampling - The first six (6) month monitoring period for small, medium-size and large systems shall begin on the following dates:~~

~~**System Size (# People Served)**~~	~~**First Six-Month Monitoring Period Begins On**~~
~~>50,000~~	~~January 1, 1992~~
~~3,301 to 50,000~~	~~July 1, 1992~~
~~≤3,300~~	~~July 1, 1993~~

(a) Standard monitoring. Standard monitoring is a six (6)-month tap sampling monitoring period that begins on January 1 or July 1 of the year in which the water system is monitoring at the standard number of sites in accordance to paragraph (3) of this section.

(i) ~~All large systems shall monitor during two (2) consecutive six (6)month periods.~~ All water systems with lead service lines, including those deemed optimized under R.61-58.11.C(2)(c), and systems that did not conduct monitoring that meets all requirements of this section (e.g., sites selected in accordance with paragraph (1) of this section, samples collected in accordance with paragraph (2) of this section, etc.) between January 15, 2021, and January 16, 2024, must begin the first standard monitoring period on January 1 or July 1 in the year following the January 16, 2024, whichever is sooner. Upon completion of this monitoring, systems must monitor in accordance with paragraph (4)(a)(ii) of this section.

(ii) ~~All small and medium-size systems shall monitor during each six (6) month monitoring period until:~~ Systems that conducted monitoring that meet all requirements of this section (e.g., sites selected in accordance with paragraph (1) of this section, samples collected in accordance with paragraph (2) of this section, etc.) between January 15, 2021, and January 16, 2024, and systems that have completed monitoring under paragraph (4)(a)(i) of this section, must continue monitoring as follows:

(A) ~~The system exceeds the lead or copper action level and is therefore required to implement the corrosion control treatment requirements under Section C above, in which case the system shall continue monitoring in accordance with paragraph (4)(b) of this section; or,~~ Systems that do not meet the criteria under paragraph (4)(d) of the section must conduct standard monitoring.

(B) ~~The system meets the lead and copper action levels during two (2) consecutive six (6) month monitoring periods, in which case the system may reduce monitoring in accordance with paragraph (4)(d) of this section~~ Systems that meet the criteria under paragraph (4)(d) of this section must continue to monitor in accordance with the criteria in paragraph (4)(d).

(C) Any system monitoring at a reduced frequency in accordance with paragraph (4)(d) of this section that exceeds an action level must resume standard monitoring beginning January 1 of the calendar year following the tap sampling monitoring period in which the system exceeded the action level. Any such system must also monitor in accordance with R.61-58.11.I(2), (3), or (4) as applicable.

(D) Any system monitoring at a reduced frequency that exceeds the lead trigger level but meets the copper action level must not monitor any less frequently than annually and must collect samples from the standard number of sites as established in paragraph (3) of this section. This monitoring must begin the calendar year following the tap sampling monitoring period in which the system exceeded the action level. Any such system must also monitor in accordance with R.61-58.11.I(2), (3), or (4) as applicable.

(E) Any system that fails to operate at or above the minimum value or within the range of values for the water quality parameters specified by the Department under R.61-58.11.D(6) for more than nine (9) days in any monitoring period specified in R.61-58.11.I must conduct standard tap water monitoring and must resume sampling for water quality parameters in accordance with R.61-58.11.I(4). This standard monitoring must begin no later than the six (6)-month period beginning January 1 of the calendar year following the water quality parameter excursion.

(F) Any water system that becomes a large water system without corrosion control treatment or any large water system without corrosion control treatment whose lead 90th percentile exceeds the lead practical quantitation level must conduct standard monitoring for at least two (2) consecutive six (6)-month tap sampling monitoring periods and then must continue monitoring in accordance with this paragraph (4)(a)(ii)(F).

(b) Monitoring After Installation of Initial or Re-Optimized Corrosion Control Treatment and Addition of New Source ~~Water~~ or Change in Treatment

(i) ~~Any large system which installs optimal corrosion control treatment pursuant to Section C(4)(d) above, shall monitor during two (2) consecutive six (6) month monitoring periods by the date specified in Section C(4)(e) above.~~ Any water system that installs or re-optimizes corrosion control treatment, as a result of exceeding the lead or copper action level, must monitor for lead and copper every six (6) months and comply with previously designated water quality parameter values, where applicable, until the Department specifies new water quality parameter values for optimal corrosion control.

(ii) ~~Any small or medium-size system which installs optimal corrosion control treatment pursuant to Section C(5)(e) above, shall monitor during two (2) consecutive six (6) month monitoring periods by the date specified in Section C(5)(f) above.~~ Any water system that reoptimizes corrosion control treatment as a result of exceeding the lead trigger level but has not exceeded the lead or copper action level must monitor annually for lead at the standard number of sites listed in paragraph (3) of this section. Samples shall be analyzed for copper on a triennial basis. Small and medium-size systems that do not exceed the lead trigger level in three (3) annual monitoring periods may reduce lead monitoring in accordance with paragraph (4)(d) of this section.

(iii) ~~Any system which installs source water treatment pursuant to Section E(1)(c) above, shall monitor during two (2) consecutive six (6) month monitoring periods by the date specified in Section E(1)(d) above.~~ Any water system that installs source water treatment pursuant to R.61-58.11.E(1)(c) must monitor every six (6) months until the system at or below lead and copper action levels for two (2) consecutive six (6)-month monitoring periods. Systems that do not exceed the lead or copper action level for two (2) consecutive six (6)-month monitoring periods may reduce monitoring in accordance with paragraph (4)(d) of this section.

(iv) If a water system has notified the Department in writing in accordance with R.61-58.11.L(1)(c) of an upcoming addition of a new source or long-term change in treatment, the water system shall monitor every six (6) months at the standard number of sites listed under paragraph (3) of this section until the system is at or below the lead and copper action levels for two (2) consecutive six (6)-month monitoring periods, unless the Department determines that the addition of the new source or long-term change in treatment is not significant and, therefore, does not warrant more frequent monitoring. Systems that do not exceed the lead and copper action levels, and/or the lead trigger level for two (2) consecutive six (6)-month monitoring periods may reduce monitoring in accordance with paragraph (4)(d) of this section.

(c) Monitoring After the Department Specifies Water Quality Parameter Values for Optimal Corrosion Control Treatment - ~~After the Department specifies the values for water quality control parameters under Section D(6) above, the system shall monitor during each subsequent six month monitoring period, with the first monitoring period to begin on the date the Department specifies the optimal values under Section D(6) above.~~

(i) After the Department specifies the values for water quality control parameters under R.61-58.11.D(6), the system must conduct standard six (6)-month monitoring for two (2) consecutive six (6)-month tap sampling monitoring periods. Systems may then reduce monitoring in accordance with paragraph (4)(d) of this section as applicable, following a Department determination that reduced monitoring is approved.

(ii) Systems required to complete the re-optimization steps in R.61-58.11.C(4) due to the exceedance of the lead trigger level that do not exceed the lead and copper action levels must monitor for

two (2) consecutive six (6)-month tap sampling monitoring periods. Systems may then reduce monitoring in accordance with paragraph (4)(d) of this section as applicable following a Department determination that reduced monitoring is approved.

(d) Reduced Monitoring Based on 90th Percentile Levels

Reduced monitoring refers to an annual or triennial tap sampling monitoring period. The reduced monitoring frequency is based on the 90th percentile value for the water system.

(i) ~~A small or medium-size water system that meets the lead and copper action levels during each of two (2) consecutive six (6) month monitoring periods may reduce the number of samples in accordance with paragraph (3) of this section, and reduce the frequency of sampling to once per year. A small or medium water system collecting fewer than five (5) samples as specified in paragraph (3) of this section, that meets the lead and copper action levels during each of two consecutive six- month monitoring periods may reduce the frequency of sampling to once per year. In no case can the system reduce the number of samples required below the minimum of one sample per available tap. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period.~~ A water system that meets the criteria for reduced monitoring under paragraph (4)(d) of this section must collect these samples from sampling sites identified in paragraph (1) of this section. Systems monitoring annually or less frequently must conduct the lead and copper tap sampling during the months of June, July, August, or September unless the Department has approved a different sampling period in accordance with paragraph (4)(d)(i)(A) of this section.

(A) The Department, at its discretion, may approve a different tap sampling period for conducting the lead and copper tap sampling for systems collecting samples at a reduced frequency. Such a period must be no longer than four (4) consecutive months, within one (1) calendar year, and must represent a time of normal operation where the highest levels of lead are most likely to occur. For a non-transient, non-community water system that does not operate during the months of June through September and for which the period of normal operation where the highest levels of lead are most likely to occur is not known, the Department must designate a period that represents normal operation for the system. This monitoring must begin during the period approved or designated by the Department in the calendar year immediately following the end of the second six (6)-month monitoring period for systems initiating annual monitoring and during the three (3)-year period following the end of the third consecutive year of annual monitoring for systems initiating triennial monitoring.

(B) Systems monitoring annually that have been collecting samples during the months of June through September and that receive Department approval to alter their tap sampling monitoring period under paragraph (4)(d)(i)(A) of this section must collect their next round of samples during a time period that ends no later than twenty-one (21) months after the previous round of sampling. Systems monitoring triennially that have been collecting samples during the month of June through September and receive Department approval to alter their sampling collection period as per paragraph (4)(d)(i)(A) of this section must collect their next round of samples during a time period that ends no later than forty-five (45) months after the previous tap sampling period. Subsequent monitoring must be conducted annually or triennially, as required by this section.

(C) Small systems with waivers granted pursuant to paragraph (7) of this section that have been collecting samples during the months of June through September and receive Department approval to alter their tap sampling period as per paragraph (4)(d)(i)(A) of this section must collect their next round of samples before the end of the nine (9)-year period.

(ii) Any water system that meets the lead trigger level and the copper action level ~~and maintains the range of values for the water quality control parameters reflecting optimal corrosion control treatment specified by the Department under Section D(6) above,~~ during each of two (2) consecutive six (6)-month tap sampling monitoring periods may reduce the monitoring frequency ~~of monitoring~~ to ~~once per year~~ annual monitoring and must sample at the standard number of sampling sites for lead and the reduced number of sites for ~~to reduce the number of lead and~~ copper ~~samples~~ in accordance with paragraph (3) of this section ~~if it receives written approval from the Department. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period. The Department shall review monitoring, treatment, and other relevant information submitted by the water system in accordance with Section L below, and shall notify the system in writing when it determines the system is eligible to commence reduced monitoring pursuant to this paragraph. The Department shall review, and where appropriate, revise its determination when the system submits new monitoring or treatment data, or when other data relevant to the number and frequency of tap sampling becomes available.~~ Systems operating under optimal corrosion control treatment (OCCT) must also have maintained the range of optimal water quality parameters (OWQPs) set by the Department in accordance with R.61-58.11.D(6) for the same period and receive a written determination from the Department approving annual monitoring based on the Department's review of monitoring, treatment, and other relevant information submitted by the system as required by R.61-58.11.L. This sampling must begin no later than the calendar year immediately following the last calendar year in which the system sampled.

(iii) ~~A small or medium-size water system that meets the lead and copper action levels during three (3) consecutive years of monitoring may reduce the frequency of monitoring for lead and copper from annually to once every three (3) years. Any water system that meets the lead action level and maintains the range of values for the water quality control parameters reflecting optimal corrosion control treatment specified by the Department under Section D(6), during three consecutive years of monitoring may reduce the frequency of monitoring from annually to once every three years if it receives written approval from the Department. Samples collected once every three years shall be collected no later than every third calendar year. The Department shall review monitoring, treatment, and other relevant information submitted by the water system in accordance with Section L below, and shall notify the system in writing, when it determines the system is eligible to reduce the frequency of monitoring to once every three years. The Department shall review, and where appropriate, revise its determination when the system submits new monitoring or treatment data, or when other data relevant to the number and frequency of tap sampling becomes available.~~ Any water system that exceeds the lead trigger level but not the lead and copper action levels during two (2) consecutive six (6)-month tap sampling monitoring periods must monitor no less frequently than annually at the standard number of sampling sites for lead and copper specified in paragraph (3) of this section. Systems operating OCCT must also have maintained the range of OWQPs set by the Department in accordance with R.61-58.11.D(6) for the same period of six (6)-month monitoring and receive a written determination from the Department approving annual monitoring based on the Department's review of monitoring, treatment, and other relevant information submitted by the system as required by R.61-58.11.L. This sampling must begin no later than the calendar year immediately following the last calendar year in which the system sampled.

(iv) ~~A water system that reduces the number and frequency of sampling shall collect these samples from representative sites included in the pool of targeted sampling sites identified in paragraph (1) of this section. Systems sampling annually or less frequently shall conduct the lead and copper tap sampling during the months of June, July, August or September.~~ Any water system that exceeds the lead trigger level but not the lead and copper action levels during three (3) consecutive years of monitoring may reduce the tap sampling monitoring period for copper to once every three (3) years; however, the system may not reduce the tap sampling monitoring period for lead. Systems operating OCCT must also maintain the range of OWQPs set by the Department in accordance with R.61-58.11.D(6) and receive a written determination from the Department approving triennial monitoring based on the Department's review of monitoring,

treatment, and other relevant information submitted by the system as required by R.61-58.11.L. This sampling must begin no later than the third calendar year immediately following the last calendar year in which the system sampled.

~~(A) The Department, at its discretion, may approve a different period for conducting the lead and copper tap sampling for systems collecting a reduced number of samples. Such a period shall be no longer than four (4) consecutive months and must represent a time of normal operation where the highest levels of lead are most likely to occur. For a non-transient non- community water system that does not operate during the months of June through September, and for which the period of normal operation where the highest levels of lead are most likely to occur is not known, the Department shall designate a period that represents a time of normal operation for the system. This sampling shall begin during the period approved or designated by the Department in the calendar year immediately following the end of the second consecutive six-month monitoring period for systems initiating annual monitoring and during the three-year period following the end of the third consecutive calendar year of annual monitoring for systems initiating triennial monitoring.~~

~~(B) Systems monitoring annually, that have been collecting samples during the months of June through September and that receive Department approval to alter their sample collection period under paragraph (4)(a)(iv)(A) of this section, must collect their next round of samples during a time period that ends no later than forty-five (45) months after the previous round of sampling. Subsequent rounds of sampling must be collected annually or triennially, as required by this section. Small systems with waivers, granted pursuant to paragraph (7) of this section, that have been collecting samples during the months of June through September and receive Department approval to alter their sample collection period under paragraph (4)(d)(iv)(A) of this section, must collect their next round of samples before then end of the nine (9) year period.~~

(v) ~~Any water system that demonstrates for two (2) consecutive six (6) month monitoring periods that the tap water lead level computed under Section B(1)(c) above, is less than or equal to 0.005 mg/L and the tap water copper level computed under Section B(1)(c) above, is less than or equal to 0.65 mg/L may reduce the number of samples in accordance with paragraph (3) of this section and reduce the frequency of sampling to once every three (3) calendar years.~~ Any small or medium-size system that does not exceed the lead trigger level and the copper action level during three (3) consecutive years of monitoring (standard monitoring completed during both six (6)-month periods of a calendar year shall be considered one (1) year of monitoring) may sample at the reduced number of sites for lead and copper in accordance with paragraph (3) of this section and reduce the monitoring frequency to triennial monitoring. Systems operating OCCT must also have maintained the range of OWQPs set by the Department in accordance with R.61-58.11.D(6) for the same three (3)-year period and receive a written determination from the Department approving triennial monitoring based on the Department's review of monitoring, treatment, and other relevant information submitted by the system as required by R.61-58.11.L. This sampling must begin no later than three (3) calendar years after the last calendar year in which the system sampled.

(vi) ~~(A) A small or medium-size water system subject to reduced monitoring that exceeds the lead or copper action level shall resume sampling in accordance with paragraph (4)(c) of this section and collect the number of samples specified for standard monitoring under paragraph (3) of this section. Such a system shall also conduct water quality parameter monitoring in accordance with Section I(2), (3) or (4) below (as appropriate), during the monitoring period in which it exceeded the action level. Any such system may resume annual monitoring for lead and copper at the tap at the reduced number of sites specified in paragraph (3) of this section after it has completed two subsequent consecutive six-month rounds of monitoring that meet the criteria of paragraph (4)(d)(i) of this section and/or may resume triennial monitoring for lead and copper at the reduced number of sites after it demonstrates through subsequent rounds of monitoring that it meets the criteria of either paragraph (4)(d)(iii) or (4)(d)(v) of this section.~~ Any

water system that demonstrates for two (2) consecutive six (6)- month monitoring periods that its 90th percentile lead level, calculated under R.61-58.11.B(3)(d), is less than or equal to 0.005 mg/L and the 90th percentile copper level, calculated under R.61-58.11.B(3)(d), is less than or equal to 0.65 mg/L may sample at the reduced number of sites for lead and copper in accordance with paragraph (3) of this section and reduce the frequency of monitoring to triennial monitoring. For water systems with corrosion control treatment, the system must maintain the range of values for the water quality parameters reflecting OCCT specified by the Department under R.61-58.11.D(6) to qualify for reduced monitoring pursuant to this paragraph (4)(d)(vi).

~~(B) Any water system subject to the reduced monitoring frequency that fails to meet the lead action level during any four-month monitoring period or that fails to operate at or above the minimum value or within the range of values for the water quality parameters specified by the Department under Section D(6) above, for more than nine (9) days in any six-month period specified in Section I(4) below, shall conduct tap water sampling for lead and copper at the frequency specified in paragraph (4)(c) of this section, collect the number of samples specified for standard monitoring under paragraph (3) of this section, and shall resume monitoring for water quality parameters within the distribution system in accordance with Section I(4) below. This standard tap water sampling shall begin no later than the six-month period beginning January 1 of the calendar year following the lead action level exceedance or water quality parameter excursion. Such a system may resume reduced monitoring for lead and copper at the tap and for water quality parameters within the distribution system under the following conditions:~~

~~(1) The system may resume annual monitoring for lead and copper at the tap at the reduced number of sites specified in paragraph (3) of this section after it has completed two subsequent six-month rounds of monitoring that meet the criteria of paragraph (4)(d)(ii) of this section and the system has received written approval from the Department that it is appropriate to resume reduced monitoring on an annual frequency. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period.~~

~~(2) The system may resume triennial monitoring for lead and copper at the tap at the reduced number of sites after it demonstrates through subsequent rounds of monitoring that it meets the criteria of either paragraph (4)(d)(iii) or (4)(d)(v) of this section and the system has received written approval from the Department that it is appropriate to resume triennial monitoring.~~

~~(3) The system may reduce the number of water quality parameter tap water samples required in accordance with Section I(5)(a) below, and the frequency with which it collects such samples in accordance with Section I(5)(b) below. Such a system may not resume triennial monitoring for water quality parameters at the tap until it demonstrates, in accordance with the requirements of Section I(5)(b) below, that it has re-qualified for triennial monitoring.~~

~~(vii) Any water system subject to a reduced monitoring frequency under paragraph (4)(d) of this section shall notify the Department in writing in accordance with Section L(1)(c) of any upcoming long-term change in treatment or addition of a new source as described in that section. The Department must review and approve the addition of a new source or long-term change in water treatment before it is implemented by the water system. The Department may require the system to resume sampling in accordance with paragraph (4)(c) of this section and collect the number of samples specified for standard monitoring under paragraph (3) of this section or take other appropriate steps such as increased water quality parameter monitoring or re-evaluation of its corrosion control treatment given the potentially different water quality considerations~~

(5) Additional Monitoring by Systems - The results of any monitoring conducted in addition to the minimum requirements of this section (such as customer-requested sampling) shall be considered by the

water system and the Department in making any determinations (i.e., calculating the 90th percentile lead or copper level) under this section. Water systems with lead service lines that are unable to collect the minimum number of samples from Tier 1 or Tier 2 sites shall calculate the 90th percentile using data from all the lead service line sites and the highest lead and copper values from lower tier sites to meet the specified minimum number of samples. Systems must submit data from additional Tier 3, Tier 4, or Tier 5 sites to the Department but may not use these results in the 90th percentile calculation. Water systems must include customer-requested samples from known lead service line sites in the 90th percentile calculation if the samples meet the requirements of this section.

(6) Invalidation of ~~lead or copper tap water samples~~ Lead and Copper Tap Samples used in the Calculation of the 90th Percentile. A sample invalidated under this paragraph (6) does not count toward determining lead or copper 90th percentile levels under ~~Section B(1)(c) above~~R.61-58.11.B(1)(c), or toward meeting the minimum monitoring requirements of paragraph (3) of this section.

(a) The Department may invalidate a lead or copper tap water sample at least if one of the following conditions is met.

(i) The laboratory establishes that improper sample analysis caused erroneous results.

(ii) The Department determines that the sample was taken from a site that did not meet the site selection criteria of this section.

(iii) The sample container was damaged in transit.

(iv) There is substantial reason to believe that the sample was subject to tampering.

(b) The system must report the results of all samples to the Department and all supporting documentation for samples the system believes should be invalidated.

(c) To invalidate a sample under paragraph (6)(a) of this section, the decision and the rationale for the decision must be documented in writing. The Department may not invalidate a sample solely on the grounds that a follow-up sample result is higher or lower than that of the original sample.

(d) The water system must collect replacement samples for any samples invalidated under this section if, after the invalidation of one or more samples, the system has too few samples to meet the minimum requirements of paragraph (3) of this section. Any such replacement samples must be taken as soon as possible, but no later than 20 days after the date the Department invalidates the sample or by the end of the applicable monitoring period, whichever occurs later. Replacement samples taken after the end of the applicable monitoring period shall not also be used to meet the monitoring requirements of a subsequent monitoring period. The replacement samples shall be taken at the same locations as the invalidated samples or, if that is not possible, at locations other than those already used for sampling during the monitoring period.

~~(7) Monitoring waivers for small systems . Any small system that meets the criteria of this paragraph may apply to the Department to reduce the frequency of monitoring for lead and copper under this section to once every nine years (i.e., a "full waiver") if it meets all of the materials criteria specified in paragraph (7)(a) of this section and all of the monitoring criteria specified in paragraph (7)(b) of this section. Any small system that meets the criteria in paragraphs (7)(a) and (b) of this section only for lead, or only for copper, may apply to the Department for a waiver to reduce the frequency of tap water monitoring to once every nine years for that contaminant only (i.e., a "partial waiver").~~

(7) Monitoring Waivers for Systems Serving 3,300 or Fewer Persons.

Any water system serving 3,300 or fewer persons that meets the criteria of this paragraph (7) may apply to the Department to reduce the frequency of monitoring for lead and copper under this section to once every nine (9) years (i.e., a ''full waiver'') if it meets all of the materials criteria specified in paragraph (7)(a) of this section and all of the monitoring criteria specified in paragraph (7)(b) of this section. If state regulations permit, any water system serving 3,300 or fewer persons that meets the criteria in paragraphs (7)(a) and (b) of this section only for lead, or only for copper, may apply to the Department for a waiver to reduce the frequency of tap water monitoring to once every nine (9) years for that contaminant only (i.e., a ''partial waiver'').

(a) Materials criteria. The system must demonstrate that its distribution system and service lines and all drinking water supply plumbing, including plumbing conveying drinking water within all residences and buildings connected to the system, are free of lead-containing materials and/or copper-containing materials, as those terms are defined in this paragraph, as follows:

(i) Lead. To qualify for a full waiver, or a waiver of the tap water monitoring requirements for lead (i.e., a "lead waiver"), the water system must provide certification and supporting documentation to the Department that the system is free of all lead-containing materials, as follows:

(A) It contains no plastic pipes which contain lead plasticizers, or plastic service lines which contain lead plasticizers; and

(B) It is free of lead service lines, lead pipes, lead soldered pipe joints, and leaded brass or bronze alloy fittings and fixtures, unless such fittings and fixtures meet the specifications of any standard established pursuant to 42 U.S.C. 300g-6(e) (SDWA section 1417(e)).

(ii) Copper. To qualify for a full waiver, or a waiver of the tap water monitoring requirements for copper (i.e., a "copper waiver"), the water system must provide certification and supporting documentation to the Department that the system contains no copper pipes or copper service lines.

(b) Monitoring criteria for waiver issuance. The system must have completed at least one 6-month round of standard tap water monitoring for lead and copper at sites approved by the Department and from the number of sites required by paragraph (3) of this section and demonstrate that the 90th percentile levels for any and all rounds of monitoring conducted since the system became free of all lead-containing and/or copper-containing materials, as appropriate, meet the following criteria.

(i) Lead levels. To qualify for a full waiver, or a lead waiver, the system must demonstrate that the 90th percentile lead level does not exceed 0.005 mg/L.

(ii) Copper levels. To qualify for a full waiver, or a copper waiver, the system must demonstrate that the 90th percentile copper level does not exceed 0.65 mg/L.

(c) Department approval of waiver application. The Department shall notify the system of its waiver determination, in writing, setting forth the basis of its decision and any condition of the waiver. As a condition of the waiver, the Department may require the system to perform specific activities (e.g., limited monitoring, periodic outreach to customers to remind them to avoid installation of materials that might void the waiver) to avoid the risk of lead or copper concentration of concern in tap water. The small system must continue monitoring for lead and copper at the tap as required by paragraphs (4)(a) through (4)(d) of this section, as appropriate, until it receives written notification from the Department that the waiver has been approved.

(d) Monitoring frequency for systems with waivers.

(i) A system with a full waiver must conduct tap water monitoring for lead and copper in accordance with paragraph (4)(d)(iv) of this section at the reduced number of sampling sites identified in paragraph (3) of this section at least once every nine (9) years and provide the materials certification specified in paragraph (7)(a) of this section for both lead and copper to the Department along with the monitoring results. Samples collected every nine (9) years shall be collected no later than every ninth calendar year.

(ii) A system with a partial waiver must conduct tap water monitoring for the waived contaminant in accordance with paragraph (4)(d)(iv) of this section at the reduced number of sampling sites specified in paragraph (3) of this section at least once every nine (9) years and provide the materials certification specified in paragraph (7)(a) of this section pertaining to the waived contaminant along with the monitoring results. Such a system also must continue to monitor for the non- waived contaminant in accordance with requirements of paragraph (4)(a) through (4)(d) of this section, as appropriate.

(iii) Any water system with a full or partial waiver shall notify the Department in writing in accordance with ~~Section~~ R.61-58.11.L(1)(c) of any upcoming long-term change in treatment or addition of a new source, as described in that section. The Department must review and approve the addition of a new source or long-term change in water treatment before it is implemented by the water system. The Department has the authority to require the system to add or modify waiver conditions (e.g., require recertification that the system is free of lead-containing and/or copper-containing materials, require additional round(s) of monitoring), if it deems such modifications are necessary to address treatment or source water changes at the system.

(iv) If a system with a full or partial waiver becomes aware that it is no longer free of lead-containing or copper-containing materials, as appropriate, (e.g., as a result of new construction or repairs), the system shall notify the Department in writing no later than sixty (60) days after becoming aware of such a change.

(e) Continued eligibility. If the system continues to satisfy the requirements of paragraph (7)(d) of this section, the waiver will be renewed automatically, unless any of the conditions listed in paragraph (7)(e)(i) through (7)(e)(iii) of this section occurs. A system whose waiver has been revoked may re-apply for a waiver at such time as it again meets the appropriate materials and monitoring criteria of paragraphs (7)(a) and (7)(b) of this section.

(i) A system with a full waiver or a lead waiver no longer satisfies the materials criteria of paragraph (7)(a)(i) of this section or has a 90th percentile lead level greater than 0.005 mg/L.

(ii) A system with a full waiver or a copper waiver no longer satisfies the materials criteria of paragraph (7)(a)(ii) of this section or has a 90th percentile copper level greater than 0.65 mg/L.

(iii) The Department notifies the system, in writing, that the waiver has been revoked, setting forth the basis of its decision.

(f) Requirements following waiver revocation. A system whose full or partial waiver has been revoked by the Department is subject to the corrosion control treatment and lead and copper tap water monitoring requirements, as follows:

(i) If the system exceeds the lead and/or copper action level, the system must implement corrosion control treatment in accordance with the deadlines specified in ~~Section~~R.61-58.11.C(5), and any other applicable requirements of this ~~subpart~~section.

(ii) If the system meets both the lead and the copper action level, the system must monitor for lead and copper at the tap no less frequently than once every three years using the reduced number of sample sites specified in paragraph (3) of this section.

(g) Pre-existing waivers. Small system waivers approved by the Department in writing prior to April 11, 2000 shall remain in effect under the following conditions:

(i) If the system has demonstrated that it is both free of lead-containing and copper-containing materials, as required by paragraph (7)(a) of this section and that its 90th percentile lead levels and 90th percentile copper levels meet the criteria of paragraph (7)(b) of this section, the waiver remains in effect so long as the system continues to meet the waiver eligibility criteria of paragraph (7)(e) of this section. The first round of tap water monitoring conducted pursuant to paragraph (7)(d) of this section shall be completed no later than nine years after the last time the system has monitored for lead and copper at the tap.

(ii) If the system has met the materials criteria of paragraph (7)(a) of this section but has not met the monitoring criteria of paragraph (7)(b) of this section, the system shall conduct a round of monitoring for lead and copper at the tap demonstrating that it meets the criteria of paragraph (7)(b) of this section no later than September 30, 2000. Thereafter, the waiver shall remain in effect as long as the system meets the continued eligibility criteria of paragraph (7)(e) of this section. The first round of tap water monitoring conducted pursuant to paragraph (7)(d) of this section shall be completed no later than nine (9) years after the round of monitoring conducted pursuant to paragraph (7)(b) of this section.

(8) Follow-up Samples for ‘‘Find-and-fix’’ under R.61-58.11.D(10).

Systems shall collect a follow-up sample at any site that exceeds the action level within thirty (30) days of receiving the sample results. These follow-up samples may use different sample volumes or different sample collection procedures to assess the source of elevated lead. Systems shall submit samples collected under this section to the Department but shall not include such samples in the 90th percentile calculation.

(9) Public Availability of Tap Monitoring Results used in the 90th Percentile Calculation.

All water systems must make available to the public the results of compliance tap water monitoring data, including data used in the 90th percentile calculation under R.61-58.11.B(3)(d), within sixty (60) days of the end of the applicable tap sampling period. Nothing in this section requires water systems to make publicly available the addresses of the sites where the tap samples were collected. Large systems shall make available the monitoring results in a digital format. Small and medium-size systems shall make available the monitoring results in either a written or digital format. Water systems shall retain tap sampling monitoring data in accordance with recordkeeping requirements under R.61-58.11.M.

I. Monitoring ~~requirements~~Requirements for Water Quality Parameters.

All large water systems, and all small and medium-size systems that exceed the lead or copper action level, ~~shall~~ and all small and medium-size water systems with corrosion control treatment that exceed the lead trigger level must monitor water quality parameters in addition to lead and copper in accordance with this section. ~~The requirements of this section are summarized in the table at the end of this section.~~

(1) General Requirements

(a) Sample Collection Methods

(i) Tap samples shall be representative of water quality throughout the distribution system taking into account the number of persons served, the different sources of water, the different treatment methods employed by the system, and seasonal variability. Tap sampling under this section is not required to be conducted at taps targeted for lead and copper sampling under ~~Section H(1) above~~R.61-58.11.H(1). Sites selected for tap samples under this section must be included in the site sample plan specified under R.61-58.11.H(1)(a). The site sample plan must be updated prior to changes to the sampling locations. [Note: Systems may find it convenient to conduct tap sampling for water quality parameters at sites used for coliform sampling under ~~R.61-58.5(G), Microbiological Contaminant Sampling and Analytical Requirements~~ R. 61-58.5.G if they also meet the requirements of this section.]

(ii) Samples collected at the entry point(s) to the distribution system ~~shall~~ must be from locations representative of each source after treatment. If a system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of normal operating conditions (i.e., when water is representative of all sources being used).

(b) Number of Samples

(i) ~~Systems shall collect two tap samples for applicable water quality parameters during each monitoring period specified under paragraphs (2) through (5) of this section from the following number of sites.~~ Systems must collect two (2) tap samples for applicable water quality parameters during each monitoring period specified under paragraphs (2) through (5) of this section from the minimum number of sites listed in table 1 to this paragraph (1)(b)(i). Systems that add sites as a result of the ''find-and-fix'' requirements in R.61-58.11.D(10) must collect tap samples for applicable water quality parameters during each monitoring period under paragraphs (2) through (5) of this section and must sample from that adjusted minimum number of sites. Systems are not required to add sites if they are monitoring at least twice the minimum number of sites list in table 1 to this paragraph (1)(b)(i).

Table 1 To Paragraph (1)(b)(i)

System Size (# People Served)	**# Of Sites For Water Quality Parameters**
>100,000	25
10,001 to 100,000	10
3,301 to 10,000	3
501 to 3,300	2
101 to 500	1
<=100	1

(ii) ~~Except as provided in paragraph (3)(c) of the section, systems shall collect two (2) samples for each applicable water quality parameter at each entry point to the distribution system during each monitoring period specified in paragraph (2) of this section. During each monitoring period specified in paragraphs (3) through (5) of this section, systems shall collect one (1) sample for each applicable water quality parameter at each entry point to the distribution system .~~

(A) Except as provided in paragraph (3)(b) of this section, water systems without corrosion control treatment must collect two (2) samples for each applicable water quality parameter at each entry

point to the distribution system during each monitoring period specified in paragraph (2) of this section. During each monitoring period specified in paragraphs (3) through (5) of this section, water systems must collect one (1) sample for each applicable water quality parameter at each entry point to the distribution system.

(B) During each monitoring period specified in paragraphs (3) through (5) of the section, water systems with corrosion control treatment must continue to collect one (1) sample for each applicable water quality parameter at each entry point to the distribution system no less frequently than once every two (2) weeks.

(2) Initial Sampling for Water Systems- ~~All large water systems shall measure the applicable water quality parameters as specified below at taps and at each entry point to the distribution system during each six (6) month monitoring period specified in Section H(4)(a) above. All small and medium-size systems shall measure the applicable water quality parameters at the locations specified below during each six (6) month monitoring period specified in Section (H)(4)(a) during which the system exceeds the lead or copper action level.~~

Any large water system without corrosion control treatment must monitor for water quality parameters as specified in paragraphs (2)(a) and (b) of this section during the first two (2) six (6)-month tap sampling monitoring periods beginning no later than January 1 of the calendar year after the system either becomes a large water system, or fails to maintain their 90th percentile for lead below the practical quantitation limit (PQL) for lead. Any medium or small system that exceeds the lead or copper action level and any system with corrosion control treatment for which the Department has not designated optimal water quality parameters (OWQPs) that exceeds the lead trigger level shall monitor for water quality parameters as specified in paragraphs (2)(a) and (b) of this section for two (2) consecutive six (6)-month periods beginning the month immediately following the end of the tap sampling period in which the exceedance occurred.

(a) At taps:

(i) pH;

(ii) Alkalinity; and

~~(iii) Orthophosphate, when an inhibitor containing a phosphate compound is used;~~

~~(iv) Silica, when an inhibitor containing a silicate compound is used;~~

~~(v) Calcium;~~

~~(vi) Conductivity; and,~~

~~(vii) Water temperature.~~

(b) At each entry point to the distribution system: all of the applicable parameters listed in paragraph (2)(a) ~~above.~~ of this section.

(3) Monitoring After Installation of Optimal Corrosion Control or Re-optimized Corrosion Control Treatment ~~- Any large system which installs optimal corrosion control treatment pursuant to Section C(4)(d) above, shall measure the water quality parameters at the locations and frequencies specified below during each six (6) month monitoring period specified in Section H(4)(b)(i) above. Any small or medium-size system which installs optimal corrosion control treatment shall conduct such monitoring during each six~~

~~(6) month monitoring period specified in Section H(4)(b)(ii) above, in which the system exceeds the lead or copper action level.~~

(a) ~~At taps, two samples for:~~ Any system that installs or modifies corrosion control treatment pursuant to R.61-58.11.C(4)(e) or (5)(e) and is required to monitor pursuant R.61-58.11.C(4)(f) or (5)(f) must monitor the parameters identified in paragraphs (3)(a)(i) and (ii) of this section every six (6) months at the locations and frequencies specified in paragraphs (3)(a)(i) and (ii) of this section until the Department specifies new water quality parameter values for optimal corrosion control pursuant to paragraph (4) of this section. Water systems must collect these samples evenly throughout the six (6)-month monitoring period so as to reflect seasonal variability.

(i) ~~pH;~~At taps, two (2) samples each for:

(A) pH;

(B) Alkalinity;

(C) Orthophosphate, when an inhibitor containing an orthophosphate compound is used;

(D) Silica, when an inhibitor containing a silicate compound is used.

(ii) ~~Alkalinity;~~ Except as provided in paragraph (3)(a)(iii) of this section, at each entry point to the distribution system, at least one sample no less frequently than every two weeks (biweekly) for:

(A) pH;

(B) When alkalinity is adjusted as part of optimal corrosion control, a reading of the dosage rate of the chemical used to adjust alkalinity, and the alkalinity concentration; and

(C) When a corrosion inhibitor is used as part of optimal corrosion control, a reading of the dosage rate of the inhibitor used, and the concentration of orthophosphate or silica (whichever is applicable).

(iii) ~~Orthophosphate, when an inhibitor containing a phosphate compound is used;~~ Any groundwater system can limit entry point sampling described in paragraph (3)(a)(ii) of this section to those entry points that are representative of water quality and treatment conditions throughout the system. If water from untreated groundwater sources mixes with water from treated groundwater sources, the system must monitor for water quality parameters both at representative entry points receiving treatment and representative entry points receiving no treatment. Prior to the start of any monitoring under this paragraph (3)(a)(iii), the water system must provide to the Department written information identifying the selected entry points and documentation, including information on seasonal variability, sufficient to demonstrate that the sites are representative of water quality and treatment conditions throughout the system.

~~(iv) Silica, when an inhibitor containing a silicate compound is used; and,~~

~~(v) Calcium, when calcium carbonate stabilization is used as part of corrosion control.~~

(b) ~~Except as provided in paragraph (3)(c) of the section at each entry point to the distribution system, one (1) sample every two (2) weeks (bi-weekly) for:~~ The Department has the discretion to require small and medium-size systems with treatment for which the Department has not designated OWQPs that exceed the lead trigger level but not the lead and copper action levels to conduct water quality parameter monitoring

as described in paragraph (3)(a) of this section or the Department can develop its own water quality control parameter monitoring structure for these systems.

~~(i) pH;~~

~~(ii) When alkalinity is adjusted as part of optimal corrosion control, a reading of the dosage rate of the chemical used to adjust alkalinity, and the alkalinity concentration; and,~~

~~(iii) When a corrosion inhibitor is used as part of optimal corrosion control, a reading of the dosage rate of the inhibitor used, and the concentration of orthophosphate or silica (whichever is applicable).~~

~~(c) Any ground water system can limit entry point sampling described in paragraph (3)(b) of this section to those entry points that are representative of water quality and treatment conditions throughout the system. If water from untreated ground water sources mixes with water from treated ground water sources, the system must monitor for water quality parameters both at representative entry points receiving treatment and representative entry points receiving no treatment. Prior to the start of any monitoring under this paragraph, the system shall provide to the Department written information identifying the selected entry points and documentation, including information on seasonal variability, sufficient to demonstrate that the sites are representative of water quality and treatment conditions throughout the system.~~

(4) Monitoring After the Department Specifies Water Quality Parameter Values for Optimal Corrosion Control ~~— After the Department specifies the values for applicable water quality control parameters reflecting optimal corrosion control treatment under Section D(6) above, all large systems shall measure the applicable water quality parameters in accordance with paragraph (3) of this section and determine compliance with the requirements of Section D(7) every six (6) months with the first six (6) month period to begin on either January 1 or July 1, whichever comes first, after the Department specifies the optimal values under Section D(6) above. Any small or medium-size system shall conduct such monitoring during each six (6) month period specified in this paragraph in which the system exceeds the lead or copper action level. For any such small and medium-size system that is subject to a reduced monitoring frequency pursuant to Section H(4)(d) at the time of the action level exceedance, the start of the applicable six-month monitoring period under this paragraph shall coincide with the start of the applicable monitoring period under Section H(4)(d) above. Compliance with Department-designated optimal water quality parameter values shall be determined as specified under Section D(7).~~

(a) After the Department specifies the values for applicable water quality parameters reflecting optimal corrosion control treatment under R.61-58.11.D(6), systems must monitor for the specified optimal water quality parameters during six (6)-month periods that begin on either January 1 or July 1. Such monitoring must be spaced evenly throughout the six (6)-month monitoring period so as to reflect seasonal variability and be consistent with the structure specified in paragraphs (3)(a)(i) through (iii) of this section.

(i) All large systems must measure the applicable water quality parameters specified by the Department and determine compliance with the requirements of R.61-58.11.D(7) every six (6) months with the first six (6)-month period to begin on either January 1 or July 1, whichever comes first, after the Department specifies the optimal values under R.61-58.11.D(6).

(ii) Any small or medium-size water system that exceeds an action level must begin monitoring during the six (6)-month period immediately following the tap sampling monitoring period in which the exceedance occurs and continue monitoring until the water system no longer exceeds the lead and copper action levels and meets the optimal water quality control parameters in two (2) consecutive six (6)-month tap sampling monitoring periods under R.61-58.11.H(4)(c). For any such small and medium-size system that is subject to a reduced monitoring frequency pursuant to R.61-58.11.H(4)(d) at the time of the action

level exceedance, the start of the applicable six (6)-month monitoring period under this paragraph must coincide with the start of the applicable tap sampling monitoring period under R.61-58.11.H(4)(d).

(iii) Compliance with Department-designated optimal water quality parameter values must be determined as specified under R.61-58.11.D(7).

(b) Any small or medium-size system that exceeds the lead trigger level, but not the lead and copper action levels for which the Department has set optimal water quality control parameters must monitor as specified in paragraph (4)(a) of this section every six (6) months, until the system no longer exceeds the lead trigger level in two (2) consecutive tap sampling monitoring periods.

(c) The Department has the discretion to continue to require systems described in paragraph (4)(b) of this section to monitor optimal water quality control parameters.

(5) Reduced Monitoring

(a) Any large water system that maintains the range of values for the water quality parameters reflecting optimal corrosion control treatment specified by the Department under R.61-58.11.D(6) and does not exceed the lead trigger level during each of two (2) consecutive six (6)-month monitoring periods under paragraph (4) of this section ~~shall~~ must continue monitoring at the entry point(s) to the distribution system as specified in paragraph ~~(3)(b)~~ (3)(a)(ii) of this section. Such system may collect two (2) tap samples for applicable water quality parameters from the following reduced number of sites during each six (6) month monitoring period. Water systems must collect these samples evenly throughout the six (6)-month monitoring period so as to reflect seasonal variability.

Reduced # Of Sites **System Size** **(# People Served)**	**For Water Quality** **Parameters**
>100,000	10
10,001 to 100,000	7
3,301 to 10,000	3
501 to 3,300	2
101 to 500	1
≤100	1

(b) (i) Any water system that maintains the range of values for the water quality parameters reflecting optimal corrosion control treatment specified by the Department under ~~Section D(6) above~~ R.61-58.11.D(6) and does not exceed the lead trigger level or copper action level during three (3) consecutive years of monitoring may reduce the frequency with which it collects the number of tap samples for applicable water quality parameters specified in this paragraph (5)(a) of this section from every six (6) months to annually. This sampling begins during the calendar year immediately following the end of the monitoring period in which the third consecutive year of six (6)-month monitoring occurs. ~~Any water system that maintains the range of values for the water quality parameters reflecting optimal corrosion control treatment specified by the Department under D(6) during three (3) consecutive years of annual monitoring under this paragraph may reduce the frequency with which it collects the number of tap samples for applicable water quality parameters specified in paragraph (5)(a) of this section from annually to every three (3) years. This sampling begins no later than the third calendar year following the end of the monitoring period in which the third consecutive year of monitoring occurs.~~

(ii) A water system may reduce the frequency with which it collects tap samples for applicable water quality parameters specified in paragraph (5)(a) of this section to every ~~three (3) years~~ every year if it demonstrates during two (2) consecutive monitoring periods that its tap water lead level at the 90th percentile is less than or equal to the PQL for lead ~~specified in Section K(1)(a)(ii) above~~ of 0.005 mg/L, that its tap water copper level at the 90th percentile is less than or equal to 0.65 mg/L ~~for copper~~ in ~~Section B(1)(b) above~~R.61-58.11.B(1)(b), and that it also has maintained the range of values for the water quality parameters reflecting optimal corrosion control treatment specified by the Department under ~~Section D(6) above~~ R.61-58.11.D(6). ~~Monitoring conducted every three (3) years shall be done no later than every third calendar year.~~

(c) A water system that conducts sampling annually ~~shall~~must collect these samples evenly throughout the year so as to reflect seasonal variability.

(d) Any water system subject to reduced monitoring frequency that fails to operate at or above the minimum value or within the range of values for the water quality parameters specified by the Department under ~~Section D(6) above~~R.61-58.11.D(6), for more than nine (9) days in any six (6) month period specified in ~~Section D(7) above~~R.61-58.11.D(7), ~~shall~~ must resume distribution system tap water sampling in accordance with the number and frequency requirements in paragraph (4) of this section. Such a system may resume annual monitoring for water quality parameters at the tap at the reduced number of sites specified in paragraph (5)(a) of this section after it has completed two (2) subsequent consecutive six (6) month rounds of monitoring that meet the criteria of ~~that~~ paragraph (5)(a) of this section and/or may resume ~~triennial~~ annual monitoring for water quality parameters at the tap at the reduced number of sites after it demonstrates through subsequent rounds of monitoring that it meets the criteria of either paragraph (5)(b)(i) or (5)(b)(ii) of this section.

(6) Additional Monitoring by Systems ~~– The results of any monitoring conducted in addition to the minimum requirements of this section shall be considered by the system and the Department in making any determinations (i.e., determining concentrations of water quality parameters) under this section or Section D above.~~

The results of any monitoring conducted in addition to the minimum requirements of this section must be considered by the water system and the Department in making any determinations (i.e., determining concentrations of water quality parameters) under this section or R.61-58.11.D.

(7) Additional Sites Added from Find-and-fix.

Any water system that conducts water quality parameter monitoring at additional sites through the ''find-and-fix'' provisions pursuant to R.61-58.11.D(10) must add those sites to the minimum number of sites specified under paragraphs (1) through (5) of this section unless the system is monitoring at least twice the minimum number of sites.

~~SUMMARY OF MONITORING REQUIREMENTS FOR WATER QUALITY PARAMETERS~~[1]

~~Monitoring Period~~	~~Parameters~~[2]	~~Location~~	~~Frequency~~
~~Initial Monitoring.~~	~~pH, alkalinity, orthophosphate or silica~~[3]~~, calcium, conductivity, temperature.~~	~~Taps and at entry point(s) to distribution system.~~	~~Every 6 months.~~

Monitoring Period	Parameters[2]	Location	Frequency
After Installation of Corrosion Control.	pH, alkalinity, orthophosphate or silica[3], calcium[4].	Taps.	Every 6 months.
	pH, alkalinity, dosage rate and concentration (if alkalinity adjusted as part of corrosion control), inhibitor dosage rate and inhibitor residual[5].	Entry point(s) to distribution system[6].	No less frequently than every two weeks.
After Department Specifies Parameter Values for Optimal Corrosion Control.	pH, alkalinity, orthophosphate or silica[3], calcium[4].	Taps.	Every 6 months.
	pH, alkalinity dosage rate and concentration (if alkalinity adjusted as part of corrosion control), inhibitor dosage rate and inhibitor residual [5].	Entry point(s) to distribution system[6].	No less frequently than every two
Reduced Monitoring.	pH, alkalinity, orthophosphate or silica[3], calcium[4].	Taps.	Every 6 months, annually[7] or every 3 years[8]; reduced number of sites.
	pH, alkalinity dosage rate and concentration (if alkalinity adjusted as part of corrosion control), inhibitor dosage rate and inhibitor residual[5].	Entry point(s) to distribution system[6].	No less frequently than every two weeks.

[1]Table is for illustrative purposes; consult the text of this section for precise regulatory requirements.
[2]Small and medium size systems have to monitor for water quality parameters only during monitoring periods in which the system exceeds the lead or copper action level.
[3] Orthophosphate must be measured only when an inhibitor containing a phosphate compound is used. Silica must be measured only when an inhibitor containing silicate compound is used.
[4]Calcium must be measured only when calcium carbonate stabilization is used as part of corrosion control.
[5]Inhibitor dosage rates and inhibitor residual concentrations (orthophosphate or silica) must be measured only when an inhibitor is used.
[6]Ground water systems may limit monitoring to representative locations throughout the system.
[7]Water systems may reduce frequency of monitoring for water quality parameters at the tap from every six months to annually if they have maintained the range of values for water quality parameters reflecting optimal corrosion control during 3 consecutive years of monitoring.
[8]Water systems may further reduce the frequency of monitoring for water quality parameters at the tap from annually to once every 3 years if they have maintained the range of values for water quality parameters reflecting optimal corrosion control during 3 consecutive years of annual monitoring. Water systems may accelerate to triennial monitoring for water quality parameters at the tap if they have maintained 90th percentile lead levels less than or equal to 0.005 mg/L, 90th percentile copper levels less than or equal to 0.65 mg/L, and the range of water quality parameters designated by the Department under Section D(5) above, as representing optimal corrosion control during two consecutive six-month monitoring periods.

J. Monitoring Requirements for Lead and Copper in Source Water.

(1) Sample Location, Collection Methods, and Number of Samples

(a) A water system that fails to meet the lead or copper action level on the basis of tap samples collected in accordance with ~~Section H~~ R.61-58.11.H above, shall collect lead and copper source water samples in accordance with the requirements regarding sample location, number of samples, and collection methods.

(i) Groundwater systems shall take a minimum of one (1) sample at every entry point to the distribution system ~~which is representative of each well after treatment~~ after any application of treatment or in the distribution system at a point which is representative of each source after treatment (hereafter called a sampling point). The system shall take one (1) sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(ii) Surface water systems shall take a minimum of one sample at every entry point to the distribution system after any application of treatment or in the distribution system at a point which is representative of each source after treatment (hereafter called a sampling point). The system shall take each sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

NOTE: For the purposes of this paragraph, surface water systems include systems with a combination of surface and ground sources.

(iii) if a system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of normal operating conditions (i.e., when water is representative of all sources being used).

(iv) The Department may reduce the total number of samples which must be analyzed by allowing the use of compositing. Compositing of samples must be done by certified laboratory personnel. Composite samples from a maximum of five (5) samples are allowed, provided that if the lead concentration in the composite sample is greater than or equal to 0.001 mg/L or the copper concentration is greater than or equal to 0.160 mg/L, then either:

(A) A follow-up sample shall be taken and analyzed within fourteen (14) days at each sampling point included in the composite; or

(B) If duplicates of or sufficient quantities from the original samples from each sampling point used in the composite are available, the system may use these instead of resampling.

(b) Where the results of sampling indicate an exceedance of maximum permissible source water levels established under ~~Section E(2)(d)~~ R. 61-58.11.E(2)(d) above, the Department may require that one additional sample be collected as soon as possible after the initial sample was taken (but not to exceed two weeks) at the same sampling point. If a Department- required confirmation sample is taken for lead or copper, then the results of the initial and confirmation sample shall be averaged in determining compliance with the Department- specified maximum permissible levels. Any sample value below the detection limit shall be considered to be zero. Any value above the detection limit but below the PQL shall either be considered as the measured value or be considered one-half the PQL.

(2) Monitoring Frequency After System Exceeds Tap Water Action Level ~~-- Any system which exceeds the lead or copper action level at the tap shall collect one source water sample from each entry point to the distribution system no later than six (6) months after the end of the monitoring period during which the lead or copper action level was exceeded. For monitoring periods that are annual or less frequent, the end of the~~

~~monitoring period is September 30 of the calendar year in which the sampling occurs, or if the Department has established an alternate monitoring period, the last day of that period.~~

Any system which exceeds the lead or copper action level at the tap for the first time or for the first time after an addition of a new source or installation of source water treatment required under R.61-58.11.E(2)(b) shall collect one (1) source water sample from each entry point to the distribution system no later than six (6) months after the end of the tap sampling period during which the lead or copper action level was exceeded. For tap sampling periods that are annual or less frequent, the end of the tap sampling period is September 30 of the calendar year in which the sampling occurs, or if the Department has established an alternate monitoring period, the last day of that period. If the Department determines that source water treatment is not required under R.61-58.11.E(2)(b), the Department may waive source water monitoring, for any subsequent lead or copper action level exceedance at the tap, in accordance with the requirements in paragraphs (2)(a)(i) through (iii) of this section.

(a) The Department may waive source water monitoring for lead or copper action level exceedance at the tap under the following conditions:

(i) The water system has already conducted source water monitoring following a previous action level exceedance;

(ii) The Department has determined that source water treatment is not required; and

(iii) The system has not added any new water sources.

(b) [Reserved]

(3) Monitoring Frequency After Installation of Source Water Treatment and Addition of New Source – ~~Any system which installs source water treatment pursuant to Section E(1)(c) above, shall collect an additional source water sample from each entry point to the distribution system during two consecutive six (6) month monitoring periods by the deadline specified in Section E(1)(d) above.~~

(a) Any system which installs source water treatment pursuant to R.61-58.11.E(1)(c) shall collect one (1) source water sample from each entry point to the distribution system during two (2) consecutive six (6)-month monitoring periods by the deadline specified in R.61-58.11.E(1)(d).

(b) Any system which adds a new source shall collect one (1) source water sample from each entry point to the distribution system until the system demonstrates that finished drinking water entering the distribution system has been maintained below the maximum permissible lead and copper concentrations specified by the Department in R.61-58.11.E(2)(d) or the Department determines that source water treatment is not needed.

(4) Monitoring ~~frequency~~Frequency after Department ~~specifies maximum permissible source water levels or determines that source water treatment is not needed.~~ Specifies Maximum Permissible Source Water Levels

(a) A system shall monitor at the frequency specified ~~below in cases where the Department specifies maximum permissible source water levels under Section E(2)(d) above, or determines that the system is not required to install source water treatment under Section E(2)(b) above.~~ in paragraphs (4)(a) and (b) of this section, in cases where the Department specifies maximum permissible source water levels under R.61-58.11.E(2)(d).

(i) A water system using only groundwater shall collect samples once during the three (3) year compliance period (as that term is defined in R.61-58.B, Definitions) in effect when the applicable Department determination under paragraph (4)(a) of this section is made. Such systems shall collect samples once during each subsequent compliance period. Triennial samples shall be collected every third calendar year.

(ii) A water system using surface water (or a combination of surface and groundwater) shall collect samples once during each calendar year, the first annual monitoring period to begin during the year in which the applicable Department determination is made under paragraph (4)(a) of this section.

(b) A system is not required to conduct source water sampling for lead and/or copper if the system meets the action level for the specific contaminant in tap water samples during the entire source water sampling period applicable to the system under paragraph (4)(a)(i) or (ii) of this section.

(5) Reduced Monitoring Frequency

(a) A water system using only ground water may reduce the monitoring frequency for lead and copper in source water to once during each nine (9)-year compliance cycle (as that term is defined in R.61-58.B, Definitions) provided that the samples are collected no later than every ninth calendar year and if the systems meets ~~one of~~ the following criteria:

(i) The system demonstrates that finished drinking water entering the distribution system has been maintained below the maximum permissible lead and copper concentrations specified by the Department in ~~Section E(2)(d) above~~ R.61-58.11.E(2)(d), during at least three (3) consecutive ~~compliance~~ monitoring periods under paragraph (4)(a) of this section; or

(ii) The Department has determined that source water treatment is not needed and the system demonstrates that, during at least three consecutive compliance periods in which sampling was conducted under paragraph (4)(a) of this section, the concentration of lead in source water was less than or equal to 0.005 mg/L and the concentration of copper in source water was less than or equal to 0.65 mg/L.

(b) A water system using surface water (or a combination of surface and ground waters) may reduce the monitoring frequency in paragraph (4)(a) of this section to once during each nine (9)-year compliance cycle (as that term is defined in R.61-58.B, Definitions) provided that the samples are collected no later than every ninth calendar year and if the system meets ~~one of~~ the following criteria:

(i) The system demonstrates that finished drinking water entering the distribution system has been maintained below the maximum permissible lead and copper concentrations specified by the Department in Section E(2)(d) above, for at least three (3) consecutive years; or

(ii) The Department has determined that source water treatment is not needed and the system demonstrates that, during at least three (3) consecutive years, the concentration of lead in source water was less than or equal to 0.005 mg/L and the concentration of copper in source water was less than or equal to 0.65 mg/L.

(c) A water system that uses a new source of water is not eligible for reduced monitoring for lead and/or copper until concentrations in samples collected from the new source during three consecutive monitoring periods are below the maximum permissible lead and copper concentrations specified by the Department in ~~Section E(1)(e) above~~ R.61-58.11.E(1)(e).

K. Analytical Methods.

(1) Analyses for lead, copper, pH, ~~conductivity, calcium,~~ alkalinity, orthophosphate, and silica, and temperature shall be conducted using EPA approved methods and other requirements listed in 40 CFR ~~141.89~~ 141.23(k)(1).

(a) Analyses under ~~this section~~ R.61-58.11 shall only be conducted by laboratories that are certified by the Department.

(b) The Department has the authority to allow the use of previously collected monitoring data for purposes of monitoring, if the data were collected and analyzed in accordance with the requirements of this section.

(c) All lead and copper levels measured between the PQL and the MDL must be either reported as measured or they can be reported as one half the PQL specified for lead and copper in paragraph (1)(d) below. All levels below the lead and copper MDL must be reported as zero.

(d) The Practical Quantitation Level, or PQL for lead is 0.005 mg/L. The Practical Quantitation Level, or PQL for copper is 0.050 mg/L.

L. Reporting Requirements.

All water systems shall report all of the following information to the Department in accordance with this section.

(1) Reporting requirements for tap water monitoring for lead and copper and for water quality parameter monitoring.

(a) Notwithstanding the requirements of R.61-58.6.B(1), ~~Except~~ except as provided in paragraph (1)(a)(viii) of this section a water system ~~shall~~ must report the information specified ~~below~~ in paragraphs (1)(a)(i) through (ix) of this section for all tap water samples specified in ~~Section H~~R.61-58.11.H and for all water quality parameter samples specified in ~~Section I~~R.61-58.11.I within the first ten (10) days following the end of each applicable tap sampling monitoring period specified in ~~Sections H,~~ R.61-58.11.H and R.61-58.11.I ~~I above~~ (i.e., every six (6) months, annually, every three (3) years, or every nine (9) years). For ~~monitoring~~ tap sampling periods with a duration less than six (6) months, the end of the tap sampling monitoring period is the last date samples can be collected during that tap sampling period as specified in ~~section H and I~~R. 61-58.11.H and R.61-58.11.I.

(i) The results of all tap samples for lead and copper including the location of each site and the site selection criteria under ~~Section H(1)(c), (d), (e), (f), and/or (g) above, under which the site was selected for the system's sampling pool;~~ R.61-58.11.H(1)(c) through (j), used as the basis for which the site was selected for the water system's sampling pool, accounting for R.61-58.11.H(1)(k);

(ii) Documentation for each tap water lead or copper sample for which the water system requests invalidation pursuant to ~~Section H(5)(b)~~R.61-58.11.H(5)(b) above;

(iii) ~~The 90th percentile lead and copper concentrations measured from among all lead and copper tap water samples collected during each monitoring period (calculated in accordance with Section B.3(c) above) unless the Department calculates the system's 90th percentile lead and copper levels under paragraph (8) of this section;~~ Water systems with lead service lines, galvanized service lines requiring replacement, or lead status unknown service lines in the lead service line inventory conducted under R.61-58.11.F(1) must re-evaluate the tap sampling locations used in their sampling pool prior to the compliance date

specified in R.61-58.11.B(1) and thereafter prior to the next round of tap sampling conducted by the system, or annually, whichever is more frequent.

(A) By the start of the first applicable tap sampling monitoring period in R.61-58.11.H(4), the water system must submit a site sample plan to the Department in accordance with R.61-58.11.H, including a list of tap sample site locations identified from the inventory in R.61-58.11.F(1), and a list of tap sampling water quality parameter (WQP) sites selected under R.61-58.11.I(1)(a). The site sample plan must be updated and submitted to the Department prior to any changes to sample site locations. The Department may require modifications to the site sample plan as necessary.

(B) For water systems with lead service lines with insufficient lead service line sites to meet the minimum number required in R.61-58.11.H, documentation in support of the conclusion that there are an insufficient number of lead service line sites meeting the criteria under R.61-58.11.H(1)(c) or (d) for community water systems or R.61-58.11.H(1)(h) for non-transient, non-community water systems, as applicable;

(iv) ~~With the exception of initial tap sampling conducted pursuant to Section H(4)(a) above, the system shall designate any site which was not sampled during previous monitoring periods, and include an explanation of why sampling sites have changed~~The 90th percentile lead and copper concentrations measured from among all lead and copper tap water samples collected during each tap sampling period (calculated in accordance with R. 61-58.11.B(3)(d), unless the State calculates the water system's 90th percentile lead and copper levels under paragraph (8) of this section;

(v) ~~The results of all tap samples for pH, and where applicable, alkalinity, calcium, conductivity, temperature, and orthophosphate or silica collected under Section I(2) through (5) above; and,~~ With the exception of initial tap sampling conducted pursuant to R.61-58.11.H(4)(a)(i), the water system must identify any site which was not sampled during previous tap sampling periods, and include an explanation of why sampling sites have changed;

(vi) ~~The results of all samples collected at the entry point(s) to the distribution system for applicable water quality parameters under Section I(2) through (5) above.~~ The results of all water quality parameter tap samples that are required to be collected under R.61-58.11.I(2) through (7);

(vii) The results of all samples collected at the entry point(s) to the distribution system for applicable water quality parameters under R.61-58.11.I(2) through(5);

~~(vii)~~(viii) A water system shall report the results of all water quality parameter samples collected under Section I(3) - (6) above, during each six (6)-month monitoring period specified in Section I(4) above, within the first ten (10) days following the end of the monitoring period unless the Department has specified a more frequent reporting requirement~~.~~; and

(ix) By the start of the first applicable tap sampling period in R.61-58.11.H(4), the water system must submit to the Department a copy of the tap sampling protocol that is provided to individuals who are sampling. The Department shall verify that wide-mouth collection bottles are used and recommendations for pre-stagnation flushing and aerator cleaning or removal prior to sample collection are not included pursuant to R.61-58.11.H(2). The tap sampling protocol shall contain instructions for correctly collecting a first-draw sample for sites without lead service lines and a first-draw and a fifth liter sample for sites with lead service lines, where applicable. If the water system seeks to modify its tap sampling protocol specified in this paragraph (1)(a)(ix), it must submit the updated version of the protocol to the Department for review and approval no later than sixty (60) days prior to use.

(b) For a non-transient non-community water system, or a community water system meeting the criteria of ~~Section G(2)(g) above~~ R.61-58.11.H(2)(e), that does not have enough taps that can provide first-draw or fifth liter samples, the system must either:

(i) Provide written documentation to the Department identifying standing times and locations for enough non-first-draw and fifth liter samples to make up its sampling pool under ~~Section H(2)(e) above~~ R.61-58.11.H(2)(e), by the start of the first applicable monitoring period under ~~Section H(4) above, that commences after April 11, 2000,~~ R.61-58.11.H(4) unless the Department has waived prior Department approval of non-first-draw and fifth liter sample sites selected by the system pursuant to ~~Section H(2)(e) above~~ R.61-58.11.H(2)(e); or

(ii) If the Department has waived prior approval of non-first-draw sample sites selected by the system, identify, in writing, each site that did not meet the six-hour minimum standing time and the length of standing time for that particular substitute sample collected pursuant to ~~Section H(2)(e)~~R. 61-58.11.H(2)(e) above, and include this information with the lead and copper tap sample results required to be submitted pursuant to paragraph (1)(a)(i) of this section.

(c) At a time specified by the Department, or if no specific time is designated by the Department, then as early as possible prior to the addition of a new source or any long-term change in water treatment, a water system ~~deemed to have optimized corrosion control under Section C(2)(e), a water system subject to reduced monitoring pursuant to Section H(4)(d), or a water system subject to a monitoring waiver pursuant to Section H(7), shall~~ must submit written documentation to the Department describing the change or addition. The Department must review and approve the addition of a new source or long-term change in treatment before it is implemented by the water system. The Department may require the system to take actions before or after the addition of a new source or long-term treatment change to ensure the system will operate and maintain optimal corrosion control treatment such as additional water quality parameter monitoring, additional lead or copper tap sampling, and re-evaluation of corrosion control treatment. Examples of long-term treatment changes include, but are not limited to, the addition of a new treatment process or modification of an existing treatment process. Examples of modifications include switching secondary disinfectants, switching coagulants (e.g., alum to ferric chloride), and switching corrosion inhibitor products (e.g., orthophosphate to blended phosphate). Long-term changes can also include dose changes to existing chemicals if the system is planning long-term changes to its finished water pH or residual inhibitor concentration. Long-term treatment changes would not include chemical dose fluctuations associated with daily raw water quality changes where a new source has not been added.

(d) Any small system applying for a monitoring waiver under ~~Section H(7)~~R.61-58.11.H(7) above, or subject to a waiver granted pursuant to ~~Section H(7)(c)~~ R.61-58.11.H(7)(c) above, shall provide the following information to the Department in writing by the specified deadline:

(i) By the start of the first applicable tap sampling monitoring period in ~~Section H(4) above~~ R.61-58.11.H(4), any small water system applying for a monitoring waiver shall provide the documentation required to demonstrate that it meets the waiver criteria of ~~Section H(7)(a) and (b) above~~ R.61-58.11.H(7)(a) and (b).

(ii) No later than nine years after the monitoring previously conducted pursuant to ~~Section H (7)(b)~~R. 61-58.11.H(7)(b) or ~~(d)(i)~~R. 61-58.11.H(7)(d)(i) above, each small system desiring to maintain its monitoring waiver shall provide the information required by ~~Section H(7)(d)(i) and (ii)~~ R. 61-58.11.H(7)(d)(i) and (ii) above.

(iii) No later than 60 days after it becomes aware that it is no longer free of lead-containing and/or copper-containing material, as appropriate, each small system with a monitoring waiver shall provide

written notification to the Department, setting forth the circumstances resulting in the lead-containing and/or copper-containing materials being introduced into the system and what corrective action, if any, the system plans to remove these materials.

~~(iv) By October 10, 2000, any small system with a waiver granted prior to April 11, 2000 and that has not previously met the requirements of Section H(7)(b) above, shall provide the information required by that paragraph~~.

(e) Each ground water system that limits water quality parameter monitoring to a subset of entry points under ~~Section I(3)(c)~~ R. 61-58.11.I(3)(c) above, shall provide, by the commencement of such monitoring, written correspondence to the Department that identifies the selected entry points and includes information sufficient to demonstrate that the sites are representative of water quality and treatment conditions throughout the system.

(2) Source Water Monitoring Reporting Requirements

(a) A water system shall report the sampling results for all source water samples collected in accordance with ~~Section J~~R. 61-58.11.J above within the first 10 days following the end of each source water monitoring period (i.e., annually, per compliance period, per compliance cycle) specified in ~~Section J~~R. 61-58.11.J above.

(b) With the exception of the first round of source water sampling conducted pursuant to ~~Section J(2)~~ R. 61-58.11.J(2) above, the system shall specify any site which was not sampled during previous monitoring periods, and include an explanation of why the sampling point has changed.

(3) Corrosion Control Treatment Reporting Requirements - By the applicable dates under ~~Section C~~R. 61-58.11.C above, systems shall report the following information:

(a) For water systems demonstrating that they have already optimized corrosion control, information required in ~~Section C(2)(b) or (c) above~~ R.61-58.11.C(2)(a) through (c).

(b) For systems required to optimize corrosion control, their recommendation regarding optimal corrosion control treatment under ~~Section D(1)~~ R. 61-58.11.D(1) above.

(c) For systems required to evaluate the effectiveness of corrosion control treatments under ~~Section D(3)~~ R. 61-58.11.D(3) above, the information required by that paragraph.

(d) For systems required to install optimal corrosion control designated by the Department under ~~Section D(4)~~ R. 61-58.11.D(4) above, a letter certifying that the system has completed installing that treatment.

(4) Source Water Treatment Reporting Requirements - By the applicable dates in ~~Section E~~R. 61-58.11.E above, systems shall provide the following information to the Department:

(a) If required under ~~Section E(2)(a)~~ R. 61-58.11.E(2)(a) above, their recommendation regarding source water treatment;

(b) For systems required to install source water treatment under ~~Section E(2)(b)~~ R. 61-58.11.E(2)(b) above, a letter certifying that the system has completed installing the treatment designated by the Department within twenty four (24) months after the Department designated the treatment.

(5) Lead Service Line Inventory and Replacement Reporting Requirements ~~– Systems shall report the following information to the Department to demonstrate compliance with the requirements of Section F above:~~

Water systems must report the following information to the Department to demonstrate compliance with the requirements of R.61-58.11.F and R.61-58.11.G:

(a) ~~No later than twelve (12) months after the end of a monitoring period in which a system exceeds the lead action level in sampling referred to in Section F(1) above, the system must submit written documentation to the Department of the materials evaluation conducted as required in Section H(1) identify the initial number of lead service lines in its distribution system at the time the system exceeds the lead action level, and provide the system's schedule for annually replacing at least seven (7) percent of the initial number of lead service lines in its distribution system.~~ No later than January 16, 2024, the water system must submit to the Department an inventory of service lines as required in R.61-58.11.F(1).

(b) ~~No later than twelve (12) months after the end of a monitoring period in which a system exceeds the lead action level in sampling referred to in Section F(1) above, and every twelve (12) months thereafter, the system shall demonstrate to the Department in writing that the system has either:~~ No later than January 16, 2024, any water system that has inventoried a lead service line, galvanized requiring replacement, or lead status unknown service line in its distribution system must submit to the Department, as specified in Section R.61-58.11.F(2), a lead service line replacement plan.

~~(i) Replaced in the previous twelve (12) months at least seven (7) percent of the initial lead service lines (or a greater number of lines specified by the Department under Section F(5) above, in its distribution system, or,~~

~~(ii) Conducted sampling which demonstrates that the lead concentration in all service line samples from an individual line(s), taken pursuant to Section H(2)(c) above, is less than or equal to 0.015 mg/L. In such cases, the total number of lines replaced and/or which meet the criteria in Section F(3) above, shall equal at least seven (7) percent of the initial number of lead lines identified under paragraph 5(a) of this section (or the percentage specified by the Department under Section F(5) above).~~

(c) ~~The annual letter submitted to the Department under paragraph (5)(b) of this section shall contain the following information:~~ The water system must provide the Department with updated versions of its inventory as required in R.61-58.11.F(1) in accordance with its tap sampling monitoring period schedule as required in R.61-58.11.H(4), but no more frequently than annually. The updated inventory must be submitted within thirty (30) days of the end of each tap sampling monitoring period.

(i) ~~The number of lead service lines scheduled to be replaced during the previous year of the system's replacement schedule;~~ When the water system has demonstrated that it has no lead, galvanized requiring replacement, or lead status unknown service lines in its inventory, it is no longer required to submit inventory updates to the Department, except as required in paragraph (5)(c)(ii) of this section.

(ii) ~~The number and location of each lead service line replaced during the previous year of the system's replacement schedule; and,~~ In the case that a water system meeting the requirements of paragraph (5)(c)(i) of this section, subsequently discovers any service lines requiring replacement in its distribution system, it must notify the Department within thirty (30) days of identifying the service line(s) and prepare an updated inventory in accordance with R.61-58.11.F(1) on a schedule established by the Department.

~~(iii) If measured, the water lead concentration and location of each lead service line sampled, the sampling method, and the date of sampling.~~

(d) ~~Any system which collects lead service line samples following partial lead service line replacement required by Section F shall report the results to the Department within the first ten days of the month following the month in which the system receives the laboratory results, or as specified by the Department. The Department, at its discretion may eliminate this requirement to report these monitoring results. Systems shall also report any additional information as specified by the Department, and in a time and manner prescribed by the Department, to verify that all partial lead service line replacement activities have taken place.~~ Within thirty (30) days of the end of each tap sampling monitoring period, the water system must certify that it conducted replacement of any encountered lead goosenecks, pigtails, and connectors in accordance with R.61-58.11.F(3).

(e) Within 30 days of the end of each tap sampling monitoring period, the water system must certify to the Department that any partial and full lead service line replacements were conducted in accordance with R.61-58.11.F(4) and (5), respectively.

(f) If the water system fails to meet the forty-five (45)-day deadline to complete a customer-initiated lead service line replacement pursuant to R.61-58.11.F(4)(d), it must notify the Department within thirty (30) days of the replacement deadline to request an extension of the deadline up to one hundred eighty (180) days of the customer-initiated lead service line replacement.

(i) The water system must certify annually that it has completed all customer-initiated lead service line replacements in accordance with R.61-58.11.F(4)(d).

(ii) [Reserved]

(g) No later than thirty (30) days after the end of the water system's annual lead service line replacement requirements under R.61-58.11.F(6) and (7), the water system must submit the following information to the Department, and continue to submit it each year it conducts lead service line replacement under R.61-58.11.F(6) and (7):

(i) The number of lead service lines in the initial inventory;

(ii) The number of galvanized requiring replacement service lines in the initial inventory;

(iii) The number of lead status unknown service lines in the inventory at the onset of the water system's annual lead service line replacement program;

(iv) The number of full lead service lines that have been replaced and the address associated with each replaced service line;

(v) The number of galvanized requiring replacement service lines that have been replaced and the address associated with each replaced service line;

(vi) The number of lead status unknown service lines remaining in the inventory;

(vii) The total number of lead status unknown service lines determined to be non-lead; and

(viii) The total number of service lines initially inventoried as ''non-lead'' later discovered to be a lead service line or a galvanized requiring replacement service line.

(h) No later than thirty (30) days after the end of each tap sampling period, any water system that has received customer refusals about lead service line replacements or customer nonresponses after a minimum

of two (2) good faith efforts by the water system to contact customers regarding full lead service line replacements in accordance with R.61-58.11.F(7)(g), must certify to the Department the number of customer refusals or non-responses it received from customers served by a lead service line or galvanized requiring replacement service line, and maintain such documentation.

(i) No later than twelve (12) months after the end of a tap sampling period in which a water system exceeds the lead action level in sampling conducted pursuant to R.61-58.11.H, the system must provide to the Department its schedule for annually replacing an average annual rate, calculated on a two (2)-year rolling basis, of at least three percent (3%), or otherwise specified in R.61-58.11.F(7)(i), of the number of known lead service lines and galvanized lines requiring replacement when the lead trigger or action level was first exceeded and lead status unknown service lines at the beginning of each year that required replacement occurs in its distribution system.

(j) No later than twelve (12) months after the end of a sampling period in which a system exceeds the lead trigger level in sampling conducted pursuant to R.61-58.11.H, and every twelve (12) months thereafter, the system shall certify to the Department in writing that the system has:

(i) Conducted consumer notification as specified in R.61-58.11.F(6)(d) and R.61-58.11.G(7); and

(ii) Delivered public education materials to the affected consumers as specified in R.61-58.11.G(1).

(iii) A water system that does not meet its annual service line replacement goal as required under R.61-58.11.F(6) must certify to the Department in writing that the water system has conducted public outreach as specified in R.61-58.11.G(8). The water system must also submit the outreach materials used to the Department.

(k) The annual submission to the Department under paragraph (5)(j) of this section must contain the following information:

(i) The certification that results of samples collected between three (3) months and six (6) months after the date of a full or partial lead service line replacement were provided to the resident in accordance with the timeframes in R.61-58.11.G(4)(b). Mailed notices postmarked within three (3) business days of receiving the results shall be considered ‘‘on time.’’

(ii) [Reserved]

(l) Any system which collects samples following a partial lead service line replacement required by R.61-58.11.F must report the results to the Department within the first ten (10) days of the month following the month in which the system receives the laboratory results, or as specified by the Department. The Department, at its discretion, may eliminate this requirement to report these monitoring results, but water systems shall still retain such records. Systems must also report any additional information as specified by the Department, and in a time and manner prescribed by the Department, to verify that all partial lead service line replacement activities have taken place.

(m) Any system with lead service lines in its inventory must certify on an annual basis that the system has complied with the consumer notification of lead service line materials as specified in R.61-58.11.G(5).

(6) Public Education Program Reporting Requirements:

(a) Any water system that is subject to the public education requirements in ~~Section G~~R.61-58.11.G shall, within ten (10) days after the end of each period in which the system is required to perform public education in accordance with ~~Section G(2)~~R. 61-58.11.G(2) above, send written documentation to the Department that contains:

(i) ~~A demonstration that the system has delivered the public education materials that meet the content requirements in Section G(1) and the delivery requirements in Section G(2); and~~ The public education materials that were delivered, and a demonstration that the water system has delivered the public education materials that meet the content requirements in R.61-58.11.G(1) and the delivery requirements in R.61-58.11.G(2); and

(ii) A list of all the newspapers, radio stations, television stations, and facilities and organizations to which the system delivered public education materials during the period in which the system was required to perform public education tasks.

(b) Unless required by the Department, a system that previously has submitted the information required by paragraph (6)(a)(ii) of this section need not resubmit the information required by paragraph (6)(a)(ii) of this section, as long as there have been no changes in the distribution list and the system certifies that the public education materials were distributed to the same list submitted previously.

(c) No later than three (3) months following the end of the ~~monitoring~~tap sampling period, each water system must mail a sample copy of the consumer notification of tap results to the Department along with a certification that the notification has been distributed in a manner consistent with the requirements of ~~Section~~ R.61-58.11G(4).

(d) Annually by July 1, the water system must demonstrate to the Department that it delivered annual consumer notification and delivered lead service line information materials to affected consumers with a lead, galvanized requiring replacement, or lead status unknown service line in accordance with R.61-58.11.G(5) for the previous calendar year. The water system shall also provide a copy of the notification and information materials to the Department.

(e) Annually by July 1, the water system must demonstrate to the Department that it conducted an outreach activity in accordance with R.61-58.11.G(8) when failing to meet the lead service line replacement goal as specified in R.61-58.11.F(6) for the previous calendar year. The water system shall also submit a copy to the Department of the outreach provided.

(f) Annually, by July 1, the water system must certify to the Department that it delivered notification to affected customers after any lead service line disturbance in accordance with R.61-58.11.G(6) for the previous calendar year. The water system shall also submit a copy of the notification to the Department.

(g) Annually, by July 1, the water system must certify to the Department that it delivered the required find-and-fix information to the Department and local health departments for the previous calendar year.

(7) Reporting of Additional Monitoring Data ~~– Any system which collects sampling data in addition to that required by this section shall report the results to the Department within the first ten (10) days following the end of the applicable monitoring period under Sections H, I and J above, during which the samples are collected.~~ Any water system which collects more samples than the minimum required, shall report the results to the Department within the first ten (10) days following the end of the applicable monitoring period under R.61-58.11.H, R.61-58.11.I, and R.61-58.11.J during which the samples are collected. This includes the monitoring data pertaining to ‘‘find-and-fix’’ pursuant to R.61-58.11.H(8) and R.61-58.11.I(7). The system must certify to the Department the number of customer refusals or nonresponses for follow-up

sampling under R.61-58.11.D(10) it received and information pertaining to the accuracy of the refusals or non-responses, within the first ten (10) days following the end of the applicable tap sampling period in which an individual sample exceeded the action level.

(8) ~~Reporting of 90th percentile lead and copper concentrations where the Department calculates a system's 90th percentile concentrations. A water system is not required to report the 90th percentile lead and copper concentrations measured from among all lead and copper tap water samples collected during each monitoring period, as required by paragraph (1)(a)(iv) of this section if:~~ Reporting of 90th Percentile Lead and Copper Concentrations Where the Department Calculates a Water System's 90th Percentile Concentrations

A water system is not required to report the 90th percentile lead and copper concentrations measured from among all lead and copper tap water samples collected during each tap sampling monitoring period, as required by paragraph (1)(a)(iv) of this section if:

(a) The Department has previously notified the water system that it will calculate the water system's 90th percentile lead and copper concentrations, based on the lead and copper tap results submitted pursuant to paragraph (8)(b)(i) of this section, and ~~has specified a date before the end of the applicable monitoring period by which the system must provide the results of lead and copper tap water samples;~~ the water system provides the results of lead and copper tap water samples no later than ten (10) days after the end of the applicable tap sampling monitoring period;

(b) The system has provided the following information to the Department by the date specified in paragraph (8)(a) of this section:

(i) The results of all tap samples for lead and copper including the location of each site and the criteria under ~~Section H(1)(c), (d), (e), (f), and/or (g) above~~R.61-58.11.H(1)(c) through (j), under which the site was selected for the system's sampling pool~~, pursuant to paragraph (1)(a)(i) of this section~~; and

(ii) An identification of sampling sites utilized during the current tap sampling monitoring period that were not sampled during previous monitoring periods, and an explanation of why sampling sites have changed; and

(c) The Department has provided the results of the 90th percentile lead and copper calculations, in writing, to the water system ~~before the end of the monitoring~~ within fifteen (15) days of the end of the tap sampling period.

(9) Reporting Requirements for a Community Water System's Public Education and Sampling in Schools and Child Care Facilities.

(a) A community water system shall send a report to the Department by July 1 of each year for the previous calendar year's activity. The report must include the following:

(i) Certification that the water system made a good faith effort to identify schools and child care facilities in accordance with R.61-58.11.N(5). The good faith effort may include reviewing customer records and requesting lists of schools and child care facilities from the primacy agency or other licensing agency. A water system that certifies that no schools or child care facilities are served by the water system is not required to include information in paragraphs (9)(a)(ii) through (iv) of this section in the report. If there are changes to schools and child care facilities that a water system serves, an updated list must be submitted at least once every five (5) years in accordance with R.61-58.11.N(5).

(ii) Certification that the water system has delivered information about health risks from lead in drinking water to the school and child care facilities that they serve in accordance with R.61-58.11.N(1)(b) and (7)(a).

(iii) Certification that the water system has completed the notification and sampling requirements of R.61-58.11.N and paragraphs (9)(a)(iii)(A) through (E) of this section at a minimum of twenty percent (20%) of elementary schools and twenty percent (20%) of child care facilities. Certification that the water system has completed the notification and sampling requirements of R.61-58.11.N(7) and paragraphs (9)(a)(iii)(A), (B), and (E) of this section for any secondary school(s) sampled. After a water system has successfully completed one (1) cycle of required sampling in all elementary schools and child care facilities identified in R.61-58.11.N(1)(a), it shall certify completion of the notification and sampling requirements of R.61-58.11.N(7) and paragraphs (9)(a)(iii)(A), (B), and (E) of this section for all sampling completed in any school or child care facility, thereafter.

(A) The number of schools and child care facilities served by the water system;

(B) The number of schools and child care facilities sampled in the calendar year;

(C) The number of schools and child care facilities that have refused sampling;

(D) Information pertaining to outreach attempts for sampling that were declined by the school or child care facility; and

(E) The analytical results for all schools and child care facilities sampled by the water system in the calendar year.

(iv) Certification that sampling results were provided to schools, child care facilities, and local and state health departments.

(b) [Reserved]

(10) Reporting Requirements for Small System Compliance Flexibility Options.

By the applicable dates provided in paragraphs (10)(a) and (b), water systems implementing requirements pursuant to R.61-58.11.O, shall provide the following information to the Department:

(a) Small water systems and non-transient, non-community water systems implementing the point-of-use (POU) device option under R.61-58.11.O(1)(c), shall report the results from the tap sampling required under R.61-58.11.O no later than ten (10) days after the end of the tap sampling monitoring period. If the trigger level is exceeded, the water system must reach out to the homeowner and/or building management within twenty-four (24) hours of receiving the tap sample results. The corrective action must be completed within thirty (30) days. If the corrective action is not completed within thirty (30) days, the system must provide documentation to the Department within thirty (30) days explaining why it was unable to correct the issue. Water systems selecting the POU device option under R.61-58.11.O(1)(c) shall provide documentation to certify maintenance of the POU devices unless the Department waives the requirement of this paragraph (10)(a).

(b) Small community water systems and non-transient, non-community water systems implementing the small system compliance flexibility option to replace all lead-bearing plumbing under R.61-58.11.O(1)(d) must provide certification to the Department that all lead-bearing material has been replaced

on the schedule established by the Department, within one (1) year of designation of the option under R.61-58.11.O(1)(d).

M. Recordkeeping Requirements.

Any system subject to the requirements of this regulation shall retain on its premises original records of all sampling data and analyses, reports, surveys, letters, evaluations, schedules, Department determinations, and any other information required by ~~Sections C through J above~~ R.61-58.11.C through R.61-58.11.J, R.61-58.11.L, R.61-58.11.N, and R.61-58.11.O. Each water system shall retain the records required by this section for no fewer than twelve (12) years.

N. Monitoring for Lead in Schools and Child Care Facilities.

All community water systems must conduct directed public education and lead monitoring at the schools and child care facilities they serve if those schools or child care facilities were constructed prior to January 1, 2014, or the date the state adopted standards that meet the definition of lead free in accordance with Section 1417 of the Safe Drinking Water Act, as amended by the Reduction of Lead in Drinking Water Act, whichever is earlier. Water systems must conduct lead sampling at elementary schools and child care facilities they serve once and on request of the facility thereafter. Water systems shall also conduct lead sampling at secondary schools they serve on request. The provisions of this section do not apply to a school or child care facility that is regulated as a public water system. The provisions in paragraph (1) of this section apply until a water system samples all the elementary schools and child care facilities they serve once as specified in paragraph (3) of this section. Thereafter, water systems shall follow the provisions as specified in paragraph (7) of this section.

(1) Public Education to Schools and Child Care Facilities

(a) By the compliance date specified in R.61-58.11.B(1)(c), each water system must compile a list of schools and child care facilities served by the system.

(b) Each water system must contact elementary schools and child care facilities identified by the system in paragraph (1)(a) of this section to provide:

(i) Information about health risks from lead in drinking water on at least an annual basis consistent with the requirements of R.61-58.11.G(1);

(ii) Notification that the water system is required to sample for lead at elementary schools and child care facilities, including:

(A) A proposed schedule for sampling at the facility;

(B) Information about sampling for lead in schools and child care facilities (EPA's 3Ts for Reducing Lead in Drinking Water Toolkit, EPA–815–B–18–007 or subsequent EPA guidance); and

(C) Instructions for identifying outlets for sampling and preparing for a sampling event thirty (30) days prior to the event.

(c) The water system must include documentation in accordance with R.61-58.11.L(9) if an elementary school or child care facility is non-responsive or otherwise declines to participate in the monitoring or education requirements of this section. For the purposes of this section, a school or child care

facility is non-responsive after the water system makes at least two (2) separate good faith attempts to contact the facility to schedule sampling with no response.

(d) The water system must contact all secondary schools in paragraph (1)(a) of this section on at least an annual basis to provide information on health risks from lead in drinking water and how to request lead sampling as specified in paragraph (7)(a) of this section.

(2) Lead Sampling in Schools and Child Care Facilities

(a) Five (5) samples per school and two (2) samples per child care facility at outlets typically used for consumption shall be collected. Except as provided in paragraphs (2)(a)(i) through (vi) of this section, the outlets shall not have point-of-use (POU) devices. The water system shall sample at the following locations:

(i) For schools: two (2) drinking water fountains, one (1) kitchen faucet used for food or drink preparation, one (1) classroom faucet or other outlet used for drinking, and one (1) nurse's office faucet, as available.

(ii) For child care facilities: one (1) drinking water fountain and one (1) of either a kitchen faucet used for preparation of food or drink or one (1) classroom faucet or other outlet used for drinking.

(iii) If any facility has fewer than the required number of outlets, the water system must sample all outlets used for consumption.

(iv) The water system may sample at outlets with POU devices if the facility has POU devices installed on all outlets typically used for consumption.

(v) If any facility does not contain the type of faucet listed above, the water system shall collect a sample from another outlet typically used for consumption as identified by the facility.

(vi) Water systems must collect the samples from the cold water tap subject to the following additional requirements:

(A) Each sample for lead shall be a first-draw sample;

(B) The sample must be two hundred fifty milliliters (250 ml) in volume;

(C) The water must have remained stationary in the plumbing system of the sampling site (building) for at least eight (8) hours but no more than eighteen (18) hours; and

(D) Samples must be analyzed using acidification and the corresponding analytical methods in R.61-58.11.K.

(b) The water system, school or child care facility, or other appropriately trained individual may collect samples in accordance with paragraph (2)(a) of this section

(3) Frequency of Sampling at Elementary Schools and Child Care Facilities

(a) Water systems shall collect samples from at least twenty percent (20%) of elementary schools served by the system and twenty percent (20%) of child care facilities served by the system per year, or according to a schedule approved by the Department, until all schools and child care facilities identified

under paragraph (1)(a) of this section have been sampled or have declined to participate. For the purposes of this section, a water system may count a refusal or non-response from an elementary school or child care facility as part of the minimum twenty percent (20%) per year.

(b) All elementary schools and child care facilities must be sampled at least once in the five (5) years following the compliance date in R.61-58.11.B(1)(c).

(c) After a water system has completed one (1) required cycle of sampling in all elementary schools and child care facilities, a water system must sample at the request of an elementary school or child care facility in accordance with paragraph (7) of this section.

(d) A water system must sample at the request of a secondary school as specified in paragraph (7) of this section. If a water system receives requests from more than twenty percent (20%) of secondary schools identified in paragraph (1)(a) of this section in any of the five (5) years following the compliance date in R.61-58.11.B(1)(c), the water system may schedule the requests that exceed twenty percent (20%) for the following year and is not required to sample an individual secondary school more than once in the five (5)-year period.

(4) Alternative School and Child Care Lead Sampling Programs

(a) If mandatory sampling for lead in drinking water is conducted for schools and child care facilities served by a community water system due to state or local law or program, the Department may exempt the water system from the requirements of this section by issuing a written waiver:

(i) If the sampling is consistent with the requirements in paragraphs (2) and (3) of this section; or

(ii) If the sampling is consistent with the requirements in paragraphs (2)(a)(i) through (vi) and (3) of this section and it is coupled with any of the following remediation actions:

(A) Disconnection of affected fixtures;

(B) Replacement of affected fixtures with fixtures certified as lead free; and

(C) Installation of POU devices; or

(iii) If the sampling is conducted in schools and child care facilities served by the system less frequently than once every five (5) years and it is coupled with any of the remediation actions specified in paragraph (4)(a)(ii) of this section; or

(iv) If the sampling is conducted under a grant awarded under Section 1464(d) of the SDWA, consistent with the requirements of the grant.

(b) The duration of the waiver may not exceed the time period covered by the mandatory or voluntary sampling and will automatically expire at the end of any twelve (12)-month period during which sampling is not conducted at the required number of schools or child care facilities.

(c) The Department may issue a partial waiver to the water system if the sampling covers only a subset of the schools or child care facilities served by the system as designated under paragraph (1)(a) of this section.

(d) The Department may issue a written waiver applicable to more than one (1) system (e.g., one (1) waiver for all systems subject to a statewide sampling program that meets the requirements of paragraph (4) of this section).

(5) Confirmation or Revision of Schools and Child Care Facilities in Inventory

A water system shall either confirm that there have been no changes to its list of schools and child care facilities served by the system developed pursuant to paragraph (1)(a) of this section, or submit a revised list at least once every five (5) years.

(6) Notification of results

(a) A water system must provide analytical results as soon as practicable but no later than thirty (30) days after receipt of the results to the school or child care facility, along with information about remediation options.

(b) A water system must provide analytical results annually to:

(i) The local and state health department; and

(ii) The Department in accordance with R.61-58.11.L(9).

(7) Lead Sampling in Schools and Child Care Facilities on Request

(a) A water system must contact schools and child care facilities identified in paragraph (1)(a) of this section on at least an annual basis to provide:

(i) Information about health risks from lead in drinking water;

(ii) Information about how to request sampling for lead at the facility; and

(iii) Information about sampling for lead in schools and child care facilities (EPA's 3Ts for Reducing Lead in Drinking Water Toolkit, EPA–815–B–18–007, or subsequent EPA guidance).

(b) A water system must conduct sampling as specified in paragraph (2) of this section when requested by the facility and provide:

(i) Instructions for identifying outlets for sampling and preparing for a sampling event at least thirty (30) days prior to the event; and

(ii) Results as specified in paragraph (6) of this section.

(c) If a water system receives requests from more than twenty percent (20%) of the schools and child care facilities identified in paragraph (1)(a) of this section in a given year, the water system may schedule sampling for those that exceed twenty percent (20%) for the following year. A water system is not required to sample an individual school or child care facility more than once every five (5) years.

(d) If voluntary sampling for lead in drinking water is conducted for schools and child care facilities served by a community water system that meets the requirements of this section, the Department may exempt the water system from the requirements of this section by issuing a written waiver in accordance with paragraph (4) of this section.

O. Small Water System Compliance Flexibility.

The compliance alternatives described in this section apply to small community water systems serving 10,000 or fewer persons and all non-transient, non-community water systems. Small community water systems and non-transient, non-community water systems with corrosion control treatment in place must continue to operate and maintain optimal corrosion control treatment (OCCT) until the Department determines, in writing, that it is no longer necessary, and meet any requirements that the Department determines to be appropriate before implementing a Department-approved compliance option described in this section.

(1) A small community water system and non-transient, non-community water systems that exceeds the lead trigger level but does not exceed the lead and copper action levels must collect water quality parameters in accordance with R.61-58.11.I(2) and evaluate compliance options in paragraphs (1)(a) through (d) of this section and make a compliance option recommendation to the Department within six (6) months of the end of the tap sampling period in which the exceedance occurred. The Department must approve the recommendation or designate an alternative from compliance options in paragraphs (1)(a) through (d) of this section within six (6) months of the recommendation by the water system. If the water system subsequently exceeds the lead action level it must implement the approved compliance option as specified in paragraph (2) of this section. Water systems must select from the following compliance options:

(a) Lead service line replacement

A water system must implement a full lead service line replacement program on a schedule approved by the Department but not to exceed fifteen (15) years. A water system must begin lead service line replacement within one (1) year after the Department's approval or designation of the compliance option.

(i) Lead service line replacement must be conducted in accordance with the requirements of R.61-58.11.F(5) and (7)(d), (h), and (i).

(ii) A water system must continue lead service line replacement even if the system's 90th percentile lead level is at or below the action level in future tap sampling monitoring periods.

(iii) A water system must have no lead service lines, galvanized service lines requiring replacement, or ''Lead status unknown'' service lines in its inventory by the end of its lead service line replacement program.

(b) Corrosion control treatment

A water system must install and maintain optimal corrosion control treatment in accordance with R.61-58.11.C and R.61-58.11.D, even if its 90th percentile is at or below the action level in future tap sampling monitoring periods. Any water system that has corrosion control treatment installed must re-optimize its corrosion control treatment in accordance with R.61-58.11.C(4). Water systems required by the Department to optimize or re-optimize corrosion control treatment must follow the schedules in R.61-58.11.C(4) or (5), beginning with Step 3 in paragraph (4)(c) or (5)(c) of R.61-58.11.C unless the Department specifies optimal corrosion control treatment pursuant to either R.61-58.11.C(4)(b)(ii) or (5)(b)(i) or (ii), as applicable.

(c) Point-of-use devices

A water system must install, maintain, and monitor POU devices in each household or building even if its 90th percentile is at or below the action level in future tap sampling monitoring periods.

(i) Location Requirements

(A) A community water system must install a minimum of one (1) POU device (at one (1) tap) in every household and at every tap that is used for cooking and/or drinking in every non-residential building in its distribution system on a schedule specified by the Department, but not to exceed one (1) year.

(B) A non-transient, non-community water system must provide a POU device to every tap that is used for cooking and/or drinking on a schedule specified by the Department, but not to exceed three (3) months.

(ii) The POU device must be independently certified by a third party to meet the American National Standards Institute standard applicable to the specific type of POU unit to reduce lead in drinking water.

(iii) The POU device must be maintained by the water system according to manufacturer's recommendations to ensure continued effective filtration, including, but not limited to, changing filter cartridges and resolving any operational issues. The POU device must be equipped with mechanical warnings to ensure that customers are automatically notified of operational problems. The water system shall provide documentation to the Department to certify maintenance of the POU devices, unless the Department waives this requirement, in accordance with R.61-58.11.L(10)(a).

(iv) The water system must monitor one-third of the POU devices each year and all POU devices must be monitored within a three (3)-year cycle. First-draw tap samples collected under this section must be taken after water passes through the POU device to assess its performance. Samples must be one-liter (1 L) in volume and have had a minimum six (6)-hour stagnation time. All samples must be at or below the lead trigger level. The water systems must report the results from the tap sampling no later than ten (10) days after the end of the tap sampling monitoring period in accordance with R.61-58.11.L(10)(a). The system must document the problem and take corrective action at any site where the sample result exceeds the lead trigger level. If the trigger level is exceeded, the water system must reach out to the homeowner and/or building management no later than twenty-four (24) hours of receiving the tap sample results. The corrective action must be completed within thirty (30) days. If the corrective action is not completed within thirty (30) days, the system must provide documentation to the Department within thirty (30) days explaining why it was unable to correct the issue.

(v) The water system must provide public education to consumers in accordance with R.61-58.11.G(10) to inform them on proper use of POU devices to maximize the units' lead level reduction effectiveness.

(vi) The water system must operate and maintain the POU devices until the system receives Department approval to select one of the other compliance flexibility options and implements it.

(d) Replacement of lead-bearing plumbing

A water system that has control over all plumbing in its buildings, and no unknown, galvanized, or lead service lines, must replace all plumbing that is not lead free in accordance with Section 1417 of the Safe Drinking Water Act, as amended by the Reduction of Lead in Drinking Water Act and any future amendments applicable at the time of replacement. The replacement of all lead-bearing plumbing must occur on a schedule established by the Department but not to exceed one (1) year. Water systems must

provide certification to the Department that all lead-bearing material has been replaced in accordance with R.61-58.11.L(10)(b).

(2)(a) A water system that exceeds the lead action level after exceeding the lead trigger level but does not exceed the copper action level must implement the compliance option approved by the Department under paragraph (1) of this section.

(b) A water system that exceeds the lead action level, but has not previously exceeded the lead trigger level, and does not exceed the copper action level must complete the provisions in paragraph (1) of this section and must implement the compliance option approved by the Department under paragraph (1) of this section.

(c) A water system that exceeds the trigger level after it has implemented a compliance option approved by the Department under paragraph (1) of this section, must complete the steps in paragraph (1) and if it thereafter exceeds the action level, it must implement the compliance option approved by the Department under paragraph (1) of this section.

Amend R.61-58.12.C.4 to read:

(4) Information on Detected Contaminants.

(a) This sub-section specifies the requirements for information to be included in each report for contaminants subject to mandatory monitoring (except Cryptosporidium). It applies to:

(i) Contaminants subject to an MCL, action level, maximum residual disinfectant level or treatment technique (regulated contaminants);

(ii) Contaminants for which monitoring is required by R.61-58.5.T, Special Monitoring for Inorganic and Organic Contaminants (unregulated contaminants); and

(iii) Disinfection by-products or microbial contaminants for which monitoring is required by Secs. 141.142 and 141.143 (Information Collection Rule for disinfection by-products (DBP) and Microbials (ICR)), of the National Primary Drinking Water Regulations (NPDWR), and which are detected in the finished water.

(b) The data relating to these contaminants shall be displayed in one table or in several adjacent tables. Any additional monitoring results which a community water system chooses to include in its report shall be displayed separately.

(c) The data shall be derived from data collected to comply with EPA and Department monitoring and analytical requirements during calendar year 1998 for the first report and subsequent calendar years thereafter except that:

(i) Where a system is allowed to monitor for regulated contaminants less often than once a year, the table(s) shall include the date and results of the most recent sampling and the report shall include a brief statement indicating that the data presented in the report are from the most recent testing done in accordance with the regulations. No data older than 5 years need be included.

(ii) Results of monitoring in compliance with the ICR (Secs. 141.142 and 141.143 of the NPDWR), need only be included for 5 years from the date of last sample or until any of the detected contaminants becomes regulated and subject to routine monitoring requirements, whichever comes first.

(d) For detected regulated contaminants (listed in Appendix D to this regulation), the table(s) shall contain:

(i) The MCL for that contaminant expressed as a number equal to or greater than 1.0 (as provided in Appendix D to this regulation);

(ii) The MCLG for that contaminant expressed in the same units as the MCL;

(iii) If there is no MCL for a detected contaminant, the table shall indicate that there is a treatment technique, or specify the action level, applicable to that contaminant, and the report shall include the definitions for treatment technique and/or action level, as appropriate, specified in paragraph(3)(c) of this section;

(iv) For contaminants subject to an MCL, except turbidity, total coliforms, fecal coliform and E.coli, the highest contaminant level used to determine compliance with R.61-58.5, Maximum Contaminant Levels in Drinking Water, and the range of detected levels, as follows:

(A) When compliance with the MCL is determined annually or less frequently: The highest detected level at any sampling point and the range of detected levels expressed in the same units as the MCL.

(B) When compliance with the MCL is determined by calculating a running annual average of all samples taken at a monitoring location: the highest average of any of the monitoring locations and the range of all monitoring locations expressed in the same units as the MCL. For the MCLs for TTHM and HAA5 in R.61 58.5.P(2)(b), systems must include the highest locational running annual average for TTHM and HAA5 and the range of individual sample results for all monitoring locations expressed in the same units as the MCL. If more than one location exceeds the TTHM or HAA5 MCL, the system must include the locational running annual averages for all locations that exceed the MCL.

(C) When compliance with the MCL is determined on a system wide basis by calculating a running annual average of all samples at all monitoring locations: the average and range of detection expressed in the same units as the MCL. The system is required to include individual sample results for the IDSE conducted under R.61 58.14 when determining the range of TTHM and HAA5 results to be reported in the annual consumer confidence report for the calendar year that the IDSE samples were taken.

Note to paragraph (4)(d)(iv): When rounding of results to determine compliance with the MCL is allowed by the regulations, rounding should be done prior to multiplying the results by the factor listed in Appendix D of this regulation;

(v) For turbidity.

(A) When it is reported pursuant to the requirements of R.61- 58.10.C, Filtration and Disinfection [criteria for avoiding filtration]: the highest monthly value. The report should include an explanation of the reasons for measuring turbidity.

(B) When it is reported pursuant to R.61-58.10.E, Filtration and Disinfection [filtration], or R.61-58.10.H(4): The highest single measurement and the lowest monthly percentage of samples meeting the turbidity limits specified in R.61-58.10.E, Filtration, or R.61-58.10.H(4): for the filtration technology being used. The report should include an explanation of the reasons for measuring turbidity;

(C) When it is reported pursuant to R.61-58.10.E or R.61-58.10.H(4) or R.61-58.10.I(6): the highest single measurement and the lowest monthly percentage of samples meeting the turbidity limits specified in R.61-58.10.E or R.61-58.10.H(4) or R.61-58.10.I(6) for the filtration technology being used. The report should include an explanation of the reasons for measuring turbidity.

(vi) For lead and copper: the 90th percentile ~~value~~ concentration of the most recent round(s) of sampling, ~~and~~ the number of sampling sites exceeding the action level, and the range of tap sampling results;

(vii) For total coliform analytical results until March 31, 2016:

(A) The highest monthly number of positive samples for systems collecting fewer than forty (40) samples per month; or

(B) The highest monthly percentage of positive samples for systems collecting at least forty (40) samples per month.

(viii) For fecal coliform and E.coli. until March 31, 2016: The total number of positive samples;

(ix) The likely source(s) of detected contaminants to the best of the operator's knowledge. Specific information regarding contaminants may be available in sanitary surveys and source water assessments, and should be used when available to the operator. If the operator lacks specific information on the likely source, the report shall include one or more of the typical sources for that contaminant listed in Appendix D to this regulation which are most applicable to the system~~.~~;

(x) For E.coli analytical results under R.61-58.17: The total number of positive samples~~.~~;

(xi) The report shall include a statement that a service line inventory (including inventories consisting only of a statement that there are no lead service lines) has been prepared and include instructions to access the service line inventory; and

(xii) The report shall notify consumers that complete lead tap sampling data are available for review and shall include information on how to access the data.

Amend R.61-58.12.D.4(a) to read:

(4) Every report must include the following lead-specific information:

(a) A short informational statement about lead in drinking water and its effects on children. The statement must include the following information: ~~If present, elevated levels of lead~~ Lead can cause serious health problems, especially for pregnant women and young children. Lead in drinking water is primarily from materials and components associated with service lines and home plumbing. [NAME OF UTILITY] is responsible for providing high quality drinking water and removing lead pipes, but cannot control the variety of materials used in plumbing components in your home. ~~When your water has been sitting for several hours, you can minimize the potential for lead exposure by flushing your tap for 30 seconds to 2 minutes before using water for drinking or cooking. If you are concerned about lead in your water, you may wish to have your water tested. Information on lead in drinking water, testing methods, and steps you can take to minimize exposure is available from the Safe Drinking Water Hotline or http://www.epa.gov/safewater/lead.~~ You share the responsibility for protecting yourself and your family from the lead in your home plumbing. You can take responsibility by identifying and removing lead materials within your home plumbing and taking steps to reduce your family's risk. Before drinking tap water, flush your pipes for several minutes by running your tap, taking a shower, doing laundry, or a load

of dishes. You can also use a filter certified by an American National Standards Institute accredited certifier to reduce lead in drinking water. If you are concerned about lead in your water and wish to have your water tested, contact [NAME OF UTILITY and CONTACT INFORMATION]. Information on lead in drinking water, testing methods, and steps you can take to minimize exposure is available at http://www.epa.gov/safewater/lead.

Amend R.61-58.12. Appendix D to read:

APPENDIX D. CONSUMER CONFIDENCE REPORTS: REGULATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Microbiological contaminants:						
Total Coliform Bacteria†	MCL: (systems that collect ≥ 40 samples/month) 5% of monthly samples are positive; (systems that collect <40 samples/month) 1 positive monthly sample.		MCL: (systems that collect ≥40 samples/month) 5% of monthly samples are positive; (systems that collect <40 samples/month) 1 positive monthly sample.	0	Naturally present in the environment	Coliforms are bacteria that are naturally present in the and are used as an indicator that other, potentially harmful bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
Total Coliform Bacteria‡	TT			N/A	Naturally present in the environment	Use language in R.51-58.12. C(11)(g)(i)(A)
Fecal coliform and E. coli†	0		0	0	Human and animal fecal waste	Fecal coliforms and E. Coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely-compromised immune systems.
E. coli‡	Routine and repeat samples are total coliform-positive and either is E. coli-positive or		Routine and repeat samples are total coliform-positive and either is E.	0	Human and animal fecal waste	E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
	system fails to take repeat samples following E. coli-positive routine sample or system fails to analyze total coliform-positive repeat sample for E. coli		coli-positive or system fails to take repeat samples following E. coli-positive routine sample or system fails to analyze total coliform-positive repeat sample for E. coli			diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely-compromised immune systems.
Fecal Indicators (enterococci or coliphage).	TT		TT	N/A	Human and animal fecal waste.	Fecal indicators are microbes whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
Total organic carbon (ppm)	TT		TT	N/A	Naturally present	Total organic carbon (TOC) has no health effects. However, total organic carbon in the environment provides a medium for the formation of disinfection by-products. These byproducts include trihalomethanes (THMs) and haloacetic acids (HAAs). Drinking water containing these by-products in excess of the MCL may lead to adverse health effects, liver or kidney problems, or nervous system effects, and may lead to an increased risk of getting cancer.
Turbidity (NTU)	TT		TT	N/A	Soil runoff	Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate the presence of disease-causing organisms.

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						These organisms include bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea and associated headaches.
Radioactive contaminants:						
Beta/photon emitters (mrem/yr)	4 mrem/yr		4	N/A	Decay of natural and man-made deposits.	Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta and photon in excess of the MCL over many years may have an increased risk of getting cancer.
Alpha emitters (pCi/L)	15 pCi/L		15	N/A	Erosion of natural deposits.	Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer.
Combined radium (pCi/L)	5 pCi/L		5	N/A	Erosion of natural deposits.	Some people who drink water containing radium-226 or 228 in excess of the MCL over many years may have an increased risk of getting cancer.
Uranium (pCi/L)	30 µg/L		30	0	Erosion of natural deposits.	Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk getting cancer and kidney toxicity.
Inorganic contaminants:						
Antimony (ppb)	.006	1000	6	6	Discharge from petroleum refineries; fire retardants; ceramics; electronics; solder.	Some people who drink water containing antimony well in excess of the MCL over many years could experience increases in blood cholesterol and decreases in blood sugar.
Arsenic (ppb)	10.010	1000	110.	10	Erosion of natural deposits; Runoff from orchards; Runoff from glass and electronics production wastes.	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						may have an increased risk of getting cancer.
Asbestos (MFL)	7 MFL		7	7	Decay of asbestos cement water mains; production wastes; erosion of natural deposits.	Some people who drink water containing asbestos in excess of the MCL over many years may have an increased risk of developing benign intestinal polyps.
Barium (ppm)	2		2	2	Discharge of drilling; wastes; Discharge from metal refineries; Erosion ofnatural deposits.	Some people who drink water containing barium in of the MCL over many years could experience an increase in their blood pressure.
Beryllium (ppb)	.004	1000	4	4	Discharge from metal refineries and coal-burning factories; Discharge from electrical, aerospace, and defense industries	Some people who drink water containing beryllium well in excess of the MCL over many years could develop intestinal lesions
Bromate (ppb)	.010	1000	10	0	By-product of drinking water chlorination.	Some people who drink water containing bromate in excess of the MCL over many years may have an increased risk of getting cancer.
Cadmium (ppb)	.005	1000	5	5	Corrosion of galvanized pipes; Erosion of natural deposits; Discharge from metal refineries; Runoff from waste batteries and paints.	Some people who drink water containing cadmium in excess of the MCL over many years could experience kidney damage.
Chloramines (ppm)	MRDL = 4		MRDL = 4	MRDLG = 4	Water additive used to control microbes.	Some people who use water containing chloramines well in excess of the MRDL could experience irritating to their eyes and nose. Some people who drink water containing chloramines well in excess of the MRDL could experience stomach discomfort or anemia.
Chlorine (ppm)	MRDL = 4		MRDL = 4	MRDLG = 4	Water additive used to control microbes	Some people who use water containing chlorine well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chlorine well in excess of the MRDL could

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						experience stomach discomfort.
Chlorine dioxide (ppb)	MRDL = .8	1000	MRDL = 800	MRDLG = 800	Water additive used to control microbes	Some infants and young children who drink water containing chlorine dioxide in excess of the MRDL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia.
Chlorite (ppm)	1		1	0.8	By-product of drinking water chlorination.	Some infants and young children who drink water containing chlorite in excess of the MCL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorite in excess of the MCL. Some people may experience anemia.
Chromium (ppb)	.1	1000	100	100	Discharge from steel and pulp; mills; Erosion of Natural deposits.	Some people who use water containing chromium well in excess of the MCL over many years could experience allergic dermatitis.
Copper (ppm)	AL=1.3		AL=1.3	1.3	Corrosion of household plumbing. Erosion of natural deposits.	Copper is an essential nutrient, but some people who drink water containing copper in excess of the action level over a relatively short amount of time could experience gastrointestinal distress. Some people who drink water containing copper in excess of the action level over many years could suffer liver or kidney damage. People with Wilson's Disease should consult their personal doctor.
Cyanide (ppb)	2	1000	200	200	Discharge from steel/metal factories; Discharge from plastic and fertilizer factories.	Some people who drink water containing cyanide well in excess of the MCL over many years could experience nerve damage or problems with their thyroid.
Fluoride (ppm)	4		4	4	Erosion of natural deposits; Water additive which	Some people who drink water containing fluoride in excess of the MCL over

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
					promotes strong teeth Discharge from fertilizer and aluminum factories	many years could get bone disease, including pain and tenderness of the bones. Fluoride in drinking water at half the MCL or more may cause mottling of children's teeth, usually in children less than nine years old. Mottling, also known as dental fluorosis, may include brown staining and/or pitting of the teeth, and occurs only in developing teeth before they erupt from the gums.
Lead ~~(ppb)~~	AL=.015	1000	AL=15	0	Corrosion of household plumbing systems; Erosion of natural deposits	~~Infants and children who drink water containing lead in excess of the action level could experience delays in their physical or mental development. Children could show slight deficits in attention span and learning abilities. Adults who drink this water over many years could develop kidney problems or high blood pressure.~~ Exposure to lead in drinking water can cause serious health effects in all age groups. Infants and children can have decreases in IQ and attention span. Lead exposure can lead to new learning and behavior problems or exacerbate existing learning and behavior problems. The children of women who are exposed to lead before or during pregnancy can have increased risk of these adverse health effects. Adults can have increased risks of heart disease, high blood pressure, kidney or nervous system problems.
Mercury [inorganic] (ppb)	.002	1000	2	2	Erosion of natural deposits;discharge from refineries and factories; Runoff from landfills; Runoff from cropland.	Some people who drink water containing inorganic mercury well in excess of the MCL over many years could experience kidney damage
Nitrate (ppm)	10		10	10	Runoff from fertilizer use;	Infants below the age of six months who drink water

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
					Leaching from septic tanks, sewage; Erosion of natural deposits.	containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
Nitrite (ppm)	1		1	1	Runoff from fertilizer use; Leaching from septic tanks sewage; Erosion of natural deposits	Infants below the age of six months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
Selenium (ppb)	.05	1000	50	50	Discharge from petroleum and metal refineries; Erosion of natural deposits; Discharge from mines.	Selenium is an essential nutrient. However, some people who drink water containing selenium in excess of the MCL over many years could experience hair or fingernail losses, numbness in fingers or toes, or problems with their circulation
Thallium (ppb)	.002	1000	2	0.5	Leaching from ore-processing sites; Discharge from electronics, glass, and drug factories.	Some people who drink water containing thallium in excess of the MCL over many years could experience hair loss, changes in their blood, or problems with their kidneys, intestines, or liver.
Synthetic organic contaminants including pesticides and herbicides:						
2,4-D (ppb)	.07	1000	70	70	Runoff from herbicide used on row crops.	Some people who drink water containing the weed killer 2,4-D well in excess of the MCL over many years could experience problems with their kidneys, liver, or adrenal glands.
2,4,5-TP [Silvex](ppb)	.05	1000	50	50	Residue of banned herbicide	Some people who drink water containing silvex in excess of the MCL over many years could experience liver problems.
Acrylamide	TT		TT	0	Added to water during sewage/ wastewater treatment.	Some people who drink water containing high levels of acrylamide over a long period of time could have problems with their nervous system or blood, and may have risk of getting cancer.

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Alachlor (ppb)	.002	1000	2	0	Runoff from herbicide used on row crops.	Some people who drink water containing alachlor in excess of the MCL over many years could have problems with their eyes, liver, kidneys, or spleen, or experience anemia, and may have an increased risk of getting cancer.
Atrazine (ppb)	.003	1000	3	3	Runoff from herbicide used on row crops.	Some people who drink water containing atrazine well in excess of the MCL over many years could experience problems with their cardiovascular system or reproductive difficulties.
Benzo(a)pyrene [PAH] (nanograms/l).	.0002	1,000,000	200	0	Leaching from linings of water storage tanks distribution lines.	Some people who drink water containing benzo(a)pyrene in excess of the MCL over many years may experience reproductive difficulties and may have an increased risk of getting cancer.
Carbofuran (ppb)	.04	1000	40	40	Leaching of soil fumigant used on rice and alfalfa.	Some people who drink carbofuran in excess of the MCL over many years could experience problems with their blood, or nervous or reproductive systems.
Chlordane (ppb)	.002	1000	2	0	Residue of banned termiticide	Some people who drink water containing chlordane in excess of the MCL over many years could experience problems with their liver or nervous system, and may have an increased risk of getting cancer.
Dalapon (ppb)	.2	1000	200	200	Runoff from herbicide used on rights of way.	Some people who drink water containing dalapon well in excess of the MCL over many years could experience minor kidney changes.
Di(2-ethylhexyl) adipate (ppb).	.4	1000	400	400	Discharge from chemical factories.	Some people who drink water containing di(2-ethylhexyl) adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement or possible reproductive difficulties.
Di(2-ethylhexyl) phthalate (ppb).	.006	1000	6	0	Discharge from rubber and chemical factories.	Some people who drink water containing di(2-ethylhexyl) phthalate well in excess of the MCL over many years may have

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer.
Dibromochloropropane (ppt)	.0002	1,000,000	200	0	Runoff/leaching from soil fumigant used on soybeans, cotton, pineapples, and orchards.	Some people who drink water containing DBCP in excess of the MCL over many years could experience reproductive problems and may have an increased risk of getting cancer.
Dinoseb (ppb)	.007	1000	7	7	Runoff from herbicide used on soybeans and vegetables.	Some people who drink water containing dinoseb well in excess of the MCL over many years could experience reproductive difficulties.
Diquat (ppb)	.02	1000	20	20	Runoff from herbicide use.	Some people who drink water containing diquat in excess of the MCL over many years could get cataracts.
Dioxin [2,3,7,8-TCDD] (ppq).	.00000003	1,000,000,000	30	0	Emissions from waste incineration and other combustion; Discharge from chemical factories.	Some people who drink water containing dioxin in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
Endothall (ppb)	.1	1000	100	100	Runoff from herbicide use.	Some people who drink water containing endothall in excess of the MCL over many years could experience problems with their stomach or intestines.
Endrin (ppb)	.002	1000	2	2	Residue of banned insecticide.	Some people who drink water containing endrin in excess of the MCL over many years could experience liver problems.
Epichlorohydrin.	TT		TT	0	Discharge from industrial chemical factories; An impurity of some water treatment chemicals.	Some people who drink water containing high levels of epichlorohydrin over a long period of time could experience stomach problems, and may have an increased risk of getting cancer.
Ethylene dibromide (ppt)	.00005	1,000,000	50	0	Discharge from petroleum refineries.	Some people who drink water containing ethylene dibromide in excess of the MCL over many years could experience problems with their liver, stomach, reproductive system, or kidneys, and may have an

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						increased risk of getting cancer.
Glyphosate (ppb)	.7	1000	700	700	Runoff from herbicide use	Some people who drink water containing glyphosate in excess of the MCL over many years could experience problems with their kidneys or reproductive difficulties.
Heptachlor (ppt)	.0004	1,000,000	400	0	Residue of banned pesticide.	Some people who drink water containing heptachlor in excess of the MCL over many years could experience liver damage and may have an increased risk of getting cancer.
Heptachlor epoxide (ppt)	.0002	1,000,000	200	0	Breakdown of heptachlor.	Some people who drink water containing heptachlor epoxidein excess of the MCL over many years could experience liver damage, and may have an increased risk of getting cancer.
Hexachlorobenzene (ppb)	.001	1000	1	0	Discharge from metal refineries and agricultural chemical factories.	Some people who drink water containing Hexachlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys, or adverse reproductive effects and may have an increased risk of getting cancer
Hexachlorocyclopentadiene (ppb)	.05	1000	50	50	Discharge from chemical factories	Some people who drink water containing hexachlorocyclopentadiene well in excess of the MCL over many years could experience problems with their kidneys or stomach.
Lindane (ppt)	.0002	1,000,000	200	200	Runoff/leaching from insecticide used on cattle, lumber, gardens.	Some people who drink water containing lindane in excess of the MCL over many years could experience problems with their kidneys or liver.
Methoxychlor (ppb)	.04	1000	40	40	Runoff/leaching from insecticide used on fruits, vegetables, alfalfa, livestock.	Some people who drink water containing methoxychlor in excess of the MCL over many years could experience reproductive difficulties
Oxamyl [Vydate] (ppb)	.2	1000	200	200	Runoff/leaching from insecticide used on apples	Some people who drink water containing oxamyl in excess of the MCL over many years could

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
					potatoes and tomatoes.	experience slight nervous system effects.
PCBs [Polychlorinated biphenyls] (ppt).	.0005	1,000,000	500	0	Runoff from landfills Discharge of waste chemicals	Some people who drink water containing PCBs in excess of the MCL over many years could experience changes in their skin, problems with their thymus gland, immune deficiencies, or reproductive or nervous system difficulties, and may have an increased risk of getting cancer.
Pentachlorophenol (ppb)	.001	1000	1	0	Discharge from wood preserving factories	Some people who drink water containing pentachlorophenolin excess of the MCL over many years could experience problems with their liver or kidneys, and may have an increased risk of getting cancer.
Picloram (ppb)	.5	1000	500	500	Herbicide runoff	Some people who drink water containing picloram in excess of the MCL over many years could experience problems with their liver.
Simazine (ppb)	.004	1000	4	4	Herbicide runoff	Some people who drink water containing simazine in excess of the MCL over many years could experience problems with their blood.
Toxaphene (ppb)	.003	1000	3	0	Runoff/leaching from insecticide used on cotton and cattle.	Some people who drink water containing toxaphene in excess of the MCL over many years could have problems with their kidneys, liver, or thyroid, and may have an increased risk of getting cancer
Volatile organic contaminants:						
Benzene (ppb)	.005	1000	5	0	Discharge from factories; Leaching from gas storage tanks and landfills.	Some people who drink water containing benzene in excess of the MCL over many years could experience anemia or a decrease in blood platelets, and may have an increased risk of getting cancer.
Carbon tetrachloride (ppb)	.005	1000	5	0	Discharge from chemical plants and other industrial activities.	Some people who drink water containing carbon tetrachloride in excess of the MCL over many years could experience problems

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						with in their liver and may have an increased risk of getting cancer.
Chlorobenzene (ppb)	.1	1000	100	100	Discharge from chemical and agricultural chemical factories	Some people who drink water containing chlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys.
o-Dichlorobenzene (ppb)	.6	1000	600	600	Discharge from industrial chemical	Some people who drink water containing o-dichlorobenzene well in excess of the MCL over liver, kidneys, or circulatory systems.
p-Dichlorobenzene (ppb)	.075	1000	75	75	Discharge from industrial chemical factories	Some people who drink water containing p-dichlorobenzene in excess of the MCL over many years could experience anemia, damage to their liver, kidneys, or spleen, or changes in their blood.
1,2-Dichloroethane (ppb)	.005	1000	5	0	Discharge from industrial chemical factories.	Some people who drink water containing 1,2-dichloroethane in excess of the MCL over many years may have an increased risk of getting cancer
1,1-Dichloroethylene (ppb)	.007	1000	7	7	Discharge from industrial chemical factories.	Some people who drink water containing 1,1-dichloroethylene in excess of the MCL over many years could experience problems with their liver.
cis-1,2-Dichloroethylene (ppb)	.07	1000	70	70	Discharge from industrial chemical factories.	Some people who drink water containing cis-1,2-dichloroethy -lene in excess of the MCL over many years could experience problems with their liver.
trans-1,2-Dichloroethylene (ppb).	.1	1000	100	10	Discharge from industrial chemical factories.	Some people who drink water containing trans-1,2-dichloro-ethy lene well in excess of the MCL over many years could experience problems with their liver.
Dichloromethane (ppb)	.005	1000	5	0	Discharge from pharmaceutical and chemical factories	Some people who drink water containing dichloromethane in excess of the MCL over many years could have liver problems and may have an increase risk of getting cancer.
1,2-Dichloropropane (ppb)	.005	1000	5	0	Discharge from industrial	Some people who drink water containing 1,2-

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
					chemical factories.	Dichloropropane excess of the MCL over many years may have an increased risk of getting cancer.
Ethylbenzene (ppb)	.7	1000	700	700	Discharge from petroleum refineries.	Some people who drink water containing ethylbenzene well in excess of the MCL over many years could experience problems with their liver or kidneys.
Haloacetic Acids (HAA) (ppb).	.060	1000	60	N/A	By-product of drinking water disinfection.	Some people who drink water containing haloacetic acids in excess of the MCL over many years may have an increased risk of getting cancer.
Styrene (ppb)	.1	1000	100	100	Discharge from rubber and plastic factories and leaching from landfills.	Some people who drink water containing styrene well in excess of the MCL over many years could have problems with their liver, kidneys or circulatory system.
Tetrachloroethylene (ppb)	.005	1000	5	0	Discharge from factories and dry cleaners.	Some people who drink water containing tetrachloroethylene in excess of the MCL over many years could have problems with their liver, and may have an increased risk of getting cancer.
1,2,4-Trichlorobenzene (ppb)	.07	1000	70	70	Discharge from textile-finishing factories.	Some people who drink water containing 1,2,4-trichlorobenzene well in excess of the MCL over many years could experience changes in their adrenal glands.
1,1,1-Trichloroethane (ppb)	.2	1000	200	200	Discharge from metal degreasing sites and other factories.	Some people who drink water containing 1,1,1-trichloroethane in excess of the MCL over many years could experience problems with their liver, nervous system, or circulatory system.
1,1,2-Trichloroethane (ppb).	.005	1000	5	3	Discharge from industrial chemical factories.	Some people who drink water containing 1,1,2-trichloroethane well in excess of the MCL over many years could have problems with their liver, kidneys, or immune systems.
Trichloroethylene (ppb)	.005	1000	5	0	Discharge from metal degreasing sites and other factories	Some people who drink water containing trichloroethylene in excess of the MCL over many

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
						years could experience problems with their liver and may have an increased risk of getting cancer.
TTHMs [Total trihalomethanes] (ppb)	0.10/.080	1000	100/80	N/A	By-product of drinking water disinfection.	Some people who drink water containing trihalomethanes in excess of the MCL over many years may experience problems with their liver, kidneys, or central nervous systems, and may have an increased risk of getting cancer.
Toluene (ppm)	1		1	1	Discharge from petroleum factories.	Some people who drink water containing toluene well in excess of the MCL over many years could have problems with their nervous system, kidneys, or liver.
Vinyl Chloride (ppb)	.002	1000	2	0	Leaching from PVC piping; Discharge from from plastics factories.	Some people who drink water containing vinyl chloride in excess of the MCL over many years may have an increased risk of getting cancer.
Xylenes (ppm)	10		10	10	Discharge from petroleum factories; Discharge from chemical factories.	Some people who drink water containing xylenes in excess of the MCL over many years could experience damage to their nervous system.

Key:
AL=Action Level
MCL=Maximum Contaminant Level
MCLG=Maximum Contaminant Level Goal
MFL=million fibers per liter
MRDL=Maximum Residual Disinfectant Level
MRDLG=Maximum Residual Disinfectant Level Goal
mrem/year=millirems per year (a measure of radiation absorbed by the body)
N/A=Not Applicable
NTU=Nephelometric Turbidity Units (a measure of water clarity)
pCi/l=picocuries per liter (a measure of radioactivity)
ppm=parts per million, or milligrams per liter (mg/L)
ppb=parts per billion, or micrograms per liter (µg/l)
ppt=parts per trillion, or nanograms per liter
ppq=parts per quadrillion, or picograms per liter
TT=Treatment Technique

Appendix D to R.61-58.12 - endnotes

1These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.
†Until March 31, 2016
‡Beginning April 1, 2016

Amend R.61-58.16.D to read:

D. Sanitary Surveys For Ground Water Systems.

(1) Ground water systems must provide the Department, at the Department's request, any existing information that will enable the Department to conduct a sanitary survey.

(2) For the purposes of R.61-58.16, a "sanitary survey," as conducted by the Department, includes, but is not limited to, an onsite review of the water source(s) (identifying sources of contamination by using results of source water assessments or other relevant information where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water.

(3) The sanitary survey must include an evaluation of the applicable components listed in paragraphs R.61-58.16.D(3)(a) through (h).

(a) Source.

(b) Treatment <u>including corrosion control treatment and water quality parameters as applicable</u>.

(c) Distribution system.

(d) Finished water storage.

(e) Pumps, pump facilities, and controls.

(f) Monitoring, reporting, and data verification.

(g) System management and operation.

(h) Operator compliance with Department requirements.

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.

Legal Authority: 1976 Code Sections 44-55-10 et seq.

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 REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The adoption of these proposed amendments will allow the Department to maintain primary enforcement authority for the Safe Drinking Water Act in the state. The proposed amendments will comply with Title

40, Parts 141 and 142 of the Code of Federal Regulations (40 CFR 141 and 142). These proposed amendments update several aspects of the control of lead and copper in drinking water, to include sample site selection, monitoring procedures, corrosion control requirements, and public education requirements. The proposed amendments also require public water systems to offer to sample lead in drinking water for schools and child care facilities in their service areas.

DETERMINATION OF COSTS AND BENEFITS:

These proposed amendments may result in a cost savings to the regulated community in that it will allow public water systems to correspond and interact with state regulators as opposed to federal regulators. There is no anticipated increase in costs to the state or its political subdivisions resulting from these proposed revisions.

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:

There are no anticipated effects on the environment from these proposed amendments. These proposed amendments provide an opportunity for enhanced public health protection by reducing the public's exposure to lead in drinking water.

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

There will be no detrimental effect on the environment if these proposed amendments are not adopted. If the proposed revisions are not adopted, the intended reduction of the public's exposure to lead in drinking water may not occur.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 5135
R.61-58, State Primary Drinking Water Regulations

As of the October 24, close of the Notice of Proposed Regulation comment period:

Name	Section
South Carolina Environmental Law Project	61-58.11(F)(7)
Comment: The commenter asks that the Department use the authority granted under the proposed amendments to increase mandatory lead service line replacement rates above the minimum required annual rate of three percent (3%) provided for under the proposed amendments. **Department Response: The Department will consider all available and relevant information in applying State discretion where such is provided for under the proposed amendments. USEPA has committed to promulgating an additional regulation referred to as the Lead and Copper Rule Improvements prior to the effective date of these proposed amendments that will further address mandatory lead service line replacement.**	

Name	Section
Comment: **Department Response:**	

Name	Section
Comment: **Department Response:**	

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
SUMMARY SHEET

(X) ACTION
( ) INFORMATION

I. TITLE: Placement of Substances in Schedule III for Controlled Substances

II. SUBJECT: Request for Placement of Substances in Schedule III Pursuant to S.C. Code Section 44-53-160(B).

III. INTRODUCTION

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule III substances are listed in S.C. Code Section 44-53-230. South Carolina Code Section 44-53-160 provides for the manner in which changes in schedule of controlled substances are made in South Carolina. Pursuant to S.C. Code Section 44-53-160(B), the South Carolina Board of Health and Environmental Control (Board) is authorized to add, delete, or reschedule a substance as a controlled substance during the time the General Assembly is not in session after providing notice and a hearing to interested parties. The addition, deletion, or rescheduling of a substance pursuant to this subsection has the full force of law unless overturned by the General Assembly.

The Department is requesting the Board's approval of three substances to be added to schedule III of the South Carolina Controlled Substances Act. All three substances are schedule III controlled substances under the federal Controlled Substances Act, 21 U.S.C. 801 et seq., and are not scheduled as controlled substances under the South Carolina Controlled Substances Act.

IV. BACKGROUND

A. Ketamine's Salts, Isomers, and Salts of Isomers

On July 13, 1999, the Drug Enforcement Administration (DEA) published a final rule[1] placing the substance ketamine, including its salts, isomers, and salts of isomers, into schedule III of the federal Controlled Substances Act.

On December 11, 2014, pursuant to S.C. Code Section 44-53-160(B), the Department requested, and the Board adopted[2], the scheduling of the List of Substances for Inclusion in the South Carolina Controlled Substances Act[3] (List), including the placement of ketamine into schedule III. However, the Department's request, and the Board's adoption, did not include ketamine's "salts, isomers, and salts of isomers."

Esketamine (brand name: Spravato) is the enantiomer (isomer) of ketamine, that is indicated for, in conjunction with an oral antidepressant, the treatment of treatment-resistant depression in adults. Esketamine is available only through a restricted program under a Risk Evaluation and Mitigation Strategy

[1] https://www.deadiversion.usdoj.gov/fed_regs/rules/1999/fr0713.htm; https://www.govinfo.gov/content/pkg/FR-1999-07-13/pdf/99-17803.pdf.

[2] https://scdhec.gov/sites/default/files/docs/Health/docs/BoardORders/SignedBoardDesignationLettter.pdf

[3] https://scdhec.gov/sites/default/files/docs/Health/docs/BoardORders/ListOfSubstances.pdf.

(REMS) because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse. Even though the substance is subject to abuse and diversion, esketamine is not currently a controlled substance under the South Carolina Controlled Substances Act since it is an enantiomer (isomer) of ketamine.

B. Perampanel, including its Salts, Isomers, and Salts of Isomers

On December 2, 2013, the DEA published a final rule[4] placing the substance perampanel, [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benzonitrile], including its salts, isomers, and salts of isomers, into schedule III of the federal Controlled Substances Act. Perampanel (brand name: Fycompa) is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older, and for the adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

The DEA placed perampanel into schedule III of the federal Controlled Substances Act after finding that perampanel has a potential for abuse less than the drugs or other substances in schedules I and II, perampanel has a currently accepted medical use in treatment in the United States, and abuse of perampanel may lead to moderate or low physical dependence or high psychological dependence.

C. Anabolic Steroids

In 1989, Act No. 115 added Article 14 to Chapter 53, Title 44, Code of Laws of South Carolina Act, thereby defining the term "anabolic steroid" in Section 44-53-1510(A).

Effective February 27, 1991, the federal Anabolic Steroids Control Act of 1990 (Title XIX of Pub. L. 101-647) first established and regulated anabolic steroids as a class of drugs under Schedule III of the federal Controlled Substances Act.

On December 11, 2014, pursuant to S.C. Code Section 44-53-160(B), the Department requested, and the Board adopted, the scheduling of the List. S.C. Code Section 44-53-1510(A), defining the term "anabolic steroid," is on the List but without a request to schedule the substance. Therefore, anabolic steroids are not a controlled substance under the South Carolina Controlled Substances Act, but anabolic steroids have been in schedule III under the federal Controlled Substances Act since 1990.

V. RECOMMENDATION

Pursuant to S.C. Code Section 44-53-160(B), the Department recommends the placement of ketamine's salts, isomers, and salts of isomers; perampanel, including its salts, isomers, and salts of isomers; and anabolic steroids in schedule III for controlled substances in South Carolina and the amendment of Section 44-53-230 of the South Carolina Code of Laws to include:

> (c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:
>
> ( ) *ketamine, including its salts, isomers, and salts of isomers*
>
> ( ) *perampanel, including its salts, isomers, and salts of isomers*

[4] https://www.govinfo.gov/content/pkg/FR-2013-12-02/pdf/2013-28778.pdf.

(f) Anabolic Steroids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers:

(1) Anabolic steroids

The Department recommends the Board place ketamine, including its salts, isomers, and salts of isomers; perampanel, including its salts, isomers, and salts of isomers; and anabolic steroids, in schedule III of the South Carolina Controlled Substances Act.

Lisa Thomson
Director
Bureau of Drug Control

Gwen C. Thompson
Director
Healthcare Quality

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

December 8, 2022

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Placement of Zipeprol in Schedule I for Controlled Substances in South Carolina

II. SUBJECT: Placement of Zipeprol in Schedule I for Controlled Substances

III. FACTS:

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, the Chairmen of the Judiciary Committee of the House of Representatives, the Clerks of the Senate and House, and the Code Commissioner, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 21, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing zipeprol (chemical name: 1-methoxy-3-[4-(2- methoxy-2-phenylethyl)piperazin-1-yl]- 1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act ("CSA"). This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to

schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol. This final rule has an effective date of December 21, 2022, *Federal Register*, Volume 87, Number 223, pages 70717-70721; *https://www.govinfo.gov/content/pkg/FR-2022-11-21/pdf/2022-25206.pdf.*

IV. ANALYSIS:

Zipeprol (chemical name: 1-methoxy3-[4-(2-methoxy-2- phenylethyl)piperazin-1-yl]-1- phenylpropan-2-ol) is pharmacologically an opioid drug with some hallucinogenic properties that has no approved medical use in the United States. In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

On May 20, 2013, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's ("DEA") August 3, 2009 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for zipeprol. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data, and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of zipeprol. As such, DEA is permanently scheduling zipeprol as a controlled substance under the CSA.

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1) Zipeprol has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., morphine).

2) Zipeprol has no currently accepted medical use in treatment in the United States.

3) There is a lack of accepted safety for use of zipeprol under medical supervision.

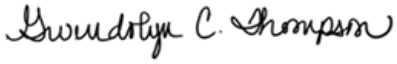
V. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing zipeprol in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, warrants control in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) Zipeprol (1-methoxy-3-[4- (2-methoxy-2-phenylethyl) piperazin-1-yl]-1- phenylpropan-2-ol)

Submitted by:

Lisa Thomson
Director, Bureau of Drug Control



Gwen Thompson
Director for Healthcare Quality

Attachment:
Federal Register, Volume 87, Number 223, November 21, 2022

expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle [18F]FP–CIT.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. Any person planning to handle [18F]FP–CIT will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements.

Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Administrative Procedure Act

DEA finds that good cause exists for adopting this rule as a final rule with an immediate effective date under 5 U.S.C. 553(d) because this final rule relieves a restriction.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[7]

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended to read as follows:

PART 1308— SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.12, revise paragraphs (b)(4)(i) and (ii) and add paragraph (b)(4)(iii) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(4) * * *

(i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(ii) [123I]ioflupane; or

(iii) [18F]FP–CIT.

* * * * *

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25212 Filed 11–18–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–477]

Schedules of Controlled Substances: Placement of Zipeprol in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol.

DATES: Effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] Based on those

[7] 44 U.S.C. 3501–3521.

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

determinations, as appropriate, the Secretary of HHS (Secretary) shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to 21 U.S.C. 811(a) and (b).[3] The CSA also stipulates that in certain circumstances where the permanent section 811(a) scheduling will not be completed in time as required by the 1971 Convention, the Attorney General shall, after satisfying other specified conditions, issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under the 1971 Convention.[4]

In the event that the Secretary did not so consult with the Attorney General to make a determination about the existing legal controls, and the Attorney General did not issue a temporary order, the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).[5]

Background

Zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol) is pharmacologically an opioid drug with some hallucinogenic properties that has no approved medical use in the United States.

In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On May 20, 2013, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 3, 2009 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for zipeprol. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data, and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *http://www.regulations.gov* under docket number DEA–477.

Notice of Proposed Rulemaking To Schedule Zipeprol

On May 14, 2020, DEA published a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of zipeprol in schedule I.'' [6] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before June 15, 2020. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before July 13, 2020.

Comments Received

DEA received eight comments on the proposed rule to control zipeprol in schedule I of the CSA.

Support for Rulemaking

Comments: Three commenters recognized zipeprol's high potential for abuse and adverse health effects, including reports of hallucinations, seizures, overdoses, and deaths. Thus, these commenters supported the placement of zipeprol in schedule I.

DEA Response: DEA appreciates these comments in support of this rulemaking.

Dissent for Rulemaking

Five commenters opposed the placement of zipeprol in schedule I, and provided various reasons as discussed below.

Comment: One commenter contended that it is not appropriate for DEA to schedule zipeprol as health experts, not law enforcement, should regulate and oversee all schedules I through III substances, and specifically that the Secretary of HHS is responsible for adding new substance to the CSA schedules.

DEA Response: DEA disagrees. Congress through the enactment of the CSA provided specific roles and procedures for both law enforcement (DEA) and the medical community (HHS) in controlled drugs with potential for abuse.[7] These procedures were followed in promulgating this final rule.

Comment: One commenter stated that all drugs need to be deregulated and decriminalized, and the focus of the law enforcement should be directed towards addressing social and non-drug related public health matters such as violent crime, unsolved murders, and control of obesity.

DEA Response: This comment is outside the scope of this rule insofar as it addresses drugs other than zipeprol. Regarding zipeprol, however, DEA maintains that control of zipeprol is needed and is appropriate. As stated in the background section, zipeprol is an opioid drug with some hallucinogenic properties that has no approved medical use in the United States.

In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention. As a party to the 1971 Convention, the United States is taking action to place appropriate controls on zipeprol by scheduling it under the CSA.

Comment: One of two commenters mistakenly believe that zipeprol is a schedule II controlled substance under the CSA and that the proposed rule would reclassify zipeprol from schedule II to schedule I. The first commenter stated that reclassifying zipeprol to schedule I control does not warrant priority as it is not currently being used in the United States nor is it being actively manufactured or used in other countries, and there is a need for reclassification of many other drugs. This commenter added that marijuana needs to be reclassified from its current schedule I control.

DEA Response: DEA emphasizes to these commenters that zipeprol is not currently scheduled under the CSA. Perhaps the commenters are thinking of zipeprol's control status under the 1971 Convention. As noted in the background section, the Committee on Narcotic Drugs added zipeprol to Schedule II of the 1971 Convention in March 1995. DEA further notes that classification of a drug under the 1971 Convention, and its relevant schedules, is different from that of the CSA.[8]

[3] Id.

[4] 21 U.S.C. 811(d)(4)(A).

[5] 28 CFR 0.100.

[6] 85 FR 28899.

[7] 21 U.S.C. 811(a) and (b).

[8] The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States. See

Regarding the comment about reclassifying marijuana, this current rulemaking pertains only to the scheduling of zipeprol. Therefore, this comment is outside the scope of this rule.

Comment: A commenter noted that zipeprol and dextromethorphan (DXM, unscheduled under the CSA) are both cough suppressants with potential for abuse; however, adding control of DXM should take priority over reclassifying control of zipeprol as DXM is available and ''wildly abused'' in the United States.

DEA Response: This current rulemaking pertains only to the scheduling of zipeprol. Therefore, this comment is outside the scope of this rule.

Comment: One commenter recognized zipeprol's high potential for abuse and dependence but expressed that zipeprol has an accepted medical use as a cough suppressant. The commenter noted that schedule I, by definition, is only for drugs with both no accepted medical use and a high potential for abuse. Therefore, the commenter contends that zipeprol should instead be placed in schedule II.

DEA Response: DEA does not agree. While zipeprol was previously marketed and used in other countries in the 1980s and 1990s as a cough suppressant (antitussive), hallucinations, convulsions, and opioid-like tolerance, along with both a psychological and physical dependence, have been reported following its ingestion. As discussed in HHS's eight-factor analysis, zipeprol is not approved by the Food and Drug Administration for use in the United States. As explained in the NPRM, the medical and scientific evaluation and scheduling recommendation issued by the Assistant Secretary for Health of HHS (Assistant Secretary for HHS) concludes that zipeprol has no currently accepted medical use in treatment in the United States, has high potential for abuse, and lacks accepted safety for use under medical supervision. Following DEA's proposed determination to place zipeprol in schedule I, as outlined in the NPRM, the Administrator maintains the appropriateness of that schedule placement and concludes that zipeprol warrants control in schedule I of the CSA.[9] Further, regarding the appropriateness of placing zipeprol in schedule I of the CSA, DEA notes that Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. As a party to the 1971 Convention, the United States is taking action to place appropriate controls on zipeprol by scheduling it under the CSA.

DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c) and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the NPRM, after careful review of all relevant data, DEA concurred with HHS' assessment that zipeprol has a high potential for abuse with no currently accepted medical use in treatment the United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.'' [10] The other four schedules require the drug or other substance to have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions (schedule II) or a currently accepted medical use in treatment in the United States (schedules III through V).[11] DEA is therefore promulgating this final rule placing zipeprol in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of zipeprol. As such, DEA is permanently scheduling zipeprol as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V.[12] The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[13] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Zipeprol has a high potential for abuse. This potential is comparable to certain schedule II substances (*e.g.,* morphine);

(2) Zipeprol has no currently accepted medical use in treatment in the United States; [14] and

(3) There is a lack of accepted safety for use of zipeprol under medical supervision.

Based on these findings, the Administrator concludes that zipeprol, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, warrants control in schedule I of the CSA.[15]

Requirements for Handling Zipeprol

Effective as of December 21, 2022, zipeprol will be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) zipeprol, or who desires to handle zipeprol, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who handles zipeprol and is not registered with DEA must submit an application for registration and may not continue to handle zipeprol after the effective date of this rule, unless DEA has approved that application, pursuant to 21 U.S.C.

21 U.S.C. 812(b). In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychotropic substances annexed to the Convention, and altered in accordance with Article 2.

[9] 21 U.S.C. 812(b)(1).

[10] 21 U.S.C. 812(b).

[11] Id.

[12] 21 U.S.C. 812(a).

[13] 21 U.S.C. 812(b).

[14] Although there is no evidence suggesting that zipeprol has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[15] 21 U.S.C. 812(b)(1).

822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of zipeprol as of the effective date of this rule, or may transfer all such quantities of currently held zipeprol to a person registered with DEA. Zipeprol is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Zipeprol is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling zipeprol must also comply with the employee screening requirements of 21 CFR parts 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of zipeprol must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture zipeprol in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of zipeprol must take an inventory of zipeprol on hand pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including zipeprol) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including zipeprol) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to zipeprol, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding zipeprol to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes or orders zipeprol must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of zipeprol must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving zipeprol not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance zipeprol, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that zipeprol has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for zipeprol in the United States. Therefore, DEA estimates that no United States entity currently handles zipeprol and does not expect any United States entity to handle zipeprol in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding paragraph (b)(92) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(92) Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl) piperazin-1-yl]-1-phenylpropan-2-ol)	9873

* * * * *

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25206 Filed 11–18–22; 8:45 am]

BILLING CODE 4410–09–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 212

RIN 0412–AA97

Implementation of the Freedom of Information Act

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This regulation updates certain procedures and standards USAID follows in processing requests for records under the Freedom of Information Act (FOIA).

DATES: Effective December 7, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher A. Colbow, Bureau for Management, Office of Management Services, Information Records Division, U.S. Agency for International Development, 1300 Pennsylvania Avenue, USAID Annex, Room 2.4.0A, Washington, DC 20523; tel. 202–916–4661; *foia@usaid.gov.*

SUPPLEMENTARY INFORMATION: This rule makes revisions to 22 CFR part 212, USAID's regulations under the Freedom of Information Act (FOIA) and the Privacy Act. The Agency is revising its regulations to update several procedural provisions, including methods for submitting requests under the FOIA, and initial appeals of denials of requests, for records of the Office of the USAID Inspector General (OIG). The Inspector General Act of 1978, as amended (5 U.S.C. App. 3) was enacted to, ''create independent and objective units,'' to perform investigative and monitoring functions within Executive Departments and Agencies of the Federal Government, including USAID. These revisions will further the OIG's independence and streamline the processing of requests that seek OIG records.

List of Subjects in 22 CFR Part 212

Freedom of Information.

For the reasons stated in the preamble, USAID revises 22 CFR part 212 to read as follows:

PART 212—PUBLIC INFORMATION

Authority: Pub. L. 114–185, 130 Stat. 538.

Subpart A—General Provisions

§ 212.1 Purpose and scope.

This subpart contains the rules that the United States Agency for International Development (hereinafter ''USAID'' or ''the Agency'') follows in processing requests for records under the Freedom of Information Act (''FOIA''), 5 U.S.C. 552. The rules in this subpart should be read in conjunction with the text of the FOIA. Requests made by individuals for records about themselves under the Privacy Act of 1974, are processed under Subpart O. Definitions of FOIA terms are referenced in subpart L of this part.

§ 212.2 Policy.

(a) As a general policy, USAID follows a balanced approach in administering the FOIA. USAID recognizes the right of the public to access information in the possession of the Agency. USAID also recognizes the legitimate interests of organizations or persons who have submitted records to the Agency or who would otherwise be affected by release of records. USAID has no discretion to release certain records, such as trade secrets and confidential commercial information, prohibited from release by law. USAID's policy calls for the fullest responsible disclosure consistent with those requirements of administrative necessity and confidentiality which are recognized under the FOIA.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

December 8, 2022

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE**: Request for Placement of Mesocarb in Schedule I for Controlled Substances in South Carolina

II. **SUBJECT:** Placement of Mesocarb in Schedule I for Controlled Substances

III. **FACTS:**

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Chairman of the Medical, Military, Public and Municipal Affairs Committee, the Chairman of the Judiciary Committee of the House of Representatives, the Clerks of the Senate and House, and the Code Commissioner, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 22, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing mesocarb (chemical name: N-phenyl-N′ -(3-(1- phenylpropan-2-yl)-1,2,3-oxadiazol-3- ium-5-yl) carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act ("CSA"). This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who

handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle mesocarb. This final rule has an effective date of December 22, 2022, *Federal Register* 87, Number 224, pages 71247-71250; *https://www.govinfo.gov/content/pkg/FR-2022-11-22/pdf/2022-25219.pdf.*

IV. ANALYSIS:

Mesocarb (chemical name: N-phenyl-N′-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl) carbamimidate) is a central nervous system ("CNS") stimulant. At its 38th session (March 1995), the United Nations Commission on Narcotic Drugs added mesocarb to Schedule IV of the 1971 Convention, thus notifying all parties to the 1971 Convention.

On April 3, 2012, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's August 12, 2008 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for mesocarb. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of mesocarb. As such, DEA is permanently scheduling mesocarb as a controlled substance under the CSA.

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1) Mesocarb has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., methamphetamine or amphetamine).

2) Mesocarb has no currently accepted medical use in treatment in the United States.

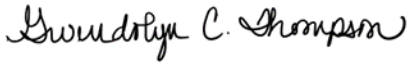
3) There is a lack of accepted safety for use of mesocarb under medical supervision.

V. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing Mesocarb in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its salts, isomers, and salts of isomers in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) Mesocarb (N-phenyl-N ′-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl) carbamimidate)

Submitted by:



Lisa Thomson
Director, Bureau of Drug Control

Gwen Thompson
Director for Healthcare Quality

Attachment:
Federal Register 87, Number 224, November 22, 2022

requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. The CGBPA deems rules issued under that statute a ''consumer product safety rule.'' Therefore, once a rule issued under the CGBPA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

J. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule can take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a ''major rule.''

Pursuant to the CRA, this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1460

Consumer protection, Gasoline, Incorporation by reference, Safety.

For the reasons stated above, the Commission amends 16 CFR part 1460 as follows:

PART 1460—CHILDREN'S GASOLINE BURN PREVENTION ACT REGULATION

■ 1. Revise the authority citation for part 1460 to read as follows:

Authority: Sec. 2, Pub. L. 110–278, 122 Stat. 2602; and Pub. L. 116–260, div. FF, title IX, § 901(c).

■ 2. Revise § 1460.2 to read as follows:

§ 1460.2 Definition.

Portable fuel container means any portable gasoline container intended for use by consumers and any receptacle for gasoline, kerosene, or diesel fuel, including any spout, cap, and other closure mechanism and component of such receptacle or any retrofit or aftermarket spout or component intended or reasonably anticipated to be for use with such receptacle, produced or distributed for sale to or use by consumers for transport of, or refueling of internal combustion engines with, gasoline, kerosene, or diesel fuel.

■ 3. Revise § 1460.3 to read as follows:

§ 1460.3 Requirements for child-resistance for closures on portable gasoline containers.

Each portable gasoline container manufactured on or after December 22, 2022 for sale in the United States shall conform to the child-resistance requirements for closures on portable gasoline containers specified in sections 2 through 7 of ASTM F2517–22e1. ASTM F2517–22e1, *Standard Specification for Determination of Child Resistance of Portable Fuel Containers for Consumer Use,* approved June 1, 2022 is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Office of the Secretary, U.S. Consumer Product Safety Commission at: Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* A read-only copy of the standard is available for viewing on the ASTM website at *www.astm.org/READINGLIBRARY/.* This material may be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959; telephone (610) 832–9585; *www.astm.org.*

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–25308 Filed 11–21–22; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–397]

Schedules of Controlled Substances: Placement of Mesocarb in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places mesocarb (chemical name: *N*-phenyl-*N*′-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle mesocarb.

DATES: Effective date: December 22, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)—(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] Based on those determinations, as appropriate, the Secretary of HHS (Secretary) shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to 21 U.S.C. 811(a) and (b).[3] The CSA also

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

[3] Id.

stipulates that in certain circumstances where the permanent section 811(a) scheduling will not be completed in time as required by the 1971 Convention, the Attorney General shall, after satisfying other specified conditions, issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under the 1971 Convention.[4]

In the event that the Secretary did not so consult with the Attorney General to make a determination about the existing legal controls, and the Attorney General did not issue a temporary order, the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).[5]

Background

Mesocarb (chemical name: *N*-phenyl-*N′*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) is a central nervous system (CNS) stimulant.

At its 38th session (March 1995), the United Nations Commission on Narcotic Drugs added mesocarb to Schedule IV of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On April 3, 2012, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 12, 2008 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for mesocarb. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *https://www.regulations.gov* under docket number DEA–397.

Notice of Proposed Rulemaking To Schedule Mesocarb

On August 11, 2021, DEA published a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of mesocarb in schedule I.'' [6] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before September 10, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before October 12, 2021.

Comments Received

DEA received two comments on the proposed rule to control mesocarb in schedule I of the CSA.

Support for rulemaking: One commenter supported the placement of mesocarb in schedule I due to the continued abuse of controlled substances.

DEA Response: DEA appreciates the comment in support of this rulemaking.

Opposition to rulemaking: One commenter opposed the placement of mesocarb in schedule I by suggesting it be placed in schedule II due to the infrequent use in the United States and its availability and use in other countries.

DEA Response: DEA does not agree. DEA is not aware of any availability or source of mesocarb in the United States, and the commenter did not provide any evidence of its use in the United States. As discussed in HHS's eight-factor analysis, mesocarb is not approved by the United States Food and Drug Administration (FDA) for use in the United States. As explained in the NPRM, the medical and scientific evaluation and scheduling recommendation issued by the Assistant Secretary for Health of HHS (Assistant Secretary) concludes that mesocarb has no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision.

In addition, DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c), and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the NPRM, after careful review of all data, DEA concurred with HHS' assessment that mesocarb has a high potential for abuse with no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.'' [7] The other four schedules require the drug or other substance to have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions (schedule II) or a currently accepted medical use in treatment in the United States (schedules III through V).[8] DEA is therefore promulgating this final rule placing mesocarb in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of mesocarb. As such, DEA is permanently scheduling mesocarb as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V.[9] The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[10] After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Mesocarb has a high potential for abuse. This potential is comparable to certain schedule II substances (*e.g.,* methamphetamine or amphetamine);

(2) Mesocarb has no currently accepted medical use in treatment in the United States; [11] and

[4] 21 U.S.C. 811(d)(4)(A).

[5] 28 CFR 0.100.

[6] 86 FR 43978.

[7] 21 U.S.C. 812(b).

[8] Id.

[9] 21 U.S.C. 812(a).

[10] 21 U.S.C. 812(b).

[11] Although there is no evidence suggesting that mesocarb has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR

(3) There is a lack of accepted safety for use of mesocarb under medical supervision.

Based on these findings, the Administrator concludes that mesocarb, including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.[12]

Requirements for Handling Mesocarb

Effective as of December 22, 2022, mesocarb will be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) mesocarb, or who desires to handle mesocarb, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who handles mesocarb and is not registered with DEA must submit an application for registration and may not continue to handle mesocarb after the effective date of this rule, unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of mesocarb as of the effective date of this rule, or may transfer all such quantities of mesocarb to a person registered with DEA. Mesocarb is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Mesocarb is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling mesocarb must also comply with the employee screening requirements of 21 CFR parts 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of mesocarb must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture mesocarb in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of mesocarb must take an inventory of mesocarb on hand pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including mesocarb) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including mesocarb) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to mesocarb, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding mesocarb to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes or orders mesocarb must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of mesocarb must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving mesocarb not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance mesocarb, including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical

10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[12] 21 U.S.C. 812(b)(1).

analysis with, or possess) mesocarb, or propose to handle mesocarb.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that mesocarb has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for mesocarb in the United States. Therefore, DEA estimates that no United States entity currently handles mesocarb and does not expect any United States entity to handle mesocarb in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by redesignating paragraphs (f)(7) through (10) as paragraphs (f)(8) through (11) and adding a new paragraph (f)(7) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(7) Mesocarb (*N*-phenyl-*N′*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate)	1227

* * * * *

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25219 Filed 11–21–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice: 11858]

RIN 1400–AF58

International Traffic in Arms Regulations: Prohibited Exports, Imports, and Sales to or From Certain Countries—Cyprus

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to reflect current defense trade policy towards Cyprus.

DATES: This rule is effective November 22, 2022.

FOR FURTHER INFORMATION CONTACT: Sarah Heidema, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–1282, or email *DDTCCustomerService@state.gov*. ATTN: Regulatory Change, ITAR Section 126.1 Cyprus Country Policy Update.

SUPPLEMENTARY INFORMATION: Section 1250A(d) of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92) and section 205(d) of the Eastern Mediterranean Security and Energy Partnership Act of 2019 (Pub. L. 116–94, Div. J.) provide that the policy of denial for exports, re-exports, and transfers of defense articles on the United States Munitions List to the Republic of Cyprus shall remain in place unless the President determines and certifies to the appropriate congressional committees not less than annually that: (A) the Government of the Republic of Cyprus is continuing to cooperate with the United States Government in efforts to implement reforms on anti-money laundering regulations and financial regulatory oversight; and (B) the Government of the Republic of Cyprus has made and is continuing to take the steps necessary to deny Russian military vessels access to ports for refueling and servicing.

On April 14, 2020, the President delegated to the Secretary of State the functions and authorities vested by section 1250A(d) of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92) and section 205(d) of the Eastern Mediterranean Security and Energy Partnership Act of 2019 (Pub. L. 116–94, Div. J.) (85 FR 35797, June 12, 2020). On September 12, 2022, utilizing these authorities, the Secretary of State certified to the appropriate congressional committees that the Republic of Cyprus meets the statutory requirements to remove the policy of denial for exports, re-exports, and transfers of defense articles to the Republic of Cyprus for fiscal year 2023. The Secretary of State further approved the suspension of the policy of denial for exports, reexports, and transfers of defense articles and defense services to the Republic of Cyprus for fiscal year 2023. In conjunction with the Secretary of State's decision, the Under Secretary for Arms Control and International Security used the Department's delegated authority (Executive Order 13637) under the Arms Export Control Act (22 U.S.C. 2751 *et seq.*) to suspend the policy of denial for retransfers and temporary imports destined for or originating in the Republic of Cyprus and brokering activities involving the Republic of Cyprus for fiscal year 2023. Accordingly, the Department now amends section 126.1 of the International Traffic in Arms Regulations (22 CFR parts 120 through

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

December 8, 2022

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE**: Request for Placement of Amineptine in Schedule I for Controlled Substances in South Carolina

II. **SUBJECT:** Placement of Amineptine in Schedule I for Controlled Substances

III. **FACTS:**

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Chairman of the Medical, Military, Public and Municipal Affairs Committee, the Chairman of the Judiciary Committee of the House of Representatives, the Clerks of the Senate and House, and the Code Commissioner, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 17, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing amineptine (chemical name: 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl) amino] heptanoic acid), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture,

distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle amineptine. This final rule was published on November 17, 2022, with an effective date of December 19, 2022, *Federal Register* 87, no. 221, pages 68895-68898; *https://www.govinfo.gov/content/pkg/FR-2022-11-17/pdf/2022-25003.pdf.*

IV. ANALYSIS:

Amineptine (chemical name: 7- [(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5- yl)amino]heptanoic acid) is a synthetic tricyclic antidepressant with central nervous system ("CNS") stimulating properties. In April 2003, the United Nations Commission on Narcotic Drugs ("CND"), on the advice of the Director-General of the World Health Organization ("WHO"), added amineptine to Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

On November 8, 2011, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's ("DEA") August 12, 2008 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for amineptine. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of amineptine. As such, DEA is permanently scheduling amineptine as a controlled substance under the CSA.

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1) Amineptine has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., amphetamine or cocaine).

2) Amineptine has no currently accepted medical use in treatment in the United States.

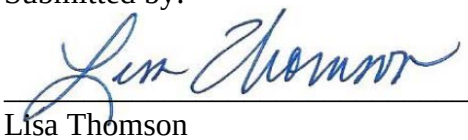
3) There is a lack of accepted safety for use of amineptine under medical supervision.

V. RECOMMENDATION:

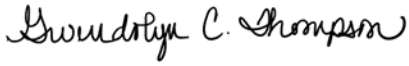
Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing amineptine in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its salts, isomers, and salts of isomers to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)

Submitted by:



Lisa Thomson
Director, Bureau of Drug Control



Gwen Thompson
Director for Healthcare Quality

Attachment:
Federal Register, Volume 87, Number 221, November 17, 2022

(u) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on December 22, 2022.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0250, dated November 17, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on June 24, 2016 (81 FR 31844, May 20, 2016).

(i) Airbus Service Bulletin A330–27–3199, dated July 15, 2014.

(ii) [Reserved]

(5) The following service information was approved for IBR on November 26, 2019 (84 FR 56378, October 22, 2019).

(i) Airbus A330 Airworthiness Limitations Section (ALS) Part 4, System Equipment Maintenance Requirements (SEMR), Revision 07, dated October 15, 2018.

(ii) [Reserved]

(6) For EASA AD 2021–0250, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(7) For Airbus SAS service information, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *airbus.com.*

(8) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(9) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 2, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

Editorial Note: This document was received for publication by the Office of the Federal Register on November 10, 2022.

[FR Doc. 2022–24991 Filed 11–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–371]

Schedules of Controlled Substances: Placement of Amineptine in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places amineptine (chemical name: 7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle amineptine.

DATES: Effective date: December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary of HHS (Secretary) did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).[3]

Background

Amineptine (chemical name: 7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid) is a synthetic tricyclic antidepressant with central nervous system (CNS) stimulating properties.

In April 2003, the United Nations Commission on Narcotic Drugs (CND), on the advice of the Director-General of the World Health Organization (WHO), added amineptine to Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On November 8, 2011, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 12, 2008 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for amineptine. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data, and conducted its own analysis under the eight factors stipulated in 21 U.S.C.

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

[3] 28 CFR 0.100.

811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *https://www.regulations.gov* under docket number DEA–371.

Notice of Proposed Rulemaking to Schedule Amineptine

On July 22, 2021, DEA published a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of amineptine in schedule I.'' [4] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before August 23, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before September 20, 2021.

Comments Received

DEA received three comments on the proposed rule to control amineptine in schedule I of the CSA.

Support for rulemaking: Two commenters recognized the dangers and public health risks, and supported the placement of amineptine in schedule I.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Opposition to rulemaking: One commenter opposed the placement of amineptine in schedule I due to the lack of abuse in the United States, and contended it showed potential as an ''anti-addictive agent and antidepressant'' in clinical settings.

DEA Response: DEA does not agree. As discussed in DEA and HHS eight-factor analyses which accompanied the published NPRM, amineptine is not approved by the Food and Drug Administration for use in the United States. While amineptine has previously been used in Europe and Asia as an antidepressant, its use has been withdrawn from the market in 49 of 66 countries. Strong evidence of abuse, severe adverse effects including hepatotoxicity, pancreatic injury, and severe acne eruption that required hospitalization, and overconsumption, have been documented by the WHO's Expert Committee on Drug Dependence report [5] and HHS in their scientific and medical evaluation where amineptine was recommended for control in schedule I of the CSA.[6]

In addition, DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c), and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the proposed rulemaking, after careful review of all data, DEA concurred with HHS' assessment that amineptine has a high potential for abuse, and it has no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.'' [7] DEA is therefore promulgating this final rule placing amineptine in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of amineptine. As such, DEA is permanently scheduling amineptine as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[8] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Amineptine has a high potential for abuse. This potential is comparable to certain schedule II substances (*e.g.,* amphetamine or cocaine);

(2) Amineptine has no currently accepted medical use in treatment in the United States; [9] and

(3) There is a lack of accepted safety for use of amineptine under medical supervision.

Based on these findings, the Administrator concludes that amineptine, including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.[10]

Requirements for Handling Amineptine

Amineptine is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) amineptine, or who desires to handle amineptine, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles amineptine and is not registered with DEA must submit an application for registration and may not continue to handle amineptine, unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of currently held amineptine, or may transfer all quantities of currently held amineptine to a person registered with DEA. Amineptine is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Amineptine is subject to schedule I security requirements and

[4] 86 FR 38619.

[5] World Health Organization (WHO) Critical Review of Psychoactive Substances prepared for evaluation by the 33rd Meeting of the WHO Expert Committee on Drug Dependence. Annex, 2002.1–14.

[6] While HHS's Secretary is the expert on scientific and medical matters in scheduling decisions of this type, DEA is not bound by HHS's recommendation to schedule a substance. DEA's Administrator is obligated to determine ''that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control'' prior to following set rulemaking proceedings for control. 21 U.S.C. 811(b); *see* 76 FR 77330, 77334–77335, Dec. 12, 2011. This is what DEA is doing in this rulemaking.

[7] 21 U.S.C. 812(b).

[8] 21 U.S.C. 812(b).

[9] Although there is no evidence suggesting that amineptine has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[10] 21 U.S.C. 812(b)(1).

must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling amineptine must also comply with the employee screening requirements of 21 CFR parts 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of amineptine must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture amineptine in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of amineptine must take an inventory of amineptine on hand pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including amineptine) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including amineptine) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to amineptine, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding amineptine to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes amineptine must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of amineptine must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving amineptine not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance amineptine, including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle amineptine.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that amineptine has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for amineptine in the United States. DEA is not aware of any availability or source of amineptine in the United States. Therefore, DEA estimates that no United States entity currently handles amineptine and does not expect any United States entity to handle amineptine in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to the Government Accountability Office, the House, and the Senate under the CRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995.[11]

[11] 44 U.S.C. 3501–3521.

This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by re-designating paragraphs (f)(1) through (f)(9) as paragraphs (f)(2) through (f)(10), and adding a new paragraph (f)(1) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(1) Amineptine (7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid) 1219

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on November 9, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25003 Filed 11–16–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9947]

RIN 1545–BO90

Section 199A Rules for Cooperatives and Their Patrons; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to Treasury Decision 9947, published in the **Federal Register** on Tuesday, January 19, 2021. Treasury Decision 9947 contained final regulations under the qualified business income provisions of the Internal Revenue Code regarding the deduction for income attributable to domestic production activities of specified agricultural or horticultural cooperatives.

DATES: These corrections are effective on *November 17, 2022* and applicable after January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jason Deirmenjian at (202) 317–4470 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9947) subject to this correction are issued under sections 1381 through 1388 and section 199A(g) of the Internal Revenue Code.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.199A–7 is amended by:

■ a. Revising the first sentence of paragraph (c)(1).

■ b. Revising the second sentence of paragraph (c)(2) introductory text.

■ c. Revising paragraphs (c)(2)(ii) and (iii).

■ d. Revising the first sentence of paragraph (c)(3).

■ e. Revising the first sentence of paragraph (d)(1).

■ f. Revising the first sentence of paragraph (d)(3)(i).

■ g. Redesignating paragraph (d)(3)(ii)(B)(i*2*) as paragraph (d)(3)(ii)(B)(*2*).

The revisions read as follows:

§ 1.199A–7 Section 199A(a) Rules for Cooperatives and their patrons.

* * * * *

(c) * * *

(1) * * * QBI means the net amount of qualified items of income, gain, deduction, and loss with respect to any trade or business as determined under the rules of section 199A(c)(3) and § 1.199A–3(b). * * *

(2) * * * In situations where the patron receives distributions described in paragraph (c)(1) of this section, the Cooperative must determine whether those distributions include qualified items of income, gain, deduction, and loss as determined under rules of section 199A(c)(3) and § 1.199A–3(b). * * *

* * * * *

(ii) The distributions are qualified items of income, gain, deduction, and loss as determined under rules of section 199A(c)(3) and § 1.199A–3(b) at the Cooperative's trade or business level;

(iii) The distributions are not items from an SSTB as defined in section 199A(d)(2) at the Cooperative's trade or business level (except as permitted by the threshold rules in section 199A(d)(3) and § 1.199A–5(a)(2)); and

* * * * *

(3) * * * In the case of a Cooperative that makes distributions described in paragraph (c)(1) of this section to a patron, the Cooperative must determine the amount of qualified items of income, gain, deduction, and loss as determined under the rules of section 199A(c)(3) and § 1.199A–3(b) in those distributions. * * *

(d) * * *

(1) * * * This section provides guidance on the determination of SSTBs as defined in section 199A(d)(2) and § 1.199A–5. * * *

* * * * *

(3) * * *

(i) * * * In the case of a Cooperative that makes distributions described in paragraph (c)(1) of this section to a