SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 10, 2020

( ) ACTION/DECISION
(X) INFORMATION

I. TITLE: Healthcare Quality Administrative and Consent Orders.

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

III. FACTS: For the period of July 1, 2020 through July 31, 2020, Healthcare Quality reports nine (9) Consent Orders totaling $10,350 in assessed monetary penalties. No Administrative Orders or Emergency Suspension Orders were executed during the reporting period.

Healthcare Quality Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Emergency Suspension Orders	Assessed Penalties
Bureau of Facilities Oversight	Community Residential Care Facility	0	1	0	$1,500
	In-Home Care Provider	0	3	0	$3,700
Bureau of Healthcare Professionals	Paramedic	0	2	0	$0
Bureau of Radiological Health	Dental Facility	0	2	0	$3,450
	Chiropractic Facility	0	1	0	$1,700
TOTAL		**0**	**9**	**0**	**$10,350**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Director of Healthcare Quality

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

September 10, 2020

Bureau of Facilities Oversight

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Community Residential Care Facility	498	21,939

1. Rosewood Assisted Living – Pauline, SC

Inspections and Investigations: The Department notified the facility on several occasions beginning in September 2019 that the facility was required to submit a license renewal application and the license renewal fee in order to renew their license. The Department found that the facility repeatedly violated regulatory requirements by letting their license expire.

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

Enforcement Action: The parties agreed to resolve the matter with a consent order after the Department notified the facility that their license was expired and no longer valid. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $1,500 against the facility. The facility was required to pay the full amount of the penalty within 30 days of executing the Consent Order. The Department will reissue the facility's renewal license upon receipt of the full monetary penalty.

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

Prior Enforcement Actions: None in the past five years.

Facility Type	Total # of Licensed Providers
In-Home Care Provider	710

2. Devoted Care and Transitional Services LLC – Columbia, SC

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

Violations: The Department found the provider failed to comply with Regulation 61-122, *Standards for Licensing In-Home Care Providers*, by continuously failing to submit the renewal application and fees within the specified timeframe. The provider repeatedly failed to timely submit a renewal application and pay the required fees.

Enforcement Action: The parties agreed to resolve the matter with a consent order after the Department notified the provider that their license was expired and no longer valid. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $1,500 against the provider. The provider was required to pay the full amount of the penalty within 30 days of executing the Consent Order. The Department will reissue the provider's renewal license upon receipt of the full monetary penalty.

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

Prior Enforcement Actions: None in the past five years.

3. Charles Lea Center – Spartanburg, SC

Inspections and Investigations: The Department notified the provider beginning in March 2020 that the provider was required to submit a license renewal application and the license renewal fee in order to renew their license. The Department found that the provider violated a regulatory requirement by letting their license expire.

Violations: The Department found the provider failed to comply with Regulation 61-122, *Standards for Licensing In-Home Care Providers*, by failing to submit the renewal application and fees within the specified timeframe.

Enforcement Action: The parties agreed to resolve the matter with a consent order after the Department notified the provider that their license was expired and no longer valid. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $750 against the provider. The provider was required to pay the full amount of the penalty within 30 days of executing the Consent Order. The Department will issue the provider's renewal license upon receipt of the full monetary penalty.

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

Prior Enforcement Actions: None in the past five years.

4. Carolina In-Home Care – Sumter, SC

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

Violations: The Department found the provider failed to comply with Regulation 61-122, *Standards for Licensing In-Home Care Providers*, by continuously failing to submit the renewal application and fees

within the specified timeframe. The provider repeatedly failed to timely submit a renewal application and pay the required fees.

Enforcement Action: The parties agreed to resolve the matter with a consent order after the Department notified the provider that their license was expired and no longer valid. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $1,500 against the provider. The provider was required to pay the full amount of the penalty within 30 days of executing the Consent Order. The Department will reissue the provider's renewal license upon receipt of the full monetary penalty.

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

Prior Enforcement Actions: None in the past five years.

Bureau of Healthcare Professionals

Provider Type	Total # of Certified Providers
Paramedic	3933

5. James Doyle Rinaldi – Paramedic

Inspections and Investigations: Based on information received by the Department, the Department conducted an investigation of alleged conduct of Mr. Rinaldi while working for Medtrust Medical Transport in January 2020 and found that Mr. Rinaldi was in in violation of statutory and regulatory requirements.

Violations: The Department determined that Mr. Rinaldi violated the Emergency Medical Services (EMS) Act and Regulation 61-7, *Emergency Medical Services*, by instructing his EMT partner to attend and treat a patient that required the higher level of care of a paramedic. The patient was also administered a drug that can only be given and monitored by a paramedic, not an EMT. Mr. Rinaldi committed misconducted as defined by the EMS Act and Regulation because after he initiated care of a patient, he discontinued such care or abandoned the patient without the patient's consent or without providing for further administration of care by an equal or higher medical authority. Specifically, Mr. Rinaldi, a paramedic, instructed his EMT partner to attend and treat the patient in need of a higher level of care while Mr. Rinaldi drove the ambulance.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In July 2020, the parties executed a consent order imposing a three-month suspension of Mr. Rinaldi's Paramedic Certification. Mr. Rinaldi has been temporarily issued an EMT Certification for the duration of the suspension and will then be reissued his Paramedic Certificate within 90 days of executing the Consent Order. Mr. Rinaldi is also required take the National Association of Emergency Medical Technicians' Principles of Ethics and Leadership course within 12 months of executing the Consent Order.

Remedial Action: Mr. Rinaldi is currently serving the three-month suspension of his Paramedic Certification and has a temporary EMT Certification. Mr. Rinaldi has not taken the required ethics and leadership course.

Prior Enforcement Actions: None in the past five years.

6. Danny J. Tinnel – Paramedic

Inspections and Investigations: In November 2018, the Beaufort County EMS reported to the Department that Mr. Tinnel was involved in a motor vehicle incident that was in violation of statutory and regulatory requirements. The Department investigated the reported violation.

Violations: The Department determined that Mr. Tinnel violated the EMS Act and Regulation 61-7, *Emergency Medical Services*, by driving 17 miles per hour over the posted speed limit while responding to a call and was involved in a motor vehicle accident. The South Carolina Highway Patrol investigation concluded that Mr. Tinnel's speed was greater than what is reasonable under conditions. The Department determined this was misconduct as defined by the EMS Act and Regulation because Mr. Tinnel was careless, reckless, or irresponsible in the operation of an emergency vehicle.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In July 2020, the parties executed a consent order requiring Mr. Tinnel to take an Emergency Vehicles Operation class as determined by the Department within 90 days of executing the Consent Order. Mr. Tinnel also agreed to not operate an emergency vehicle for 90 days upon the date of execution of this Consent Order.

Remedial Action: Mr. Tinnel has not taken the Emergency Vehicle Operations class.

Prior Enforcement Actions: None in the past five years.

Bureau of Radiological Health

Facility Type	Total # of Registered Dental X-Ray Facilities
Dental Facility	1,774

7. James G. Agnew, DMD – Boiling Springs, SC

Inspections and Investigations: The Department conducted a routine inspection in July 2019 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays*, for repeatedly failing to conduct equipment performance testing on dental x-ray systems when testing was due.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $1,700 against the registrant. The registrant was required to pay $255 of the assessed penalty within 30 days of executing the Consent Order. The remaining $1,445 of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

8. McMillan Dental Care – Orangeburg, SC

Inspections and Investigations: The Department conducted a routine inspection in July 2019 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays*, for repeatedly failing to conduct equipment performance testing on dental x-ray systems and checking lead aprons when due.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $1,750 against the registrant. The registrant was required to pay $265 of the assessed penalty within 30 days of executing the Consent Order. The remaining $1,485 of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

Facility Type	Total # of Registered Chiropractic X-Ray Facilities
Chiropractic Facility	485

9. James Island Family Chiropractic, LLC – Charleston, SC

Inspections and Investigations: The Department conducted a routine inspection in May 2019 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays*, for repeatedly failing to conduct equipment performance testing on medical radiographic x-ray systems when testing was due.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In July 2020, the parties executed a consent order imposing a civil monetary penalty of $1,700 against the registrant. The registrant was required to pay $255 of the assessed penalty within 30 days of executing the Consent Order. The remaining $1,445 of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
September 10, 2020

_____ ACTION/DECISION

__X__ INFORMATION

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

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

3. **FACTS:** For the reporting period of July 1, 2020, through July 31, 2020, the Office of Environmental Affairs issued twenty-four (24) Consent Orders with total assessed civil penalties in the amount of one hundred twenty-one thousand, five hundred thirty dollars ($121,530.00). Also, ten (10) Administrative Orders were reported during this period with total assessed civil penalties in the amount of three thousand, three hundred dollars ($3,300.00).

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	0	0	1	$21,250.00
Aboveground Tanks	0	0	0	0
Solid Waste	1	$3,300.00	0	0
Hazardous Waste	0	0	3	$20,000.00
Infectious Waste	0	0	2	$35,400.00
Mining	0	0	0	0
SUBTOTAL	**1**	**$3,300.00**	**6**	**$76,650.00**
Water				
Recreational Water	0	0	7	$9,280.00
Drinking Water	0	0	2	$4,200.00
Water Pollution	0	0	3	$15,400.00
Dam Safety	0	0	0	0
SUBTOTAL	**0**	**0**	**12**	**$28,880.00**
Air Quality				
SUBTOTAL	**0**	**0**	**1**	**$13,000.00**
Environmental Health Services				
Food Safety	0	0	1	$500.00
Onsite Wastewater	9	0	4	$2,500.00
SUBTOTAL	**9**	**0**	**5**	**$3,000.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**10**	**$3,300.00**	**24**	**$121,530.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
September 10, 2020

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Consent Order 20-0058-UST
Order Date: July 23, 2020
Individual/Entity: **Lucky Strike Investments, Inc.**
Facility: Corner Stop 19
Location: 1215 Greenwood Road
Laurens, SC 29360-0881
Mailing Address: 401 Black Oak Court
Spartanburg, SC 29306
County: Laurens
*Previous Orders: None
Permit/ID Number: 05667
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.20(c)(1)(ii), 280.31(a), and 280.31(c), 280.70(a) (2012 and Supp. 2019)

Summary: Lucky Strike Investments, Inc. (Individual/Entity) owns and operates underground storage tanks (USTs) in Laurens County, South Carolina. The Department conducted inspections on May 6, 2019, and February 11, 2020. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment for an UST system; failed to operate and maintain corrosion protection equipment continuously; failed to inspect the impressed current system every sixty (60) days; failed to continue release detection and/or corrosion protection for a temporarily closed UST and failed to pay annual UST registration fees.

Action: The Individual/Entity is required to: either submit proof that the USTs at the Facility have been permanently closed, or proof that the corrosion protection system has been tested prior to November 24, 2019, or proof that metal integrity testing has been initiated; submit proof that the ball float vent valves and caps have been repaired and/or replaced; and pay annual tank registration fees and associated late fees for fiscal year 2020 in the amount of four hundred twenty dollars ($420.00). The Department has assessed a total civil penalty in the amount of twenty-one thousand, two hundred fifty dollars ($21,250.00). The Individual/Entity shall pay a civil penalty in the amount of twenty-one

thousand, two hundred fifty dollars **($21,250.00)**.

Updates: No updates to report.

Solid Waste Enforcement

2) Order Type and Number: Administrative Order 20-08-SW
Order Date: July 10, 2020
Individual/Entity: **Tina Yeargin and Mary Ross**
Facility: Tina Yeargin and Mary Ross
Location: 117 Perry Drive
Iva, SC 29655
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: Solid Waste Policy and Management Act of 1991, S.C. Code Ann. 44-96-10 et seq. (Rev. 2018 & Supp. 2019); Solid Waste Management: Waste Tires, R.61-107.3, Part III.A.1.a. (2015)

Summary: Tina Yeargin and Mary Ross (Individuals/Entities), own property located in Anderson County, South Carolina. The Department conducted a site visit on December 3, 2019 and discovered approximately 800 waste tires stored on the property without a permit for a waste tire collection facility. The Individuals/Entities have violated the Solid Waste Policy and Management Act and the Solid Waste Management: Waste Tire Regulation as follows: failed to obtain a permit to operate a waste tire collection facility from the Department before storing greater than one hundred twenty (120) waste tires.

Action: The Individuals/Entities are required to: dispose of the waste tires at a facility permitted by the Department to accept waste tires and provide disposal receipts to the Department. The Department has assessed a total civil penalty in the amount of three thousand, three hundred dollars ($3,300.00). The Individuals/Entities shall pay a civil penalty in the amount of three thousand, three hundred dollars **($3,300.00)**.

Updates: No updates to report.

Hazardous Waste Enforcement

3) Order Type and Number: Consent Order 20-09-HW
Order Date: July 28, 2020
Individual/Entity: **Lowe's Home Centers, LLC – Lowe's Store 385**
Facility: Lowe's Home Centers, LLC – Lowe's Store 385
Location: 390 Harbison Boulevard
Columbia, SC 29212
Mailing Address: 1000 Lowe's Boulevard MC LPH28,
Mooresville, NC 28115
County: Richland
Previous Orders: None
Permit/ID Number: SCR 000 784 967
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2019).

Summary: Lowe's Home Centers, LLC – Lowe's Store 385 (Individual/Entity) is a retail store located in Richland County, South Carolina. The Department conducted an inspection on February 11, 2020. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to close containers during accumulation, except when adding, removing, consolidating, or venting hazardous waste; failed to label or mark containers with the words "Hazardous Waste," an indication of the hazards of contents, and the date upon which each period of accumulation began; failed to maintain records documenting the arrangements made with the local emergency responders; failed to post the name and emergency telephone number of the emergency coordinator next to the telephone; failed to ensure all employees were thoroughly familiar with proper hazardous waste handling and emergency procedures; failed to keep a copy of each signed manifest received from the designated facility onsite for three (3) years; failed to record the date and time of hazardous waste inspections in an inspection log; failed to manage spent lead-acid batteries in accordance with R.61-79.266.80; failed to contain universal waste lamps in containers that are structurally sound and adequate to prevent breakage and a release; failed to label each universal waste lamp or container with one of the following phrases: "Universal Waste – Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)"; and failed to demonstrate the length of time universal waste had accumulated from the date it became a waste.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six thousand one hundred fifty dollars ($6,150.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand one hundred fifty dollars **($6,150.00)**.

Updates: The civil penalty has been paid.

4) Order Type and Number: Consent Order 20-10-HW
Order Date: July 28, 2020
Individual/Entity: **Lowe's Home Centers, LLC – Lowe's Store 1986**
Facility: Lowe's Home Centers, LLC – Lowe's Store 1986
Location: 170 Rainbow Lake Road
Boiling Springs, SC 29316
Mailing Address: 1000 Lowe's Boulevard MC LPH28,
Mooresville, NC 28115
County: Spartanburg
Previous Orders: None
Permit/ID Number: SCR 000 785 311
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2019).

Summary: Lowe's Home Centers, LLC – Lowe's Store 1986 (Individual/Entity) is a retail store located in Charleston County, South Carolina. The Department conducted an inspection on January 9, 2020. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to maintain records supporting its hazardous waste determinations, as well as records that identify whether or not a solid waste is a hazardous waste; failed to close containers during accumulation, except when adding, removing, consolidating, or venting hazardous waste; failed to label or mark containers with the words "Hazardous Waste," an indication of the hazards of contents, and the date upon which each period of accumulation began; failed to inspect at least weekly, the hazardous waste central accumulation areas; failed to separate containers of incompatible waste by means of a dike, berm, wall, or other device; failed to clean up hazardous waste spillage from the floor and remove it from the spill pallet; failed to ensure all employees were thoroughly familiar with proper hazardous waste handling and emergency procedures; failed to keep a copy of each signed manifest received from the designated facility onsite for three (3) years; failed to retain onsite a copy of all certifications for three (3) years documenting the offsite treatment, storage, or disposal of hazardous waste; and failed to manage spent lead-acid batteries in accordance with R.61-79.266.80.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six thousand six hundred fifty dollars ($6,650.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand six hundred fifty dollars **($6,650.00)**.

Updates: The civil penalty has been paid.

5) Order Type and Number: Consent Order 20-11-HW
Order Date: July 28, 2020
Individual/Entity: **Lowe's Home Centers, LLC – Lowe's Store 2548**
Facility: Lowe's Home Centers, LLC – Lowe's Store 2548
Location: 2079 East Main Street
Spartanburg, SC 29307
Mailing Address: 1000 Lowe's Boulevard MC LPH28,
Mooresville, NC 28115
County: Spartanburg
Previous Orders: None
Permit/ID Number: SCR 000 785 378
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2019).

Summary: Lowe's Home Centers, LLC – Lowe's Store 2548 (Individual/Entity) is a retail store located in Spartanburg County, South Carolina. The Department conducted an inspection on January 29, 2020. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to maintain records supporting its hazardous waste determinations, as well as records that identify whether not or a solid waste is a hazardous waste; failed to close containers during accumulation, except when adding, removing, consolidating, or venting hazardous waste; failed to label or mark containers with the words "Hazardous Waste," an indication of the hazards of contents, and the date upon which each period of accumulation began; failed to inspect at least weekly, the hazardous waste central accumulation areas; failed to remove hazardous waste spillage from the spill pallet; failed to maintain aisle space in the hazardous waste storage area to allow for unobstructed movement of personnel and equipment; failed to ensure all employees were thoroughly familiar with proper hazardous waste handling and emergency procedures; failed to keep a copy of each signed manifest received from the designated facility onsite for three (3) years; failed to retain onsite a copy of all certifications for three (3) years documenting the offsite treatment, storage, or disposal of hazardous waste; failed to manage spent lead-acid batteries in accordance with R.61-79.266.80; failed to contain universal waste lamps in containers that are structurally sound and adequate to prevent breakage and a release; failed to clean up broken universal waste lamps; failed to label each universal waste lamp or container with one of the following phrases: "Universal Waste – Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)"; and failed to demonstrate the length of time universal waste had accumulated from the date it became a waste.

Action: The Individual/Entity has corrected all violations. 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 fifty dollars **($7,200.00)**.

Updates: The civil penalty has been paid.

Infectious Waste Enforcement

6) Order Type and Number: Consent Order 20-03-IW
Order Date: July 23, 2020
Individual/Entity: **Bon Secours St. Francis Hospital**
Facility: Bon Secours St. Francis Hospital
Location: 2095 Henry Tecklenburg Drive
Charleston, SC 29414
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: SC-10-0263G
Violations Cited: The South Carolina Infectious Waste Management Act**,** S.C. Code Ann. § 44-93-10 et seq. (2002) and the South Carolina Infectious Waste Management Regulation, 8 S.C. Code Ann. Regs. 61-105 (2010).

Summary: Bon Secours St. Francis Hospital (Individual/Entity) is a full-service hospital located in Charleston County, South Carolina. The Department conducted inspections on November 26, 2019, and March 10, 2020. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the Infectious Waste Management Regulations as follows: failed to change the contact name for the infectious waste coordinator; failed to manage infectious waste to prevent exposure to the public or a release to the environment; failed to segregate infectious waste from solid waste; failed to place and maintain all sharps in rigid leak resistant and puncture resistant containers; failed to ensure all other types of infectious waste is placed, stored, and maintained before and during transport in rigid, semi-rigid, leak resistant containers; failed to ensure containers storing infectious waste were sufficient to prevent bursting and tearing; failed to ensure containers of infectious waste were sealed and closed tightly and securely; failed to use red or orange plastic bags inside of containers storing infectious waste; failed to label containers of infectious waste with the universal biohazard symbol sign, the Department issued generator identification number, the date the container was placed in storage or shipped offsite; failed to prevent unauthorized personnel from entering the infectious waste storage areas; failed to label storage areas with the universal biohazard symbol sign; failed to disinfect any area or containers that came in contact with infectious waste prior to reuse; and failed to ensure products of conception be incinerated, cremated, interred, or donated for research.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of eighteen thousand seven hundred twenty dollars ($18,720.00). The Individual/Entity shall pay a civil penalty in the amount of eighteen thousand seven hundred twenty dollars **($18,720.00)**.

Updates: The civil penalty is being paid in accordance with a promissory note.

7)

Order Type and Number:	Consent Order 20-04-IW
Order Date:	July 23, 2020
Individual/Entity:	**Bon Secours St. Francis Hospital, Roper St. Francis Mount Pleasant Hospital, and Roper Hospital**
Facility:	Bon Secours St. Francis Hospital, Roper St. Francis Mount Pleasant Hospital, and Roper Hospital
Location:	2095 Henry Tecklenburg Drive Charleston, SC 29414 / 3500 North Highway 17 Mount Pleasant, SC 29446 / 316 Calhoun Street Charleston, SC 29401
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	SC10-0263G/SC10-1844G/SC10-0264G
Violations Cited:	The South Carolina Infectious Waste Management Act**,** S.C. Code Ann. § 44-93-10 et seq. (2002) and the South Carolina Infectious Waste Management Regulation, 8 S.C. Code Ann. Regs. 61-105 (2010).

Summary: Bon Secours St. Francis Hospital, Roper St. Francis Mount Pleasant Hospital, and Roper Hospital are full-service hospitals located in Charleston County, South Carolina (Individuals/Entities). On November 18, 2019, and March 26, 2020, the Department received documentation that the Individuals/Entities shipped untreated, regulated infectious waste to a facility not registered with the Department. The Individuals/Entities have violated the South Carolina Infectious Waste Management Act and the Infectious Waste Management Regulations as follows: failed to manage infectious waste to prevent exposure to the public or a release to the environment; offered infectious waste for offsite transport to a transporter that was not registered with the Department; failed to segregate infectious waste from solid waste; failed to place and maintain all sharps in rigid leak resistant and puncture resistant containers; failed to ensure all other types of infectious waste is placed, stored, and maintained before and during transport in rigid, semi-rigid, leak resistant containers; failed to ensure containers storing infectious waste were sufficient to prevent bursting and tearing; failed to use red or orange plastic bags inside of containers storing infectious waste; failed to label containers of infectious waste with the universal biohazard symbol sign, the Department issued generator identification number, the date the container was placed in storage or shipped offsite, and a water-resistant, indelible label; failed to treat infectious waste prior to disposal, except as indicated in Section G of the regulations; failed to report to the Department and investigate and confirm a release of infectious waste with twenty-four (24) hours; and failed to ensure products of conception be incinerated, cremated, interred, or donated for research.

Action: The Individuals/Entities have corrected all violations. The Department has assessed a total civil penalty in the amount of sixteen thousand, six hundred eighty dollars ($16,680.00). The Individuals/Entities shall pay a civil penalty in the amount of sixteen thousand, six hundred eighty dollars **($16,680.00)**.

Updates: The civil penalty is being paid in accordance with a promissory note.

BUREAU OF WATER

Recreational Waters Enforcement

8)

Order Type and Number:	Consent Order 20-002-RW
Order Date:	July 2, 2020
Individual/Entity:	**Woodside Plantation Country Club, Inc.**
Facility:	Woodside Plantation
Location:	1000 Woodside Plantation Drive Aiken, SC 29803
Mailing Address:	Same
County:	Aiken
Previous Orders:	None
Permit/ID Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-51(B)(2)

Summary: Woodside Plantation Country Club, Inc. (Individual/Entity) owns and is responsible for obtaining the proper permit to construct a pool located in Aiken County, South Carolina. The Department conducted an inspection on May 21, 2020 and discovered a splash pad had been constructed. Following the inspection, Department staff determined that a permit to construct had not been issued. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to obtain a permit to construct from the Department prior to the construction of a pool.

Action: The Individual/Entity is required to: submit a complete permit application with the associated fee to obtain a permit to construct; and, complete the construction in accordance with the permit. 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)**.

Updates: The permit application has been received. The civil penalty has been paid.

9) Order Type and Number: Consent Order 20-003-RW
Order Date: July 17, 2020
Individual/Entity: **The Gardens at Cypress Bay Property Owners' Association, Inc.**
Facility: The Gardens at Cypress Bay
Location: 4285 Hibiscus Way
Little River, SC 29566
Mailing Address: 4615 Oleander Drive, Suite 202
Myrtle Beach, SC 29577
County: Horry
Previous Orders: None
Permit/ID Number: 26-Q11-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Gardens at Cypress Bay Property Owners' 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 May 28, 2020, and June 29, 2020, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the letters and numbers on the depth marker tiles were not the appropriate size; a ladder was not tight and secure; a ladder was missing tread inserts; the foot rinse shower was not operating properly; the pool equipment room was not locked; the disinfection equipment was not accessible; a section of the perimeter fencing had openings greater than four inches; the chlorine level was not within the acceptable range of water quality standards; there was no United States Coast Guard approved life ring; the emergency notification device was not operational; 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)**.

Updates: The civil penalty has been paid. This project and Order have been closed.

10) Order Type and Number: Consent Order 20-004-RW
Order Date: July 17, 2020
Individual/Entity: **A & S of MB, LLC**
Facility: Sea Mist
Location: 305 13th Avenue South
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: None

Permit/ID Number: 26-657-1, 26-D69-1, and 26-658-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: A & S of MB, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of two public swimming pools, and one public spa located in Horry County, South Carolina. The Department conducted inspections on January 16, 2020, and June 15, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the pool walls were not clean; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring and life ring rope were deteriorated; there was no shepherd's crook; the pool rules sign was not completely filled out; the spa rules sign was not completely filled out; the current pool operator of record information was not posted to the public; the facility could not produce current valid documentation of pool operator of record certification; a pool ladder was missing a bumper; a pool wall was missing tiles; the spa main drain grates were not visible; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; 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 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)**.

Updates: The civil penalty has been paid. This project and Order have been closed.

11) Order Type and Number: Consent Order 20-005-RW
Order Date: July 22, 2020
Individual/Entity: **Blockade Runner Motor Inn, Inc.**
Facility: Blockade Runner
Location: 1910 North Ocean Boulevard
North Myrtle Beach, SC 29697
Mailing Address: Same
County: Horry
Previous Orders: 19-025-RW ($680.00)
Permit/ID Number: 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 located in Horry County, South Carolina. The Department conducted inspections on June 5, 2020, and June 30, 2020, and a violation was 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; 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 one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00).**

Updates: The civil penalty has been paid. This project and Order have been closed.

12)	Order Type and Number:	Consent Order 20-006-RW
	Order Date:	July 22, 2020
	Individual/Entity:	**Sea Bridge Homeowners Association, Inc.**
	Facility:	Sea Bridge
	Location:	112 B 12th Ave N Surfside Beach, SC 29577
	Mailing Address:	P.O. Box 16062 Surfside Beach, SC 29587
	County:	Horry
	Previous Orders:	None
	Permit/ID Number:	26-F09-1
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Sea Bridge Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 1, 2020, and June 29, 2020, and a violation was 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; there was debris and there were chlorine sticks in the skimmer baskets; 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; and, the bound and numbered log book was not maintained on a daily basis.

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

Updates: The civil penalty has been paid. This project and Order have been closed.

13)	Order Type and Number:	Consent Order 20-007-RW
	Order Date:	July 29, 2020
	Individual/Entity:	**Tahitian Taj Property Owner's Association, Inc.**
	Facility:	Tahitian Taj
	Location:	1312 South Ocean Boulevard

	North Myrtle Beach, SC 29582
Mailing Address:	Same
County:	Horry
Previous Orders:	19-011-RW ($680.00); 19-244-RW ($480.00)
Permit/ID Number:	26-1186B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Tahitian Taj Property Owner's 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 conduced inspections on June 3, 2020, and July 2, 2020, and a violation was 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 were no skimmer baskets and the skimmers were missing weirs; the chlorine level was not within the acceptable range of water quality standards; there was no shepherd's crook; the facility address was not posted at the emergency notification device; the pool rules sign was not completely filled out; the bound and numbered log book was not maintained on a daily basis; and, the gate was broken.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of three thousand, two hundred dollars ($3,200.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, two hundred dollars **($3,200.00)**.

Updates: The civil penalty has been paid. This project and Order have been closed.

14)

Order Type and Number:	Consent Order 20-008-RW
Order Date:	July 29, 2020
Individual/Entity:	**Jamaican Sands I Homeowner's Association, Inc.**
Facility:	Jamaican Sands
Location:	216 22nd Avenue North North Myrtle Beach, SC 29582
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-A86-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Jamaican Sands I Homeowner's 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 May 29, 2020, and June 29, 2020, and a violation was 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

bound and numbered log book was not maintained on a daily basis; and, the recirculation and filtration system was not operating.

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

Updates: The civil penalty has been paid. This project and Order have been closed.

Drinking Water Enforcement

15)	Order Type and Number:	Consent Order 20-018-DW
	Order Date:	July 2, 2020
	Individual/Entity:	**Town of McColl**
	Facility:	Town of McColl
	Location:	210 East Gibson Avenue McColl, SC 29570
	Mailing Address:	Same
	County:	Marlboro
	Previous Orders:	None
	Permit/ID Number:	3410003
	Violations Cited:	S.C. Code Ann. Regs. 61-113.I.1 & 61-113.G.1.a

Summary: The Town of McColl (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Marlboro County, South Carolina. The Department issued violations on August 29, 2019, and January 6, 2020, as a result of review of groundwater withdrawal records. The Individual/Entity has violated the Groundwater Use and Reporting Regulation as follows: failed to submit a Water Use Report for the 2019 reporting period and failed to submit an application to modify the Groundwater Withdrawal Permit prior to increasing the permitted limit for 2018.

Action: The Individual/Entity is required to: submit to the Department for review and approval a complete application for the renewal of the Groundwater Withdrawal Permit. 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 eight hundred dollars **($800.00)** and pay a stipulated penalty in the amount of eight hundred dollars ($800.00) should any requirement of the Order not be met.

Updates: The 2019 Waste Use Report was submitted to the Department prior to the issuance of the Order. The Groundwater Withdrawal Permit application has been submitted and approved. The civil penalty has been paid. This project and Order have been closed.

16) Order Type and Number: Consent Order 20-019-DW
Order Date: July 28, 2020
Individual/Entity: **Catawba River Water Supply Project**
Facility: Catawba River Water Plant
Location: 5107 Riverside Road
Lancaster, SC 29720
Mailing Address: P.O. Box 214
Van Wyck, SC 29744
County: Lancaster
Previous Orders: None
Permit/ID Number: 2920002
Violations Cited: S.C. Code Ann. Regs. 61-58.10.I(6)(b)(ii)

Summary: Catawba River Water Supply Project (Individual/Entity) is responsible for the proper operation and maintenance of a public water system (PWS) located in Lancaster County, South Carolina. On June 10, 2020, the Department issued a violation as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for turbidity.

Action: The Individual/Entity is required to: submit a standard operating procedure for staff to follow that includes procedures for operating, maintaining, and monitoring the PWS as well as public notice requirements. The 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)**.

Updates: The standard operating procedure has been submitted and approved. The civil penalty has been paid. This project and Order have been closed.

Water Pollution Enforcement

17) Order Type and Number: Consent Order 20-021-W
Order Date: July 1, 2020
Individual/Entity: **Haile Gold Mine, Inc.**
Facility: Haile Gold Mine WWTF
Location: 7283 Haile Gold Mine Road
Kershaw, SC
Lancaster County, SC
Mailing Address: 6911 Snowy Owl Road
Kershaw, SC 29067
County: Lancaster
Previous Orders: None
Permit/ID Number: SC0040479

Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and 61-68 (2011).

Summary: Haile Gold Mine, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Lancaster County, South Carolina. On November 22, 2019, the Department issued a violation as a result of total thallium violations reported to the Department. On March 6, 2020, a violation was issued as a result of its failure to submit analytical results for mercury from a South Carolina certified laboratory. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for thallium, and failed to submit to the Department analytical results for mercury from a South Carolina certified laboratory.

Action: The Individual/Entity is required to: submit verification of contracting with a certified laboratory for mercury analysis; submit a request to conduct a pilot study for the purpose of evaluating proposed changes in its treatment for thallium; submit a summary of the results of the pilot study; and submit an application for a construction permit if appropriate. The Department has assessed a total civil penalty in the amount of eleven thousand, two hundred dollars ($11,200.00). The Individual/Entity shall pay a civil penalty in the amount of eleven thousand, two hundred dollars **($11,200.00)**.

Updates: The Individual/Entity submitted confirmation that it has contracted with a certified laboratory for analysis of mercury. A pilot study has been completed and the Individual/Entity has reported process changes that have resulted in enhanced thallium treatment. The civil penalty has been paid.

18) Order Type and Number: Consent Order 20-022-W
Order Date: July 9, 2020
Individual/Entity: **Town of Pageland**
Facility: Southeast WWTF
Location: Off Gum Street
Pageland
Chesterfield County, SC
Mailing Address: 126 North Pearl Street
Pageland, SC 29728
County: Chesterfield
Previous Orders: 16-041-W ($3,200.00);
19-056-W ($1,400.00)
Permit/ID Number: SC0021539
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (d) (2011).

Summary: The Town of Pageland (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Chesterfield County, South Carolina. On February 24, 2020, the Department issued a violation as a result of Escherichia coli (E. coli) voilations reported to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for E coli.

Action: The Individual/Entity is required to: complete an upgrade and expansion of the WWTF and submit quarterly progress reports. The Department has assessed a total civil penalty in the amount of one thousand, four hundred dollars ($1,400.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, four hundred dollars **($1,400.00)**.

Updates: The completion of upgrades and expansion of the WWTF is due by March 1, 2021. The first installment of the civil penalty has been paid. The remaining installment payments are due November 15, 2020, February 15, 2021, and May 15, 2021.

19) Order Type and Number: Consent Order 20-023-W
Order Date: July 31, 2020
Individual/Entity: **Palmetto Wastewater Reclamation, LLC**
Facility: Alpine Utilities/Stoop Creek WWTF
Location: Old Bush River Road
Lexington County, SC
Mailing Address: 1710 Woodcreek Farms Road
Elgin, SC 29045
County: Lexington
Previous Orders: None
Permit/ID Number: SC0029483
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (d) (2011).

Summary: Palmetto Wastewater Reclamation, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of the Alpine Utilities/Stoop Creek wastewater treatment facility (WWTF) located in Lexington County, South Carolina. On January 11, 2020, the Department issued a violation as a result of Escherichia coli (E. coli) violations reported to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for E. coli.

Action: The Individual/Entity is required to: submit a construction permit application for a stormwater pump station; submit notification of the completion date for all corrective actions necessary to resolve deficiencies; and demonstrate a six (6) month

compliance confirmation monitoring period. The Department has assessed a total civil penalty in the amount of two thousand, eight hundred dollars ($2,800.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, eight hundred dollars **($2,800.00)**.

Updates: A preliminary engineering report has been submitted for the stormwater pump station and the Department determined a construction permit is not necessary. The construction of the pump station will be completed by January 31, 2020. The six (6) month compliance confirmation period will begin once construction of the pump station is complete.

BUREAU OF AIR QUALITY

20)

Order Type and Number:	Consent Order 20-003-A
Order Date:	July 17, 2020
Individual/Entity:	**Enviva Pellets Greenwood LLC**
Facility:	Enviva Pellets Greenwood LLC
Location:	200 Enviva Way Greenwood, SC 29649
Mailing Address:	Same
County:	Greenwood
Previous Orders:	None
Permit/ID Number:	1240-0133
Violations Cited:	5 S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements

Summary: Enviva Pellets Greenwood LLC, (Individual/Entity), located in Greenwood County, South Carolina, processes softwood and hardwood into pellets to be used for energy production. The Department conducted inspections on May 8, 2019, September 24, 2019, and December 4, 2019. The Individual/Entity has violated the South Carolina Air Pollution Control Regulations, as follows: failed to maintain all required calibration records; failed to document corrective action when deviations from parameter readings occurred; failed to submit operational ranges to the Department for approval; failed to submit an O&M plan to the Department; failed to conduct weekly O&M checks for baghouse cleaning systems, dust collection hoppers and conveying systems; failed to record pressure drop readings for each shift during source operation; failed to provide records of monthly maintenance checks on the RTO temperature indicator; failed to conduct required maintenance on IDE-44 and IDE-45; failed to limit opacity to 20% on September 23, 2019; failed to limit opacity to 20% on December 4, 2019; and failed to limit the use of the bypass stack other than during an emergency or mechanical failure.

Action: The Individual/Entity is required to: limit facility wide opacity to twenty (20) percent; conduct required maintenance in accordance with the regulations; comply with all terms, conditions, and limitations of Department issued air quality permits; and

review, re-assess and submit the current Best Management Practices Plan for dust control at the site. The Department has assessed a total civil penalty in the amount of thirteen thousand dollars ($13,000.00). The Individual/Entity shall pay a civil penalty in the amount of thirteen thousand dollars **($13,000.00)**.

Updates: The Department has received the updated Best Management Practices Plan for dust control and the civil penalty has been paid.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

21)	Order Type and Number:	Consent Order 2020-206-03-010
	Order Date:	July 1, 2020
	Individual/Entity:	**El Paso**
	Facility:	El Paso
	Location:	1937 Augusta Highway Lexington, SC 29072
	Mailing Address:	1317 Petsites Road Chapin, SC 29036
	County:	Lexington
	Previous Orders:	2016-206-03-079 ($800.00); 2017-206-03-019 ($4,000.00); 2017-206-03-067 ($2,250.00); 2018-206-03-018 ($4,250.00); and 2019-206-03-085 ($1,000.00)
	Permit Number:	32-206-06469
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: El Paso (Individual/Entity) is a restaurant located in Lexington County, South Carolina. The Department conducted inspections on July 18, 2018, July 12, 2019, and February 5, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clearly and individually identify with the common name of the material on all working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies.

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)**.

Updates: The civil penalty has been paid.

On Site Wastewater Enforcement

22) Order Type and Number: Administrative Order 20-69-OSWW
Order Date: July 9, 2020
Individual/Entity: **Elizabeth Carver**
Facility: Elizabeth Carver
Location: Parcel #117-00-02-003
Mailing Address: 411 Forest Acres Circle
Walhalla, SC 29691
County: Oconee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Elizabeth Carver (Individual/Entity) owns property located in Oconee County, South Carolina. The Department conducted an investigation on April 17, 2020 and observed disturbed ground around where a PVC pipe connected to a camper exits the ground. This is the area the where the complainant indicated the unpermitted OSWW system was installed. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that a permit to construct and operate any new, upgraded, or expanded onsite wastewater system is obtained from the Department prior to construction and operation of the system; and failed to ensure that each dwelling unit, building, business, or other structure occupied for more than two hours per day shall be provided with an approved method for treatment and disposal of domestic wastewater.

Action: The Individual/Entity is required to remove the unapproved OSWW system within five (5) days and immediately vacate the camper until an approved OSWW system is installed. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The OSWW system has been removed.

23) Order Type and Number: Administrative Order 20-71-OSWW
Order Date: July 9, 2020
Individual/Entity: **Arrowon Corporation**
Facility: Arrowon Corporation
Location: 300 Easley Highway (Highway 8)
Pelzer, SC 29669
Mailing Address: 500 Conneross Road
Townville, SC 29689
County: Anderson

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

Summary: Arrowon Corporation (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on March 6, 2020 and observed possible unapproved wastewater disposal methods and possible domestic wastewater discharging to the surface of the ground. During later investigative visits, Department personnel observed the cleanup of possible discharge and repairs to the OSWW system as well as the introduction of campers occupied without a Department approved means of domestic wastewater treatment and disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: allowed a dwelling unit, building, business, or other structure to be occupied more than two hours per day without an approved method for the treatment and disposal of domestic wastewater.

Action: The Individual/Entity is required to install and connect any unit occupied for more than two hours per day to an approved OSWW system within five (5) days or immediately vacate the campers until such time that a Department approved OSWW system is available at the site. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The residence at the site is vacant per the regional office.

24) Order Type and Number: Administrative Order 20-73-OSWW
Order Date: July 9, 2020
Individual/Entity: **Wayne Lowrance**
Facility: Wayne Lowrance
Location: 63 Henry Street
Camden, SC 29020
Mailing Address: Same
County: Kershaw
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

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

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

Updates: Regional staff have confirmed the discharge has ceased.

25)

Order Type and Number:	Administrative Order 20-74-OSWW
Order Date:	July 9, 2020
Individual/Entity:	**Lucas Suarez and Lucas Manuel Suarez**
Facility:	Lucas Suarez and Lucas Manuel Suarez
Location:	265 Granger Road Spartanburg, SC 29306
Mailing Address:	Same
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Lucas Suarez and Lucas Manuel Suarez (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on May 26, 2020 and observed domestic wastewater discharging into a large hole in the yard. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

Updates: The necessary repairs have been made to the OSWW system and there is no evidence of discharge.

26) Order Type and Number: Administrative Order 20-75-OSWW
Order Date: July 9, 2020
Individual/Entity: **Alan Lanning**
Facility: Alan Lanning
Location: 321 Hoyt Street
Seneca, SC 29678
Mailing Address: 2 Powell Street
Seneca, SC 29678
County: Oconee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Alan Lanning (Individual/Entity) is responsible for property located in Oconee County, South Carolina. The Department conducted an investigation on May 6, 2020 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

Updates: The residence is vacated per the county code enforcement office.

27) Order Type and Number: Administrative Order 20-76-OSWW
Order Date: July 9, 2020
Individual/Entity: **Judith Summer**
Facility: Judith Summer
Location: 470 Halfacre Road
Newberry, SC 29108
Mailing Address: Same
County: Newberry
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Judith Summer (Individual/Entity) owns property located in Newberry County, South Carolina. The Department conducted an investigation on May 14, 2020 and

observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

Updates: The Individual/Entity has reached out to the Department to explain that she is waiting for the sale of some other property to close, and then will begin making the necessary repairs to the OSWW system.

28)

Order Type and Number:	Administrative Order 20-77-OSWW
Order Date:	July 9, 2020
Individual/Entity:	**Foracene Harmon**
Facility:	Foracene Harmon
Location:	22 Parklane Court Prosperity, SC 29177
Mailing Address:	Same
County:	Newberry
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Foracene Harmon (Individual/Entity) owns property located in Newberry County, South Carolina. The Department conducted an investigation on May 4, 2020 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

Updates: The Individual/Entity has been in communication with the Department and the repairs should be completed by the first week in September.

29) Order Type and Number: Administrative Order 20-78-OSWW
Order Date: July 24, 2020
Individual/Entity: **Thomas Kirk, Sr. and Margo Sharee Harris**
Facility: Thomas Kirk, Sr. and Margo Sharee Harris
Location: 169 M R Cash Drive
Cowpens, SC 29330
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

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

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

Updates: As of August 24, 2020, the Individual/Entity has not made necessary repairs to the OSWW system, and domestic wastewater continues to discharge to the surface of the ground. Department personnel will continue working with the Individual/Entity and using further enforcement action to encourage corrective action(s) to be taken.

30) Order Type and Number: Administrative Order 20-79–OSWW
Order Date: July 24, 2020
Individual/Entity: **Joshua Wilson and Rachel Wilson**
Facility: Joshua Wilson and Rachel Wilson
Location: 940 Highway 15 South
St. George, SC 29477

Mailing Address:	201 Kent Court Summerville, SC 29485
County:	Dorchester
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Joshua Wilson and Rachel Wilson (Individual/Entity) own property located in Dorchester County, South Carolina. The Department conducted an investigation on May 29, 2020 and observed domestic wastewater discharging onto the surface of the ground and an occupied camper not connected to an approved OSWW system. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department and failed to ensure no dwelling unit, building, business, or other structure that is occupied for more than two (2) hours per day is connected to an approved method for the treatment and disposal of domestic wastewater.

Action: The Individual/Entity is required to relocate the camper to another site with an approved method of disposal and treatment for domestic wastewater within five (5) days to effectively stop the discharging of effluent, domestic wastewater, or sewage to the surface of the ground or immediately vacate the camper to eliminate the flow of domestic wastewater. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The camper has been vacated and boarded completely up, until resources are available to remove form the Site.

31)

Order Type and Number:	Consent Order 20-49-OSWW
Order Date:	July 2, 2020
Individual/Entity:	**Ben Wigington**
Facility:	Ben Wigington
Location:	104 Massingale Lane Easley, SC 29642
Mailing Address:	3311 Highway 86 Piedmont, SC 29673
County:	Pickens
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Ben Wigington (Individual/Entity) engaged in the business of repairing onsite wastewater systems at property located in Pickens County, South Carolina. The

Department conducted an investigation on March 18, 2020 and observed the Individual/Entity and their crew repairing the septic system. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of and was responsible for the construction and/or repair of an onsite sewage treatment and disposal system in South Carolina without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities as required by the Department.

Action: The Individual/Entity is required to immediately cease and desist engaging in the business of construction or repair of onsite sewage treatment and disposal systems in South Carolina without a valid Department-issued license. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

Updates: The civil penalty has been paid.

32)

Order Type and Number:	Consent Order 20-48-OSWW
Order Date:	July 9, 2020
Individual/Entity:	**Victory Excavating, LLC/Charles Barrett**
Facility:	Victory Excavating, LLC/Charles Barrett
Location:	P.O. Box 81 Cross Anchor, SC 29331
Mailing Address:	Same
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Victory Excavating, LLC and Charles Barrett (Individual/Entity) located in Spartanburg County, South Carolina, hold a Department issued license to install and repair onsite wastewater treatment and disposal systems. The Department conducted an investigation on February 25, 2020 and determined that the drainlines for two installations by the Individual/Entity were installed too deep. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that all systems for which the licensee is responsible are constructed, repaired, and cleaned in accordance with S.C. Regulation 61-56 and permits issued by the Department.

Action: The Individual/Entity is required to cease and desist installing onsite wastewater treatment and disposal systems outside the parameters of the Department issued permit; assist the owner/builder of the sites to apply for new permits from the Department; and bring the OSWW systems into compliance with any new permits issued. 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)**.

Updates: The Individual/Entity is working with regional staff to look into options on how the installed OSWW system can be brought into compliance.

33)	Order Type and Number:	Consent Order 20-56-OSWW
	Order Date:	July 23, 2020
	Individual/Entity:	**Zach Homan, Individually and d.b.a. Homan's Clearwater Company**
	Facility:	Homan's Clearwater Company
	Location:	1840 Freshly Mill Rd. Irmo, SC 29063
	Mailing Address:	Same
	County:	Lexington
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Zach Homan, Individually and d.b.a. Homan's Clearwater Company (Individual/Entity), engaged in the business of repairing an OSWW system in Lexington County, South Carolina. The Department conducted an investigation on February 10, 2020 and discovered the Individual/Entity was not licensed by the Department to construct and repair OSWW systems. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of and was responsible for the construction and/or repair of an onsite sewage treatment and disposal system in South Carolina without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities as required by the Department.

Action: The Individual/Entity is required to immediately cease and desist engaging in the business of construction or repair of onsite sewage treatment and disposal systems in South Carolina without a valid Department-issued license. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

Updates: The unapproved system has been removed from the Site.

34)	Order Type and Number:	Consent Order 20-62-OSWW
	Order Date:	July 23, 2020
	Individual/Entity:	**Peevey, Inc., doing business as Roto-Rooter of Columbia**
	Facility:	Peevey, Inc., doing business as Roto-Rooter of Columbia
	Location:	P.O. Box 5719 Columbia, SC 29250
	Mailing Address:	Same

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

Summary: Peevey, Inc., doing business as Roto-Rooter of Columbia (Individual/Entity) engaged in the business of repairing an OSWW system in Richland County, South Carolina. The Department conducted an investigation on April 21, 2020 and discovered the Individual/Entity was not licensed by the Department to construct and repair OSWW systems. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of and was responsible for the construction and/or repair of an onsite sewage treatment and disposal system in South Carolina without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities as required by the Department.

Action: The Individual/Entity is required to immediately cease and desist engaging in the business of construction or repair of onsite sewage treatment and disposal systems in South Carolina without a valid Department-issued license. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

Updates: The Individual/Entity has not obtained a Department-issued license. The civil penalty has been paid.

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

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 10, 2020

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request to Update and Revise the Current Hearing Procedure for Certified Nurse Aides

II. SUBJECT: Hearing procedure for Certified Nurse Aides

III. FACTS:

Pursuant to an agreement with the United States Department of Health and Human Services ("USDHHS") to carry out the provisions of Title XVIII[1] of the Social Security Act and annual contracts with South Carolina Department of Health and Human Services ("SCDHHS") for the provision of survey and certification services for Title XIX[2] of the Social Security Act, the South Carolina Department of Health and Environmental Control ("Department") is the state survey agency for providers/suppliers participating in the federal Medicare and Medicaid programs ("the programs"). The Department performs a number of functions concerning the programs including, but not limited to, identifying potential participants, conducting investigations and fact-finding surveys, certifying and recertifying providers to participate, and explaining requirements for participation.

Each state is required by federal law to maintain a registry of all nurse aides certified in the state. 42 U.S.C.A. §§ 1395i-3(e)(2) and -1396r(e)(2). The nurse aide registry must provide for the inclusion of specific findings by the state survey agency of abuse, neglect, or misappropriation of resident property involving an individual listed on the registry. *Id.* SCDHHS maintains South Carolina's nurse aide registry. Nursing facilities participating in the programs are prohibited from employing individuals who have had a finding of abuse, neglect, or misappropriation of resident property in the state nurse aide registry. 42 C.F.R. § 483.12(a)(3)(ii).

As the state survey agency, the Department is responsible for investigating allegations of neglect, abuse, and misappropriation of resident property by nurse aides in nursing facilities participating in the programs. *See* 42 U.S.C.A. §§ 1395i-3(g)(1)(C) and -1396r(g)(1)(C); 42 C.F.R. § 488.335(a). If the Department makes a preliminary determination that the abuse, neglect, or misappropriation occurred, it must notify the nurse aide of the nature of the allegations and of the nurse aide's right to request a hearing to rebut the allegations. 42 C.F.R. § 488.335(c). If the nurse aide requests a hearing, the Department complete the hearing and the hearing record within 120 days from the day it receives the request for the hearing. 42 C.F.R. § 488.335(d)(1). The Department must hold the hearing at a reasonable place and time convenient for the nurse aide. 42 C.F.R. § 488.335(d)(2). If the hearing results in a finding of neglect, abuse, or misappropriation of resident property, the Department must report the finding to the nurse aide registry. 42 C.F.R. § 488.335(f).

The Board of Health and Environmental Control ("Board") adopted the Hearing Procedure for Nurse Aides ("Hearing Procedures") on November 18, 1992. The Hearing Procedures were last amended by the Board on March 12, 2015.

---

[1] 42 U.S.C.A. §§ 1395, *et seq.*, Health Insurance for Aged and Disabled (Medicare).
[2] 42 U.S.C. A. §§ 1396, *et seq.*, Grants to States for Medical Assistance Programs (Medicaid).

5. The Department proposes to update and revise the current Hearing Procedure for nurse aides contesting allegations of abuse, neglect, or misappropriation of property to provide for a more streamlined review and investigation and to reflect the reorganization to Healthcare Quality.

IV. ANALYSIS:

1. The proposed update and revision of Hearing Procedure removes Office of General Counsel review as a required component of the review and investigation.

2. To reflect the changes with the reorganization of the Department's Division of Health Regulation to the Division of Healthcare Quality, the proposed Hearing Procedures removes references to the Bureau of Certification and, instead, generally references the Department.

V. RECOMMENDATION:

The Department recommends that the Board grant approval to implement the updated and revised Hearing Procedure for Certified Nurse Aides effective September 10, 2020.

Submitted by:

Phyllis Beaty for
Latonya Williams
Director
Office of Training and Compliance

Approved by:

Gwendolyn Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Section 1864 Agreement between S.C. DHEC and U.S. DHHS (CMS) – Medicare.
B. Contract between S.C. DHEC and S.C. DHHS for the purchase and provision of survey and certification services – Medicaid.
C. 42 U.S.C.A. §§ 1395i-3(g)(1)(C) and -1396r(g)(1)(C).
D. 42 C.F.R. §§ 483.12 and 488.335.
E. Current Hearing Procedure for Certified Nurse Aides.
F. Proposed Hearing Procedure for Certified Nurse Aides.

DEPARTMENT OF HEALTH & HUMAN SERVICES

orig.

Health Care Financing Administration

1864 Agreement

April 11, 1985

Region IV
101 Marietta Tower
Atlanta GA 30323

KMP 2/7/94
Ais ——

Mr. William C. Wilkins, Chief
Bureau of Health Licensure and
Certification
South Carolina Department of Health
and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Mr. Wilkins:

Enclosed is a copy of the new Federal/State Section 1864, 1874 (including related provisions of the Social Security Act) agreement which has been signed and dated. After the agreements were returned from all Region IV states it was necessary to replace the mid-pages of some agreements which had been inadvertently included in draft form. Because of this, a pagination error occurred and there is no page 18. Otherwise, the wording is exactly the same as when the signatories affixed their signatures. For confirmation, you may compare with the copy you retained.

Some states forwarded covering letters in returning their signed agreements. If so, those letters are included along with our own transmittal letter after the signature page (19). The few question(s) you raised will be addressed in the future.

Your cooperation is appreciated.

Sincerely yours,

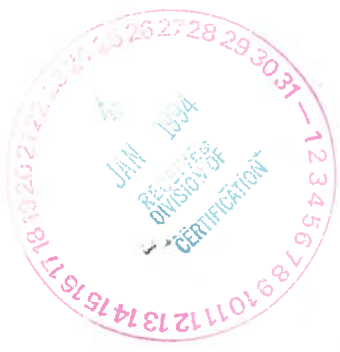
Clarence J. Boone

Clarence J. Boone
Associate Regional Administrator
Division of Health Standards and Quality

Enclosure

5000
5
$250.00

March 17, 1995



AGREEMENT Identifier Code: HCFA-85-_____

AGREEMENT BETWEEN

The Secretary of Health and Human Services

and

The State of South Carolina

To carry out the provisions of Sections 1864, 1874, and related provisions of the Social Security Act, as amended.

The Secretary of Health and Human Services, hereinafter referred to as the Secretary, and the State of South Carolina.

(S.C. Department of Health & Environmental Control, Division of Health Licensing and Certification
State Survey Agency).

Hereinafter referred to as the State, hereby agree to the following terms:

INDEX

Article I
DEFINITIONS AND DELEGATTIONS

A. Definition of terms for the purpose of this Agreement:

1. "Secretary" means the Secretary of Health and Human Services of the Secretary's delegate, unless otherwise specified.

2. "Act" means Title XVIII of the Social Security Act, as amended.

3. "HCFA" means the Health Care Financing Administration.

4. "Provider" or "provider of services" means an insitution, or distinct part of an institution, facility or agency defined in the Act and includes but is not limited to:

   a. Hospitals

   (1) General
   (2) Short term
   (3) Children's and Adolescent/Children's
   (4) Christian Science Sanatoriums
   (5) Medical-surgical
   (6) Orthopedic
   (7) Gynecological
   (8) Maternity or Obstetric
   (9) Eye, Ear, Nose and Throat
   (10) Cancer/Oncology
   (11) Psychiatric
   (12) Rehabilitation
   (13) Long Term
   (14) Swing Bed (Hospital providers of extended care services)

   b. Skilled nursing facilities

   c. Home health agencies

   d. Providers of outpatient physicial therapy and/or speech pathology services

   e. Comprehensive outpatient rehabilitation facilities

   f. Hospices

5. "Supplier" or "supplier of services" means an individual or entity whose services are described in the Act and includes but is not limited to:

   a. Independent laboratories

   b. Suppliers of portable X-ray services

c. End-stage renal disease treatment facilities

d. Chiropractors

e. Rural health clinics

f. Physical therapists in independent practice

g. Ambulatory surgical centers

6. "General instructions" means operating manuals, related written instructions, and guidelines of general application issued by the Secretary purusant to the Act and regulations in respect to matters covered by this Agreement. A general instruction for purposes of the Agreement may not be issued below the level of the Secretary's designee (i.e. Director of the Office of Survey and Certification, Regional Administrator or Associate Regional Administrator).

7. "Regulations" unless otherwise specified, means those regulations promulgated by the Secretary pursuant to the Act and codified in the Code of Federal Regulations, Title 42, Chapter IV.

8. "Federal Acquisition Regulation" means those parts of the Federal Acquisition Regulation (FAR) to which reference is made hereinafter, as in effect on April 1, 1984, codified in Title 48 of the Code of Federal Regulations, and includes the Department of Health and Human Services Acquisition Regulation.

9. "State" means the State which is a party to this Agreement and includes the State survey agency.

10. "State survey agency" refers to that component within the State government which has the primary responsibility for the performance of the functions under this Agreement.

11. "Subcontract" means any contract, agreement, purchase order, or lease (including leases of real property) to obtain space, supplies, equipment, or services under this Agreement; the term "subcontractor" means any holder of one or more subcontracts. "Subcontract" does not include an agreement between the State survey agency and other State or local government agencies.

12. "Trust Fund" means either the Federal Hospital Insurance Trust Fund established by Section 1817(a) of the Act or the Federal Supplementary Medical Insurance Trust Fund established by Section 1841(a) of the Act, or both, as may be appropriate in the context of this Agreement.

B. Federal delegations of authority for the purpose of this Agreement:

The Secretary of Health and Human Services has delegated the authority for the administration of this Agreement, except for the authority to terminate the Agreement under Section 1864 of the Act, to the Administrator of the Health Care Financing Administration. This authority has been redelegated by the

Administrator to the Deputy Administrator and to the Associate Administrator for Operations, and has been further redelegated to the Deputy Associate Administrator for Operations and the Regional Administrators. The Regional Administrator may retain the authority or redelegate it further to an Associate Regional Administrator.

Certain responsibilities for the administration of the Act have been or may be delegated to the Inspector General of the Department of Health and Human Services or to other components of the Department.

Article II
FUNCTIONS TO BE PERFORMED BY THE STATE

A. Under Section 1864(a) of the Act

1. The State upon request of the Secretary shall certify whether or not providers/suppliers within the State that are participating or are asking to participate under the Act, comply with all applicable definitions and requirements in the Act and in implementing regulations.

In performing certification related duties, the functions of the State include, but are not limited to:

(a) identifying potential providers and suppliers of services within the State;

(b) explaining the requirements and conditions for qualifying as a provider or supplier of services;

(c) surveying for the purpose of certifying to the Secretary compliance or non-compliance of providers and suppliers of services and resurveying such entities, at such times and manner as the Secretary may direct;

(d) explaining requirements for an acceptable plan of correction for cited deficiencies; and

(e) forwarding to the Secretary a completed Statement of Deficiencies and Plan of Correction, HCFA Form 2567, that is acceptable to the Secretary for each provider and supplier surveyed or resurveyed.

In making certifications the State shall apply the appropriate conditions of participation for providers and conditions for coverage for suppliers of services, including standards for life safety from fire, and other requirements incorporated by reference in the regulations. The application of such conditions, standards and requirements shall be in accordance with the nationally uniform survey procedures established in regulations and general instructions.

B. Under Sections 1864(c) and 1865(a) of the Act

1. At the request of the Secretary, the State shall conduct validation surveys of institutions accredited by the Joint Commission on Accreditation of

Hospitals or the American Osteopathic Association on a selected sample basis, or because of substantial allegations of the existence of significant deficiencies. Complaints concerning accredited institutions received by the State shall be reported to the Secretary. To the extent that the Secretary finds it desirable and in the interest of maintaining uniformity of results, representatives of the Secretary may join with the State in conducting validation surveys. The State shall assist the Secretary's representatives in investigating, documenting, and resolving differences between the findings reported by the accrediting bodies and those obtained in validation surveys. The State shall similarly conduct validation surveys of providers and suppliers, accredited by other accrediting organizations on the same basis in accordance with regulations and general instructions of the Secretary.

2. Exception. Validation surveys on a selective sample basis of clinical laboratories in accredited hospitals are not covered by this Agreement.

C. Under Section 1874 of the Act

1. The State shall certify to the Secretary whether:

(a) Suppliers of portable X-ray services performing diagnostic X-ray tests described in Section 1861(s)(3) of the Act, meet the requirements of the Act and regulations;

(b) Chiropractors furnishing the services and supplies described in Sections 1861(s)(1) and 1861(s)(2)(A) of the Act, meet the requirements of Section 1861(r)(5), including whether such chiropractors are licensed or otherwise legally authorized to perform such services, and whether they meet the uniform minimum standards prescribed by the Secretary;

(c) End-stage renal disease treatment facilities meet the requirements of Section 1881 of the Act and implementing regulations prescribed by the Secretary;

(d) Physical therapists furnishing individuals with outpatient physical therapy or speech pathology services in such therapists' offices or in such individuals' homes meet the requirements of Section 1861(p) of the Act, and implementing regulations prescribed by the Secretary (including whether such physical therapists meet State licensure requirements).

(e) Independent clinical laboratories performing diagnostic laboratory services described in Sections 1861(s)(3), (11) and (12) of the Act, meet the requirements of the Act and regulations.

(f) Clinical laboratories performing tests (diagnostic laboratory services) or procedures in interstate commerce meet the requirements of the Clinical Laboratory Improvement Act (Section 353 of the Public Health Service Act, 42 USC 263a) and regulations (42 CFR Part 74).

2. The State shall assist the Secretary in collecting financial interest information that providers and suppliers are required to furnish pursuant to

the Act and regulations.

D. Under the Prospective Payment System (PPS)

The State shall conduct surveys of providers or parts of providers in connection with requests for exemption from PPS.

E. Effect of State and Local Licensing Requirements

The State shall certify whether or not a provider or supplier is eligible or continues to be eligible for participation in or coverage under the Medicare program whether or not the State's licensure program provides for the licensing of that provider or supplier.

F. Real Party In Interest

In the performance of the functions described in this Agreement, the State acts on behalf of the Secretary as a Federal contractor, carrying on for the Secretary, the administrative responsibilities imposed pursuant to law by applying and enforcing Federal standards. The Secretary, however, is the real party in interest in administering the program established by the Act.

G. Records

The State, or any local governmental agency performing any function of the State under this Agreement, shall maintain pertinent survey, certification, statistical, or other records for a period of at least four (4) years after the date of such record.

H. Reports

The State shall make reports in the form and containing such information as the Secretary may require, and shall comply with such general instructions or regulations as the Secretary may issue regarding the accuracy of such reports. Where feasible and practicable such reporting requests will provide lead time that will facilitate any necessary adjustments in workload planning.

Article III
COMPLIANCE WITH REGULATIONS AND GENERAL INSTRUCTIONS

The State shall comply with such regulations and general instructions as the Secretary may prescribe for the administration of this Agreement. When feasible and practicable the State will be requested to apply its program knowledge and experience to participate in the development of general instructions.

Article IV
ORGANIZATION AND PERSONNEL

A. Organization

1. The State shall organize most of the functions under this Agreement within a single State survey agency.

2. The State shall provide facilities and employ qualified personnel necessary to carry out the functions under this agreement. The placement of survey personnel within the State survey agency, or any other agency of the State dedicated to fulfilling the functions of this Agreement, shall be subject to the approval of HCFA.

3. With the prior written authorization of the Secretary, the State, may utilize the services, facilities, and records of any other State agency or local governmental agency to assist the State survey agency in carrying out the functions authorized by this Agreement. Only the reasonable and necessary costs incurred by such agencies in furnishing to the State survey agency such services, facilities, or records, may be allowed under this Agreement, in accordance with Article IX.

B. Personnel

1. Personnel of the State performing functions under this Agreement shall meet the Federal surveyor qualification standards specified in general instructions.

2. Upon request of the Secretary, personnel employed or utilized by the State in carrying out the functions under this Agreement will participate in programs designed to develop and maintain the proficiency of personnel directly involved in survey or certification activities. These programs include but are not limited to surveyor orientation, basic surveyor training, and specialty surveyor training. Survey personnel will attend meetings, conferences, or training programs within or outside the State as may be required by the Secretary.

3. The State shall require any local governmental agency performing services pursuant to Paragraph A, section 2, of this Article to follow the general instructions applicable to surveyor qualifications and the merit system standards applicable to the State.

4. Standards for a merit system of personnel administration consistent with the Federal regulation in 5 CFR, Chapter I, Subpart F - Standards for a Merit System of Personnel Administration, shall be maintained by the State and made applicable to personnel in any State or local agency involved in the performance of this Agreement.

Article V
EVALUATION

A. The Secretary has the right periodically to evaluate the State's performance under this Agreement. The Secretary may maintain onsite representatives with the State or a subcontractor for the duration of any such evaluation.

B. When an evaluation is made by the Secretary on the premises of the State or a subcontractor, the State shall provide, and shall require its subcontractor(s) to provide, all reasonable facilities and assistance for the safety and convenience of the Secretary's representatives in the performance of their functions. The State shall furnish to the Secretary such records and reports as the Secretary may require to evaluate the State's performance under this Agreement. All evaluations by the Secretary shall be performed in such a manner as will not unduly delay the State's functions under this Agreement.

C. The Secretary makes evaluations primarily through a planned program of Federal surveys of providers and suppliers previously surveyed by the State and through its national State Agency Evaluation Program (SAEP).

The SAEP is designed to evaluate the manner and extent to which the State meets performance standards. Major operational specifics for the performance standards are detailed in the State Operations Manual (HCFA Pub. 7).

The performance standards include, but are not limited to the following:

1. Organization and staffing of the State survey agency enables fulfillment of the functions required under this Agreement.

2. Surveys are planned, scheduled, conducted, and processed timely.

3. Survey findings are supportable.

4. Certifications are fully documented, and consistent with applicable law, regulations, and general instructions.

5. Current written internal operating procedures are consistent with program requirements.

6. A plan of correction is requested from a provider/supplier having deficiencies that do not pose an immediate and/or serious threat to patients, or do not limit the capacity to furnish care or services. The State follows up with providers and suppliers until deficiencies are corrected.

7. When certifying noncompliance, adverse action procedures set forth in regulations and general instructions are adhered to.

8. Supervisory reviews and evaluations of surveyor performance are made routinely.

9. Required financial and budget reports are submitted on time and completed in accordance with general instructions.

10. All expenditures and charges to the program are substantiated to the Secretary's satisfaction.

11. Actual survey and certification activities are consistent with the annual activity plan and workload estimate approved by HCFA.

12. The performance of agencies utilized to perform specific functions under this Agreement are monitored.

13. Ongoing surveyor training programs develop and maintain surveyor proficiency.

14. Results of complaint investigations against providers and suppliers are considered in making certification decisions.

D. If a formal evaluation report is prepared that reflects deficiencies in the State's performance under this Agreement or proposes corrective action to be taken by the State, the Secretary shall:

1. furnish a copy to the State; and

2. discuss any corrective actions proposed in the report with the State in order to establish reasonable and practicable time frames for implementation.

E. When the Secretary determines that the State is not able or is not willing to perform part or all of the functions and responsibilities prescribed in this Agreement, the Secretary may terminate the Agreement in whole or in part, in accordance with Article VIII.

Article VI
TERM OF AGREEMENT

A. This Agreement shall begin on October 1, 1985, and end on September 30, 1986. The Agreement is automatically renewed for periods of one (1) year unless the Secretary or the State gives written notice of its intention not to renew the Agreement at least 90 days before the end of the current term.

B. Any notice under Paragraph A of this Article shall be deemed to have been given upon the date such notice was mailed, as established by the postmark or other appropriate evidence of the date of transmittal. Whenever the State gives notice of its intention not to renew this Agreement it shall, prior to mailing such notice, notify the appropriate HCFA Regional Administrator, by telephone or other oral communication, of its intention not to renew the Agreement.

Article VII
MODIFICATION OF AGREEMENT

A. This Agreement may be modified at any time by mutual written consent of the Secretary and the State.

B. The Secretary may modify this Agreement to incorporate changes in the State's functions and responsibilities as a result of changes to the Act or regulations.

C. Prior to any modification under Paragraph B of this Article, the Secretary shall consult with the State and participate in planning for adjustments which might be necessary. Thereafter, the Secretary shall provide the State written notice that the modification is to be made not more than 90 days after the date specified in the notice (or such other date as may be required by statute). If the State notifies the Secretary within 10 days of receipt of the Secretary's notification, the State may terminate this Agreement not less than 90 days after the date specified in the notice and shall not be required to implement any modification of this Agreement provided for in such notification during such 90 day period.

Article VIII
TERMINATION OF AGREEMENT

A. This Agreement may be terminated at any time by mutual written consent of the parties to the Agreement.

B. The State may terminate this Agreement at any time upon 180 days written notice to the Secretary.

C. If the Secretary determines that the State is not able or willing to carry out part or all of the functions under this Agreement (including a determination that the State has failed to meet a performance standard(s) as described in Article V and detailed in the State Operations Manual), the Secretary may terminate the Agreement in whole or in part to exclude specific classes of providers and/or suppliers identified in Article I from the State's survey and certification functions under this Agreement, or otherwise to limit or decrease its scope.

D. If this Agreement is terminated pursuant to the terms of this Article, the State shall be paid the allowable costs incurred in terminating this Agreement in accordance with Article IX, Paragraph 2.

E. If this Agreement is terminated or nonrenewed by either the Secretary or the State, the State shall use its best efforts to accomplish an orderly transition of its functions under this Agreement to the successor survey entity.

Article IX
COST OF ADMINISTRATION

A. The Secretary's fiscal obligation under this Agreement is contingent upon the apportionment to the Secretary of appropriated funds for the applicable fiscal year from which payment for the cost of performing the functions of this Agreement can be made. No legal liability on the part of the Secretary for any payment, nor any legal obligation of the State to perform, may arise until the State receives notice from the Secretary that funds have been made available for this Agreement. Moreover, in no event shall the Secretary's obligation under this Agreement exceed the amount of funds which have been obligated to this Agreement.

B. The State shall be given sufficient opportunity prior to the beginning of every Federal fiscal year to prepare a State survey agency activity plan and budget estimate based on HCFA's activity plan and budget estimate for that forthcoming Federal fiscal year. On this basis, the State will submit to the Secretary, at such time and in such form as the Secretary may prescribe, a budget request that provides an estimate of costs to be incurred by the State (through the State survey agency and other State and local agencies) for performing the functions under this Agreement for the period corresponding to the Federal fiscal year that begins on October 1 and ends on September 30. The budget request will include cost estimates accompanied by such supporting documents as may be prescribed by the Secretary.

C. The Secretary will not reimburse the State for any costs attributable to the general expenses of the State in carrying out functions of State government which are not related to this Agreement. The State budget request must equitably apportion the costs attributable to expenses incurred by the State for conducting activities related to, but distinguishable from, activities conducted under the Act and this Agreement. The Secretary will reimburse the State for HCFA's fair share of the costs attributable to such planning and other efforts as the State may perform directed towards the coordination of activities in carrying out this Agreement and other activities related to the provision of services similar to those for which payment may be made under of the Act, or

related to the facilities and personnel required for the provision of services, or related to improving the gquality of such services. The Secretary will determine the amount of such costs allocable to this Agreement on the basis of information submitted by the State, setting forth the plans propposed for coordinating its functions under this Agreement with such other activities.

D. The Secretary and the State will negotiate the amount of the annual budget, and any revisions thereto, based on the budget request submitted by the State. After the negotiations between the Secretary and the State on the amount of the annual budget, or any revisions thereto, the Secretary will issue a notice specifying such budget in an amount calculated to pay the costs of administering this Agreement. Such budgeted amount for the purpose of obligation of funds by the Secretary shall be a ceiling which the State may not exceed without the prior written approval of the Secretary.

The State may, at any time during the fiscal year, submit appropriate revisions to the estimated amount of its budget as a result of any modification to this Agreement of functions thereunder. The Secretary will determine if a revision to the amount of the estimated budget is appropriate and on that basis will make any adjustments to the budgeted amount.

E. If at any time it appears to the State that the budgeted amount is not sufficient to cover costs incurred and estimated to be incurred in the fiscal year, the State shall so notify the Secretary promptly. Such notification may be by telephone or telegraph with later confirmation by letter and will contain proposals as to how costs expected to be incurred may be reduced. The Secretary and the State will promptly negotiate ways and means of resolving the matter for the purpose of ensuring that the State will not incur costs in excess of the budgeted amount. Such resolution may include an increase in the budget, a reduction of functions to be performed by the State, a combination of both, or such other ways and means as may be agreeable to the parties. If, after negotiating in good faith, the parties are unable to find a satisfactory solution to the matter, the Secretary will give the State written notice as to what measures to take in order to avoid incurring costs in excess of the budgeted amount.

Notwithstanding any other provisions of this Agreement, if the Secretary notifies the State to abate the performance of a funtion, there shall be no obligation on the part of the Secretary for costs incurred by the State in the performance of such function beyond the effective date of the notice to abate or the date such notice is received, whichever is later.

However, the allowability of any costs incurred by the State in the implementation or any such abatement directed by the Secretary will be governed by the provisions of the Federal Acquisition Regulation applicable to termination costs.

F. The Secretary is not obligated to reimburse the State for costs incurred in excess of the budgeted amount. The State is not obligated to incur costs in excess of the budgeted amount until the Secretary notifies the State, in writing, that the budgeted amount has been increased.

G. Subject to the foregoing provisions of the Article, the Secretary shall pay to the State the total amount of allowable costs incurred by the State in the performance of this Agreement. The costs allowable under this Agreement will

be determined in accordance with Subpart 31.6 of the Federal Acquisition Regulation. The FAR provides that the allowability of costs under the Agreement will be determined in accordance with Office of Management and Budget, Circular No. A-87, "Cost Principles for State and Local Governments."

H. The STate shall comply with applicable regulations and general instructions for property purchased with funds provided under this Agreement. Funds provided by the Secretary under this Agreement will be used solely for the reasonable and necessary costs of the State in performing the functions authorized by the Agreement.

I. If the State utilizes any service or material purchased or contracted for pursuant to this Agreement for purposes other than those authorized by the Agreement, the cost of such service or material will be pro-rated, pursuant to State Operations Manual procedures issued by the Secretary and applicable cost principles. Only that part that is attributable to the performance of functions authorized by this Agreement may be considered a reasonable and necessary cost for the performance of this Agreement.

J. The State shall submit to the Secretary a report, including supporting data, of the allowable costs incurred by it during each quarter of the Federal fiscal year. This report is due to the Secretary no later than 30 days after the close of the quarter in which such costs were incurred.

Negotiations on the amount of administrative costs of the State to be allowed by the Secretary shall be undertaken by the Secretary and the State, based upon the State's quarterly statements.

Such items of costs on which the Secretary and the State are unable to agree will continue to be negotiated and, if not resolved, are subject to a subsequent determination by the Secretary in accordance with Paragraph K on this Article. To the extent unpaid, such amounts which are agreed upon shall be promptly by the Secretary.

K. If the Secretary and the State are unable to agree upon a final amount of the administrative costs of the State for a particular quarter or other period, the Secretary shall issue a final determination of the amount of such administrative costs for such period and inform the State of such costs, with a full explanation of the exceptions taken to the State's report of its allowable costs.

The State may appeal the final determination in accordance with the provisions of Article XIV of this Agreement, entitled "Disputes." Where a particular cost or type of cost is disallowed by final determination or the Secretary and the State is not in agreement with the Secretary's disallowance, the State shall, for any subsequent claims, abide by the decision of the Secretary and agrees not to be reimbursed pending resolution of any amounts of such costs. Until the issue is resolved, the State shall segregate such costs from all others, and specify the amounts of such costs on all subsequent claims. Any funds withdrawn through the letter of credit in excess of the amount finally determined to be allowable must be returned promptly to the Secretary.

L. The State shall furnish or make available such supplemental accounts, records, or other information as may be requested by the Secretary to substantiate any estimates, expenditures, or reports as may be necessary for auditing purposes, or

to verify the allowability of the State's expenditures under this Agreement.

Article X
SUBCONTRACTING

A. The State shall not enter into any subcontract to perform any of the functions set forth in Article II of this Agreement unless such subcontract received the prior written approval of the Secretary.

B. The State shall not enter into any subcontract under this Agreement not controlled by Paragraph A of this Article, if any part the cost of the subcontract is allocable to this Agreement and if the subcontract provides for payment on a cost-plus-fixed-fee-basis, regardless of amount, or where the estimated cost of such subcontract exceeds, or is expected to exceed $25,000, without the prior written approval of the Secretary.

C. Any modification to a subcontract which required the prior written approval of the Secretary must be submitted to the Secretary for prior written approval.

D. If the State enters into a subcontract, or modifies an existing subcontract without the prior written approval of the Secretary, where required, the Secretary is not obligated to reimburse the State for costs incurred with respect to such subcontract or modification.

E. The requirement for prior written approval may be waived by the Secretary in writing, where requiring such approval is administratively impracticable and the State secures the waiver in advance of entering into or modifying a subcontract. In addition, the Secretary may ratify any subcontract in writing. Such ratification shall constitute the approval of the Secretary.

F. Prior written approval given by the Secretary with respect to subcontract or modification hereto does not constitute a determination of the allowability of costs, unless so stipulated.

G. The State shall select subcontractors on a competitive basis to the maximum practicable extent consistent with the objectives and requirements of this Agreement.

H. For any subcontract or modification of a subcontract entered into or renewed under this Agreement, where the estimated cost to this Agreement under the subcontract exceeds $500,000 and is not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation, the State shall, in accordance with Subpart 15.8 of the Federal Acquisition Regulation, require a subcontractor to submit written cost or pricing data and certify that the cost of pricing data submitted were accurate, complete, and current prior to the entry into the subcontract or modification of a subcontract. The State shall, through inclusion in all such subcontracts, require subcontractors to maintain full and complete accounting records, support costs or pricing data submitted as aforesaid, to require subcontractors to provide for full access by the State, the Secretary, and the Comptroller General of the United States for the purpose of

examining the accuracy of cost or pricing data submitted as aforesaid, and in accordance with Subpart 15.8 of the Federal Acquisition Regulation, to agree to a reduction in price if the cost or pricing data submitted are found to be defective.

I. No subcontract under this Agreement may provide for payment on a cost-plus-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts may not exceed thefee limitations in subsection 16.301-3 of the Federal Acquisition Regulation.

Article XI
TRANSFER OF FUNDS THROUGH LETTER OF CREDIT

A. The Secretary will provide for an advance of funds by letter of credit to the State's designated commercial bank to authorize the withdrawal of funds from the United States Treasury in accordance with the governing Treasury instruction 31 CFR Part 205 (Circular No. 1075). Each letter of credit will authorize the State's commercial bank to process payment vouchers drawing on funds made available through the Federal Reserve Bank or branch. More specific Letter of Credit procedures are provided to each State via the Departmental Federal Assistance Financing System Users Guide.

B. The letter of credit will specify a maximum monthly amount that may be withdrawn during each month by the State. Such amounts will normally be 1/12 of the appoved annual budget unless the Secretary and the State have agreed to other allotments of payment. Amounts available for withdrawal but not withdrawn in any month may be carried over to the following months within the fiscal year. The authorized official of the State may make withdrawals only to the extent that funds are currently needed to meet estimated expenditures. Withdrawals may not be made to the extent that cash on hand or in banks renders further withdrawals unnecessary or premature. If the amount specified in the letter of credit is not sufficient to meet estimated expenditures, the letter of credit may be modified by the Secretary.

Article XII
EXAMINATION OF RECORDS

A. The Secretary and the Comptroller General of the United States or a duly authorized representative, until three (3) years after final payment under this Agreement or for any other period specified in Federal Acquisition Regulation (FAR) Subpart 4.7, "Contractor Records Retention," has access to and the right to examine any of the State's directly pertinent books, documents, papers, or other records involving transactions related to this Agreement.

B. The State agrees to include in first-tier subcontracts under this Agreement a clause to the effect that the Secretary and the Comptroller General or a duly authorized representative, until three (3) years after final payment under the subcontract or for any other period specified in FAR Subpart 4.7, has access to

and the right to examine any of the subcontractor's directly pertinent books, documents, papers, or other records involving transactions related to the subcontract. "Subcontract," as used in this Article, excludes (1) purchase orders not exceeding $10,000; and (2) subcontracts or purchase orders for public utility services at rates established to apply uniformly to the public, plus any applicable reasonable connection charge.

C. The periods of access and examination in Paragraph A and B above for records relating to (1) appeals under Article XIV; (2) litigation or settlement of claims arising from the performance of this Agreement or; (3) costs and expenses of this Agreement to which the Secretary or the Comptroller General or a duly authorized representative has taken exceptions are finally disposed of.

Article XIII
CONFIDENTIAL NATURE AND LIMITATIONS ON USE OF INFORMATION AND RECORDS

A. The State shall adopt policies and proceudres to ensure that information contained in its records and obtained from the Secretary or from any provider or supplier of services will be disclosed only as provided in the Act or regulations.

B. The Privacy Act of 1974, 5 U.S.C. 552a, is applicable to this Agreement in accordance with Paragraph A(11) of Article XV.

Article XIV
DISPUTES

A. This Agreement is subject to the Contract Disputes Act of 1978 (41 U.S.C. 601-613), referred to in this Article as the "CDA".

B. Except as provided in the CDA, all disputes arising under or relating to this Agreement shall be resolved under this Article.

C. "Claim," as used in this Article, means a written demand or written assertion by one of the parties to this Agreement seeking, as a matter or right, the payment of money in a sum certain, the adjustment or interpretation of contract terms, or other relief arising under or relating to this Agreement. A claim arising under an Agreement, unlike a claim relating to that Agreement, is a claim that can be resolved under an Article of the Agreement that provides for the relief sought by the claimant. However, a written demand or written assertion by the State seeking the payment of money exceeding $50,000 is not a claim under the CDA until certified as required by Paragraph D, Section 2 of this Article. A voucher, invoice, or other routine request for payment that is not in dispute when submitted is not a claim under the CDA. The submission may be converted to a claim under the CDA, by complying with the submission and certification requirements of this Article, if it is disputed either as to liability or amount or is not acted upon in a reasonable time.

D. 1. A claim by the State shall be made in writing and submitted to the

Secretary for a writted decision. A claim by the Government against the State shall be subject to a written decision by the Secretary.

2. For State claims exceeding $50,000, the State shall submit with the claim a certification that:

   (a) the claim is made in good faith;

   (b) supporting data are accurate and complete to the best of the State's knowledge and belief; and

   (c) the amount requested accurately reflects the contract adjustment for which the State believes the Government is liable.

3. The certification shall be executed by:

   (a) the State official in charge of the State survey agency or the agency of which the State survey agency is a component; or

   (b) as appropriate, an official of the State having overall responsibility for the conduct of the State's affairs.

E. For State claims of $50,000 or less the Secretary must, if requested in writing by the State, render a decision within 60 days of the request. For State certified claims over %50,000, the Secretary must, within 60 days, decide the claim or notify the State of the date by which the decision will be made.

F. The Secretary's decision shall be final unless the State appeals or files a suit as provided in the CDA.

G. The Government shall pay interest on the amount found due and unpaid from (1) the date the Secretary receives the claim (properly certified if required), or (2) the date payment otherwise would be due, if that day is later, until the date of payment. Simple interest on claims shall be paid at the rate, fixed by the Secretary of the Treasury as provided in the CDA, which is applicable to the period during which the Secretary receives the claim and then at the rate applicable for each 6-month period as fixed by the Treasury Secretary during the pending of the claim.

H. The State shall proceed diligently with performance of this Agreement, pending final resolution of any request for relief, claim, appeal, or action arising under the Agreement, and comply with any decision of the Secretary.

Article XV
CLAUSES INCORPORATED BY REFERENCE

The following clauses are hereby incorporated into and are made a part of this Agreement. For purposes of these clauses, the term "Contractor" means the "State", and "Contracting Officer" or "Project Officer" means the "Secretary" or "Secretary's designee."

A. Federal Acquisition Regulation (FAR) Clauses (48 CFR Chapter 1)

	Title	FAR Reference
1.	Officials Not To Benefit	52.203-1
2.	Gratutities	52.203-3
3.	Utilization of Small Business Concerns and Small Disadvantaged Business Concerns	52.219-8
4.	Utilization of Women-Owned Small Business	52.219-13
5.	Utilization of Labor surplus Area Concerns	52.220-3
6.	Convict labor	52.222-3
7.	Equal Opportunity	52.222-26
8.	Affirmative Action for Special Disabled and Vietnam Era Veterans	52.222-35
9.	Affirmative Action for Handicapped Workers	52.222-36
10.	Clean Air and Water	52.223-2
11.	Privacy Act	52.224-2
12.	Interest	52.232-17
13.	Assignment of Claims	52.232-23

B. Department of Health and Human Services Acquisition Regulation (HHSAR) Clauses (48 CFR Chapter 3)

	Title	HHSAR Reference
1.	Printing	352.268-70
2.	Rights in Data	352.227-1
3.	Required Insurance	352.228-70
4.	Withholding of Contract Payments	352.232-9
5.	Prohibition Against Use of HHS Funds to Influence Legialation or Appropriations	352.232-72
6.	Litigation and Claims	352.233-70
7.	Services or Consultants	352.237-71
8.	Notice to the Government of Delays	352.242-70
9.	Final Decisions on Audit Findings	352.242-71
10.	Foreign Travel	352.247-70
11.	Excusable Delays	352.249-14
12.	Paperwork Reduction Act	352.276-7

AGREEMENT Identifier Code: HCFA-85-__

IN WITNESS WHEREOF, the parties hereby execute this Agreement this EIGHTH day of APRIL, 1985.

State of South Carolina

By: Robert S Jackson MD
(Name)
Commissioner
(Title)

Secretary of Health and Human Services

By: Quinn R Hellund
(Name)
Regional Admin. HCFA
(Title)

CONTRACT

BETWEEN

SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

FOR THE PURCHASE AND PROVISION OF

SURVEY AND CERTIFICATION SERVICES

DATED AS OF

OCTOBER 1, 2019

A20201208A

INDEX

CONTRACT

BETWEEN

SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

FOR THE PURCHASE AND PROVISION SURVEY AND CERTIFICATION SERVICES

This Contract is entered into as of the first day of October 2019, by and between the South Carolina Department of Health and Human Services, 1801 Main Street, Post Office Box 8206, Columbia, South Carolina, 29202-8206, hereinafter referred to as "SCDHHS" and the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina 29202, hereinafter referred to as "SCDHEC".

RECITALS

WHEREAS, SCDHHS is the single state agency responsible for the administration in South Carolina of a program of Medical Assistance under Title XIX of the Social Security Act and makes all final decisions and determinations regarding the administration of the Medicaid Program.

WHEREAS, the Provider has been designated by the Secretary of the United States Department of Health and Human Services (USDHHS) as the agency to perform surveys to determine qualifications of institutions and suppliers of services to participate in the Medicare program, and federal regulations (42 CFR 431.610 (b) (2010, as amended) require that the State use the same agency to determine qualifications for participation in the Medicaid program.

WHEREAS, the United States Department of Health and Human Services has allocated funds under Title XIX of the Social Security Act to SCDHHS to perform certain administrative functions.

WHEREAS, SCDHEC represents and warrants that it meets applicable standards to receive such funds for certain administrative functions as specified by Title XIX of the Social Security Act, federal regulations promulgated pursuant thereto, and the South Carolina State Plan for Medical Assistance.

WHEREAS, SCDHEC is the agency with the authority to determine compliance of nursing facilities (NF), psychiatric residential treatment facilities (PRTFs) and intermediate care facilities for individuals with intellectual disabilities,(ICF/IID) participating in the South Carolina Medical Assistance Program in accordance with Part 42 of the Code of Federal Regulations (CFR).

WHEREAS, the role of SCDHEC is to conduct surveys to determine compliance with the Conditions of Participation and Certification and to provide such educational

services and follow-up as may be required to insure that facilities are complying with the standards for participation in the Title XIX program.

NOW THEREFORE, the parties to this Contract, in consideration of the mutual promises, covenants, and stipulations set forth herein, agree as follows:

ARTICLE I

CONTRACT PERIOD

This Contract shall take effect on October 1, 2019 and shall, unless sooner terminated in accordance with Article VII, continue in full force and effect through September 30, 2020.

ARTICLE II

DEFINITION OF TERMS AND ACRONYMS

As used in this Contract, the following terms shall have the following defined meanings:

Beneficiary: A person who has been determined eligible to receive services as provided for in the South Carolina State Plan for Medical Assistance.

CMS: Centers for Medicare and Medicaid Services

Equipment: Any item of property (other than real property) with an acquisition cost of $5,000 or more and a useful life of more than one (1) year.

Federal Financial Participation (FFP): Any funds, either title or grant, from the Federal Government.

GAO: Government Accountability Office

HIPAA: Health Insurance Portability and Accountability Act of 1996, as amended, along with its attendant regulations.

HH: Home Health Services are intermittent skilled nursing services, physical therapy, speech therapy, occupational therapy, home health aide and medical supplies.

ICF/IID: Health related facility which meets the requirements for state licensure to provide care to individuals with intellectual disabilities who do not need care in a hospital or nursing facility.

MH: Mental Health

NF: A nursing facility in an institution (or a distinct part of an institution) which meets the requirements specified in appropriate federal regulations.

Pearson Vue: SCDHHS's Contractor to operate the South Carolina Nurse Aide Registry

Policies: The general principles by which SCDHHS is guided in its management of the South Carolina State Plan for Medical Assistance, as further defined by SCDHHS promulgations and by state and federal rules and regulations.

Program: The method of provision of Title XIX services to South Carolina Beneficiaries as provided for in the South Carolina State Plan for Medical Assistance and SCDHHS regulations.

Social Security Act: Title 42, United States Code, Chapter 7, as amended.

SCDHHS Appeal Regulations: Regulations promulgated in accordance with S.C. Code Ann. §44-6-90, 10 S.C. Code of State Regs. §126-150 et seq. (2012, as amended) and S.C. Code Ann. §1-23-310 et seq. (1976, as amended).

Title XIX (Medicaid): Title 42, United States Code, Chapter 7, subchapter XIX, as amended (42 U.S.C. §1396 et seq.).

USDHHS: United States Department of Health and Human Services

ARTICLE III

SCOPE OF SERVICES

For and in consideration of the promises herein made by SCDHHS, SCDHEC agrees to provide the following:

A. Accumulate, maintain and verify to SCDHHS, upon request, full and complete information as to the ownership of each ICF/IID and nursing facility including the identity of each person having five percent (5%) or more interest; and if organized as a corporation, provide information as to the officers and the directors; and if organized as a partnership, provide the identity of each of the partners.

B. Validate certification status and report the ICF/IID and NF application to participate in the Program; certify in writing, the degree of compliance of each licensed ICF/IID and NF with reference to the standards set forth in appropriate federal regulations and Section 1861 (j) of the Social Security Act, and verify that the facility meets the following requirements of federal regulations:

1. Employs a licensed administrator
2. Operates an organized and adequate nursing service
3. Maintains professional planning and supervision of menus and meal service for patients/residents for whom special diets or dietary restrictions are medically prescribed
4. Maintains satisfactory policies and procedures relating to maintenance of medical records
5. Maintains satisfactory policies relating to the administration and distribution of drugs, medications, and biologicals
6. Maintains satisfactory policies and procedures relating to physician coverage and emergency medical attention
7. Entered into written agreements with one or more general hospitals, under which such hospitals shall provide needed diagnostic and other services, including admission, for acutely ill patients who are in need of hospital care
8. Satisfies all standards relating to environment and sanitation
9. Satisfies the requirements of the Life Safety Code (National Fire Protections Association, NFPH No. 101, 1967 and 1973) or of such

comparable State Fire and Safety Code, as are applicable to ICF/IID and Nursing facilities

10. Entered into written agreements with outside sources for professional series not available through the facility.

C. With regard to NF's compliance? In relation to Titles XVIII and XIX which established by SCDHHS for participation in the Program, SCDHEC shall notify the facilities whether or not they fail to meet any or all of the itemized requirements set out in paragraph A of this Article. SCDHEC shall make a written report to the SCDHHS and the USDHHS Regional Office listing (1) the facility's area of deficiency(s); (2) the reasonable prospects for correction of the deficiency(s) within a reasonable time frame; (3) the facility's plan for correction of the deficiency(s): and (4) the official opinion with any supporting information from the Provider as to whether the deficiency(s) does or does not jeopardize the health and safety of the patients residing in such licensed facility. For ICF/IID's participating in the Title XIX program only, the Provider shall make a written report to SCDHHS listing the aforementioned items and establishing the certification within timelines specified per federal regulations.

D. The Provider shall make on-site inspections, with qualified personnel, in accordance with CMS requirements, and file a report with SCDHHS and the USDHHS Regional Office for NF's participating in Title XVIII and XIX and with the SCDHHS for all ICF/IID's participating in the Title XIX program only. This report shall: (1) indicate whether the item(s) of deficiency found or previously identified have been corrected or is in the process of being corrected or recommend waiver when authorized by federal regulations with supporting documentation, with the exception of all skilled nursing facilities' Life Safety Code waiver which will be sent to the USDHHS Regional Office for approval; (2) indicate the progress being made by the facility in correcting the deficiency(s); and (3) include an official opinion, with any supporting information, as to whether the deficiency(s) does or does not jeopardize the health and safety or the patients. Standards for qualified personnel who perform surveys shall satisfy the Federal Surveyor Qualification Standards as specified in the Medical Services Administration, Medical Assistance Manual, part 6 (General Program Administration), Section 6-210-00, Standards for Qualified Personnel Who Perform Surveys of Skilled Nursing Homes.

E. The Provider shall employ adequate qualified staff to perform the functions set out in paragraphs A through C of this Article. When a survey is contemplated, a review of all appropriate records, both state and federal, will determine the composition of the survey team.

F. The Provider shall keep SCDHHS regularly informed of ICF/IID's and NF's failure to comply with the provisions stated in paragraph A of this Article. When the Provider learns or is informed in writing by SCDHHS of the potential failure of a facility to maintain said provisions, appropriate action shall be taken by Provider and where indicated, both agencies. SCDHHS and Provider shall maintain unrestricted interchange of information on any problem area that may arise.

G. The Provider shall submit a quarterly summary report to SCDHHS which identifies nursing facilities surveyed, and F tags cited, including scope and severity measures.

H. The Provider's Bureau of Certification (the Department) will work with SCDHHS and Pearson Vue to maintain the SC Nurse Aide Registry.

1. The Department will update the SC Nurse Aide Registry with all information relating to abuse, neglect or misappropriation of a resident's property by a certified nurse aide. Results of each investigation will be noted along with a statement by the nurse aide. A hearing will be provided for those nurse aides who request such.
2. The Department will respond to all Freedom of Information Act Requests (FOIA) as required by the state and federal laws and regulations.

I. SCDHEC has the overall responsibility to operate the State Minimum Data System (MDS) as specified by regulations and subsequent guidelines issued by CMS. SCDHEC is also responsible for providing training and technical assistance for facilities on an ongoing basis. SCDHEC will make available MDS information as requested by SCDHHS.

J. The SSA mandates the establishment of minimum health and safety standards, which must be met by providers and suppliers participating in the Medicare and Medicaid program. The SSA does not preclude an SA from establishing an agreement with another agency or contractor to perform PRTF surveys. The statue does not require the state to be ultimately responsible for determining whether the PRTF meets established health standards. Thus, any arrangement the state may have with other agencies to perform this task must maintain the state's accountability of its obligation under the State Plan.

It should be understood by both SCDHHS and SCDHEC that State licensure requirements, specifically *Regulation Number 61-103: Standards for Licensing Residential Treatment Facilities for Children and Adolescents*, apply to any PRTF operating within the State of South Carolina and remain under the jurisdiction of the Division of Health Licensing within SCDHEC. Facilities for Children and Adolescents apply to any PRTF operating within the State of South Carolina and remain under the jurisdiction of the Division of Health Licensing within SCDHEC. See Appendix B for survey process.

K. SCDHEC shall communicate in writing any requests for use of Civil Money Penalty funds.

L. SCDHEC conducts surveys of Home Health Agencies as directed by CMS to determine whether they are complying with the Conditions of Participation (COP).

PROVISION OF SPECIFIED EDUCATIONAL SERVICES BY SCDHEC

M. SCDHEC shall provide educational services as described in Section 1902(a)(24) of the Social Security Act within the capabilities of the staff of SCDHEC. Such services shall be provided as indicated and shall be directed toward assisting the facility in question to meet the standards established by applicable federal regulations.

N. SCDHEC shall report to the SCDHHS on the progress, or lack of progress, made by a facility toward meeting standards established by applicable federal regulations.

O. SCDHEC shall maintain all information and records of costs of providing educational services including part-time services of staff engaged in such duties.

P. SCDHEC and SCDHHS shall jointly develop and revise procedures to implement orderly administration for providing educational services to ICF/IID's, NF's and other providers. Records of such efforts will be maintained by SCDHEC.

Q. SCDHHS shall cooperate with the staff of Provider for the augmentation and development of a program for providing educational services to ICF/IID's and NF's participating in the Program and other providers and copies will be provided to SCDHHS upon request.

1. SCDHHS shall cooperate with the staff of Provider for the augmentation and development of a program for providing educational services to ICF/IID's and NF's participating in the Program and other providers.

ARTICLE IV

SCDHHS RESPONSIBILITIES

For and in consideration of the promises made herein by SCDHEC, SCDHHS agrees to provide the following:

A. Notify SCDHEC of any compliance matters affecting a facility before certification of the facility by SCDHHS.

B. Establish and transmit to SCDHEC the qualifications of ICF/IID's and NF's to participate in the South Carolina Medical Assistance Program (Title XIX). Such entitlement (subject to a determination of a facility's substantial compliance with applicable federal regulations) shall be for a twelve (12) month period subject to automatic cancellation at the end of the allocated time to correct the deficiency(s).

C. Issue to ICF/IID's and NF's the appropriate certification agreement which specifies the period for which the facility is certified to participate in the South Carolina Medical Assistance Program (Title XIX) and inform the Provider of this issuance.

D. Advise ICF/IID's and NF's of the scope and limitations of the South Carolina Medical Assistance Program (Title XIX) as provided in the Medicaid Guidelines For Nursing Facilities and ICF/IID Services, of the responsibility of the SCDHHS to the ICF/IID's and NF's and of the facility's contractual responsibility to the program and to the patients eligible to receive Title XIX medical care and services.

E. Review all questionable situations reported concerning an ICF/IID and NF and assess the level of correction of such situations. The SCDHHS shall provide the Provider with copies of facility complaints as received and request that Provider advise SCDHHS of results of any actions taken on such complaints and assess the results as appropriate.

F. Inform the Provider of all requests by ICF/IID's and NF's to participate in the South Carolina Medical Assistance Program (Title XIX).

G. Identify in writing those facilities that should be reviewed by the Provider where quality of services rendered, or practices of the facility, may be in question.

H. The SCDHHS shall make such reports, in such form and containing such information, to the Provider as are required in the consideration of the certification, or decertification, of ICF/IID's and NF's by the SCDHHS.

I. The SCDHHS shall permit duly authorized representative of the USDHHS, and GAO, or its designee(s), access to the provider records relative to the certification of ICF/IID and NF facilities and records of cost for providing services, for audit and other purposes.

J. The SCDHHS shall develop and implement appeals procedures in accordance with 42 CFR 431 Subpart D (2018, as amended) when such hearings are requested by an NF or ICF/IID participating in the Medicaid program.

K. The SCDHHS will review the findings of the patient classification audit, conduct a complete review where significant discrepancies demonstrate the need for additional review and adjust reimbursement mechanisms as deemed appropriate.

ARTICLE V

CONDITIONS FOR REIMBURSEMENT BY SCDHHS

SCDHHS agrees to purchase from SCDHEC and to pay for the services provided pursuant to this Contract in the manner and method herein stipulated:

SCDHHS shall reimburse the Provider actual costs incurred for the provision of services under this Contract in an amount not to exceed the total amount set forth in Appendix A, which is hereby incorporated as an integral part of this Contract. Indirect cost calculations will be based upon the current USDHHS approved indirect cost rate subject to review and approval by SCDHHS. The operational budget, which is **not** a part of this Contract, has been reviewed and approved by SCDHHS and CMS, USDHHS. If the operational budget changes during the Contract period, it is the Provider's responsibility to submit to SCDHHS documentation to support the change with a written request for a Contract Amendment, if necessary, prior to the end of the Contract period.

A. Subject to revisions of federal regulations from USDHHS, SCDHHS shall make payment under this Contract in accordance with the following method. Such payment is made upon presentation of a certified Statement by Provider. The Statement shall indicate the disposition of the amount requested by reference to the categories of expenses detailed in the budget. The Provider shall furnish SCDHHS an invoice statement each quarter indicating the recorded expenditures of funds.

1. Payment of funds to which the Provider is entitled shall be on a quarterly reimbursable basis upon receipt by SCDHHS of an Interdepartmental Transfer (IDT) and invoice from the Provider, unless more frequent payment is mutually agreed upon by the parties. IDT's must be submitted to SCDHHS by the twentieth (20th) day after the end of each quarter. The IDT and invoice shall be mailed to the following address:

Accounting Operations/Accounts Payable
South Carolina Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Or email invoices to invoices@scdhhs.gov.

2. Payment under this Contract is limited to costs incurred in accordance with the budget submitted each federal fiscal year or as amended by joint consent subsequent thereto. The Provider's proposed budget shall be submitted on a timely basis as referenced.

3. The Provider shall review the status of accounts not less frequently than once each quarter. The review shall allow observation of expenditure trends in order to avoid over-expenditure and provide early identification of any need for a Contract Amendment prior to the end of the Contract period.

4. All June monthly or quarterly billings must be received by July 3rd for fiscal month thirteen (13) processing either as actual expenditures or best estimate. All final billings must be received within ninety (90) calendar days of the end of the Contract period. Any invoices received after this period will not be paid without the approval of the SCDHHS Deputy Director of Medical Services.

B. The Provider agrees to accept full responsibility for the provision of sound fiscal and administrative procedures and for compliance with federal and state laws both financial and otherwise for any and all deviations by it from such laws and regulations.

C. The Provider is responsible for completing and electronically filing all federal responsibility reports, which includes the CMS 435-State Survey Agency Budget/Expenditure report. In accordance with Section 4626 of the State Operational Manual, the Provider must coordinate the review of the Form 435 and ensure approval by SCDHHS for Title XIX expenditures before filing.

D. All non-expendable property acquired for this program may not be used for any other purpose than those outlined in this Contract or disposed of in any manner without the written permission and mutual consent of the USDHHS Regional Office, SCDHHS, and the Provider. Such non-expendable property shall not be consumed or lose its identity and is expected to have a useful life of one (1) year or more. All such property shall be listed on a property recorded inventory by description, model and serial number, date of acquisition, cost of acquisition and identified as new or used. The property record shall be maintained by Provider.

E. The Provider must describe the service being provided under this contract, the estimated annual cost for the fiscal year, and the basis for allocating such costs to the program being affected. Indirect costs applicable to such services can be included for federal sharing only if the Provider has an Indirect Cost Rate approved by the cognizant Federal agency. The Provider shall submit documentation of a change in the approved rate with the budget letter to SCDHHS. Should the approved rate change during the Contract period, it is the

responsibility of the Provider to submit the supporting documentation and Contract Amendment request prior to the end of the Contract period.

F. If this Contract is terminated, any funds paid to the Provider under the provisions of this Contract which have not been expended or encumbered in accordance with the provisions of this Contract prior to the date the Contract was terminated, shall be accounted for in accordance with standards established by the governing disposition of such funds.

G. SCDHHS shall notify the Provider of all federal disallowances and deferrals incurred by SCDHHS as a result of services rendered by the Provider for which the Provider was appropriated state funds. The Provider and SCDHHS shall prepare an appropriate response for submission to the appropriate federal agency. These disallowances shall be funded with non-federal Provider funds.

H. To be considered as the State's share in claiming FFP, public funds must meet the conditions specified in accordance with Federal Regulation 42 CFR §433.51 (2018, as amended).

I. The Provider agrees to comply with 42 CFR Part 433 Subpart B, (2018, as amended), regarding any and all donations made by the Provider pursuant to this Contract.

ARTICLE VI

RECORDS AND AUDITS

A. Accuracy of Data and Reports

SCDHEC shall certify that all statements, reports and claims, financial and otherwise, are true, accurate, and complete. SCDHEC shall not submit for payment any claims, invoices, statements, or reports which it knows, or has reason to know, are not properly prepared or payable pursuant to federal and state law, applicable regulations, this Contract, and SCDHHS policy.

1. Maintenance of Records

SCDHEC must maintain an accounting system with supporting fiscal records adequate to assure that claims for funds are in accordance with this Contract and all applicable laws, regulations, and policies. SCDHEC further agrees to retain all financial and programmatic records, supporting documents, and statistical records and other records of Beneficiaries relating to the delivery of care or service under this Contract, and as further required by SCDHHS, for a period of four (4) years after last payment is made under this Contract (including any amendments and/or extensions to this Contract). If any litigation, claim, or other actions involving the records has been initiated prior to the expiration of the four (4) year period, the records shall be retained until completion of the action and resolution of all issues which arise from it or until the end of the four (4) year period, whichever is later. This provision is applicable to any subcontractor and must be included in all subcontracts.

2. Inspection of Records

At any time during normal business hours and as often as SCDHHS, the State Auditor's Office, the State Attorney General's Office, GAO, and USDHHS, and/or any of the designees of the above may deem necessary during the contract period (including any amendments and/or extensions to this Contract) and for a period of four (4) years after last payment under this Contract, SCDHEC shall make all program and financial records and service delivery sites open to the representatives of SCDHHS, GAO, the State Auditor, the State Attorney General's Office, USDHHS, and/or any designees of the above. SCDHHS, the State Auditor's Office, the State Attorney General's Office, GAO, USDHHS, and/or their designee(s) shall have the right to audit, review, examine and make copies, excerpts or transcripts from all records, contact and conduct private interviews with SCDHEC's Beneficiaries and employees, and conduct on-site reviews of all matters relating to service delivery as specified by this Contract. If any litigation, claim, or other action involving the records has been initiated prior to the expiration of the four (4) year period, the records shall be retained until completion of the action and resolution of all issues which arise from it or until the end of the four (4) year period, whichever is later. This provision is applicable to any subcontractor and must be included in all subcontracts.

B. Audits

In the event an audit is performed and the audit report contains audit exceptions or disallowances, it is agreed by the parties hereto that the following procedures shall be used in making the appropriate audit adjustment(s):

1. Notice of Exceptions and Disallowances

Upon completion of an audit, SCDHEC shall be furnished a written notice containing the adjustment for each exception and a statement of the amount disallowed for each exception. SCDHHS, the State Auditor's Office, CMS or their designee shall make this determination. Such notice shall further state the total sum disallowed as a result of the audit and that payment is due to SCDHHS in the full amount of the sums disallowed. Notice will be sent to SCDHEC by certified mail.

2. Disallowances - Appeals

In the event SCDHEC disagrees with the audit exceptions and disallowances, it may seek administrative appeal of such matters in accordance with the SCDHHS appeals procedures. Judicial review of any final agency decision pursuant to this Contract shall be in accordance with S.C. Code Ann. §1-23-380 (1976, as amended) and shall be the sole and exclusive remedy available to either party except as otherwise provided herein. Provided, however, any administrative appeal shall be commenced by written notice as required by SCDHHS appeals procedures.

Thirty (30) days after mailing of the notice of disallowance, all audit disallowances shall become final unless an appeal in accordance with SCDHHS appeals procedures has been filed. Payment shall be due and

should be made upon notice of disallowance regardless of the filing of an appeal. Should the amount of the disallowance be reduced for any reason, SCDHHS will reimburse SCDHEC for any excess amount previously paid. Additionally, any issue which could have been raised in an appeal shall be final and not subject to challenge by SCDHEC in any other administrative or judicial proceeding if no appeal is filed within thirty (30) calendar days of the notice of determination.

3. Disallowed Sums, Set-off

Any provision for appeal notwithstanding, SCDHEC and SCDHHS agree that, should any audit(s) result in disallowance to SCDHEC all funds due SCDHHS are payable upon notice to SCDHEC of the disallowance. SCDHHS is authorized to recoup any and all funds owed to SCDHHS by means of withholding and/or offsetting such funds against any and all sums of money for which SCDHHS may be obligated to SCDHEC under any previous contract and/or this or future contracts. In the event there is no previous contractual relationship between SCDHEC and SCDHHS, the disallowance shall be due and payable immediately upon notice to SCDHEC of the disallowance.

ARTICLE VII

TERMINATION OF CONTRACT

A. Termination for Lack of Funds

The parties covenant and agree that their liabilities and responsibilities, one to another, shall be contingent upon the availability of federal, state, and local funds for the funding of services and that this Contract shall be terminated if such funding ceases to be available. SCDHHS shall have the sole responsibility for determining the lack of availability of such federal, state, and local funds.

B. Termination for Noncompliance with the Drug Free Workplace Acts

In accordance with S. C. Code Ann. §44-107-60 (Supp. 2000, as amended), and 2 CFR Part 182 (2018, as amended), this Contract is subject to immediate termination, suspension of payment, or both if SCDHEC fails to comply with the terms of the State or Federal Drug Free Workplace Act.

C. Termination for Breach of Contract

This Contract may be canceled or terminated by either party at any time within the contract period whenever it is determined by such party that the other party has materially breached or otherwise materially failed to comply with its obligations hereunder.

D. Termination for Breach of Previous Contracts or Non-Payment of Previous Audit Exceptions

This Contract may be canceled or terminated by SCDHHS at any time within the contract period if SCDHEC, after exhaustion of all administrative and judicial appeals, has failed to make payment in full to SCDHHS for audit disallowances pursuant to any previous contract between the parties or if SCDHEC has failed to

comply with the maintenance and inspection of records requirements of any previous contract between the parties.

E. Termination for Loss of Licensure or Certification (If applicable)

In the event that SCDHEC loses its license to operate or practice from the appropriate licensing agency, this Contract shall terminate as of the date of delicensure. Further, should SCDHEC lose its certification to participate in the Title XVIII and/or Title XIX program, as applicable, this Contract shall terminate as of the date of such decertification.

F. Termination by Either Party

Either party may terminate this Contract upon providing the other party with thirty (30) days written notice of termination.

G. Notice of Termination

In the event of any termination of the Contract under this Article, the party terminating the Contract shall give notice of such termination in writing to the other party. Notice of termination shall be sent by certified mail, return receipt requested. If this Contract is terminated pursuant to Sections C, D and/or F of this Article, termination shall be effective thirty (30) days after the date of receipt unless otherwise provided by law. If this Contract is terminated pursuant to Sections A, or B, of this Article, termination shall be effective upon receipt of such notice. If this Contract is terminated pursuant to Section E of this Article, termination shall be effective upon the date listed in the notice.

ARTICLE VIII

APPEALS PROCEDURES

Requests for resolutions of disputes or claims, whether for money or other relief, arising hereunder shall be submitted to the appropriate chief procurement officer in writing not later than one (1) year after the date that SCDHEC last performs work under this Contract. Nothing herein shall preclude the State from requiring submission of an invoice for final payment within a certain time after completion and acceptance of the services and/or supplies herein specified. Pendency of a claim shall not delay payment of amounts agreed due.

ARTICLE IX

COVENANTS AND CONDITIONS

In addition to all other stipulations, covenants, and conditions contained herein, the parties to this Contract agree to the following covenants and conditions:

A. Applicable Laws and Regulations

SCDHEC agrees to comply with all applicable federal and state laws and regulations including constitutional provisions regarding due process and equal protection of the laws and including, but not limited to:

1. All applicable standards, orders, or regulations issued pursuant to the Clean Air Act of 1970, as amended (42 U.S.C. §7401, et seq.) and the Federal Water Pollution Control Act, as amended (33 U.S.C. §1251, et seq.).

2. Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. §2000d et seq.) and regulations issued pursuant thereto, (45 CFR Part 80, 2018, as amended), which provide that SCDHEC must take adequate steps to ensure that persons with limited English skills receive free of charge the language assistance necessary to afford them meaningful and equal access to the benefits and services provided under this Contract.

3. Title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. §2000e) in regard to employees or applicants for employment.

4. Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicap in programs and activities receiving or benefiting from federal financial assistance, and regulations issued pursuant thereto 45 CFR Part 84 (2018, as amended).

5. The Age Discrimination Act of 1975, as amended (42 U.S.C. §6101 et seq.), which prohibits discrimination on the basis of age in programs or activities receiving or benefiting from federal financial assistance.

6. The Omnibus Budget Reconciliation Act of 1981, as amended P.L. 97-35, which prohibits discrimination on the basis of sex and religion in programs and activities receiving or benefiting from federal financial assistance.

7. The Americans with Disabilities Act (42 U.S.C. §12101 et seq.), and regulations issued pursuant thereto.

8. The Drug Free Workplace Acts, S.C. Code Ann. §44-107-10 et seq. (Supp. 2000, as amended), and the Federal Drug Free Workplace Act of 1988 as set forth in 2 CFR Part 182 (2018, as amended).

9. Section 6002 of the Solid Waste Disposal Act of 1965 as amended by the Resource Conservation and Recovery Act of 1976 (42 U.S.C. §6962).

B. Employees of SCDHEC

No services required to be provided under this Contract shall be provided by anyone other than SCDHEC or with the prior approval of SCDHHS in accordance with Section Q.,SCDHEC's subcontractor.

C. Information on Persons Convicted of Crimes

SCDHEC agrees to furnish to SCDHHS or to the USDHHS information related to any person convicted of a criminal offense under a program relating to Medicare (Title XVIII), Medicaid (Title XIX), the Social Services Block Grant program (Title XX) or the State Children's Health Insurance Program (Title XXI) as set forth in 42 CFR §455.106 (2018, as amended). Failure to comply with this requirement may lead to termination of this Contract.

D. Safeguarding Information

SCDHEC shall safeguard the use and disclosure of information concerning applicants for or Beneficiaries of Title XIX services in accordance with 42 CFR Part 431, Subpart F (2018, as amended), SCDHHS' regulations at 10 S.C. Code of State Regs. §126-170, et seq. (2012, as amended), and all other applicable state and federal laws and regulations and shall restrict access to, and use and disclosure of, such information in compliance with said laws and regulations.

E. Political Activity

None of the funds, materials, property, or services provided directly or indirectly under this Contract shall be used for any partisan political activity, or to further the election or defeat of any candidate for public office, or otherwise in violation of the provisions of the "Hatch Act".

F. Restrictions on Lobbying

In accordance with 31 U.S.C. §1352, funds received through this Contract may not be expended to pay any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with any of the following covered federal actions: the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement. This restriction is also applicable to all subcontractors.

G. Reporting of Fraudulent Activity

If at any time during the term of this Contract, SCDHEC becomes aware or has reason to believe that, under this or any other program administered by SCDHHS, a Beneficiary of or applicant for services, an employee of SCDHEC or SCDHHS, and/or subcontractor or its employees, has improperly or fraudulently applied and/or received benefits, monies, or services pursuant to this or any other contract, such information shall be reported in confidence by SCDHEC directly to SCDHHS.

H. Integration

This Contract shall be construed to be the complete integration etween the parties. No prior or contemporaneous addition, deletion, or other amendment shall have any force or effect whatsoever unless embodied herein in writing. No subsequent novation, renewal, addition, deletion, or other amendment shall have any force or effect unless embodied in a written amendment executed and approved pursuant to Section N of this Article.

I. Governing Law

It is mutually understood and agreed that this Contract shall be governed by the laws of the State of South Carolina both as to interpretation and performance.

J. Severability

Any provision of this Contract prohibited by the laws of the State of South Carolina shall be ineffective to the extent of such prohibition without invalidating the remaining provisions of this Contract.

K. Non-Waiver of Breach

The failure of SCDHHS at any time to require performance by SCDHEC of any provision of this Contract or the continued payment of SCDHEC by SCDHHS shall in no way affect the right of SCDHHS to enforce any provision of this Contract; nor shall SCDHHS' waiver of any breach of any provision hereof be taken or held to be a waiver of any succeeding breach of such provision or as a waiver of the provision itself.

L. Non-Waiver of Rights

SCDHHS and SCDHEC hereby agree that the execution of and any performance pursuant to this Contract does not constitute a waiver, each to the other, of any claims, rights, or obligations which shall or have arisen by virtue of any previous agreement between the parties. Any such claims, rights, or obligations are hereby preserved, protected, and reserved.

M. Non-Assignability

No assignment or transfer of this Contract or of any rights hereunder by SCDHEC shall be valid without the prior written consent of SCDHHS.

N. Amendment

No amendment or modification of this Contract shall be valid unless it shall be in writing and signed by both parties hereto.

O. Amendment Due To the Unavailability of Funds

SCDHHS shall have the right to amend the total dollar amount reimbursed under this Contract, without the consent of SCDHEC, when the amendment is due to the unavailability of funds and SCDHHS is responsible for providing the matching funds. SCDHHS shall have the sole authority to determine the percentage of any reduction in the dollar amount of this Contract. The amendment shall become effective thirty (30) days from the date of written notification from SCDHHS informing SCDHEC of the reduction/amendment or upon the signature of both parties thereto, whichever is earlier. SCDHHS shall have the sole authority for determining lack of availability of such funds.

P. Extension

Prior to the end of the term of this Contract, SCDHHS shall have the option to extend or renew this Contract upon the same terms and conditions as contained herein, so long as the total contract period, including the extension, does not exceed five (5) years; provided, however, that any rate adjustment(s) shall be negotiated and set forth in writing and signed by both parties pursuant to Section N of this Article.

Q. Subcontracts

Unless otherwise expressly authorized in writing, all services to be provided hereunder shall be provided by SCDHEC directly and no subcontract for the provision of such services shall be entered into by SCDHEC without the prior written approval of SCDHHS. Any subcontracts must be submitted to SCDHHS for written approval before reimbursement shall be made for services rendered thereunder.

R. Copyrights

If any copyrightable material is developed in the course of or under this Contract, SCDHHS shall have a royalty free, non-exclusive, and irrevocable right to reproduce, publish, or otherwise use the work for SCDHHS purposes.

S. Safety Precautions

SCDHHS and USDHHS assume no responsibility with respect to accidents, illnesses, or claims arising out of any activity performed under this Contract. SCDHEC shall take necessary steps to insure or protect Beneficiaries, itself, and its personnel. SCDHEC agrees to comply with all applicable local, state, and federal occupational and safety acts, rules, and regulations.

T. Procurement Code

When applicable, SCDHEC must comply with the terms and conditions of the South Carolina Consolidated Procurement Code.

U. Titles

All titles used herein are for the purpose of clarification and shall not be construed to infer a contractual construction of language.

V. Equipment (If applicable)

Equipment is defined as an article of tangible property that has a useful life of more than one year and an acquisition cost of Five Thousand Dollars ($5,000) or more. Title to all equipment purchased with funds provided under this Contract shall rest with SCDHEC as long as the equipment is used for the program for which it was purchased. When the equipment is no longer required for the program for which it was purchased, SCDHHS shall be notified and instructions will be issued by SCDHHS pertaining to the disposition of the property.

W. Release of Reports

SCDHEC understands and agrees that all reports and assessments prepared by SCDHEC pursuant to this Contract, including drafts, must be submitted to SCDHHS for review and approval by SCDHHS. SCDHEC may not release or disclose, in any form, a report or assessment (including drafts) to any person/entity without the expressed, written consent of SCDHHS.

X. Portable Devices

All Protected Health Information (PHI) stored on portable devices must be encrypted. Portable devices include all transportable devices that perform computing or data storage, manipulation or transmission including, but not limited to, diskettes, CDs, DVDs, USB flash drives, laptops, PDAs, BlackBerrys, cell phones, portable audio/video devices (such as iPods, and MP3 and MP4 players), and personal organizers.

Y. Debarment/ Suspension/Exclusion

SCDHEC agrees to comply with all applicable provisions of 2 CRF Part 180 (2018, as amended) as supplemented by 2 CFR Part 376 (2018, as amended), pertaining to debarment and/or suspension and to require its subcontractors to comply with these same provisions to ensure that no party receiving funds from this Contract are listed on the government-wide exclusions in the System for Award Management (SAM).

Z. SCDHEC Responsibility

If under the terms of this Contract SCDHEC makes any decisions, determinations or takes any actions on behalf of SCDHHS, then SCDHEC shall be responsible for evidentiary support of its decisions, determinations or actions in any proceeding or claim asserted against SCDHHS related to such decision, determination or action. If required by SCDHHS, SCDHEC shall be responsible for retaining legal counsel to diligently and capably provide such defense. This responsibility includes, but is not limited to, any appeals before the SCDHHS Division of Appeals and Hearings.

AA. Counterparts

This Contract may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which shall constitute the same instrument. The parties agree that this Contract may be delivered by facsimile or electronic mail with a copied signature having the same force and effect of a wet ink signature.

BB. Incorporation of Schedules/Appendices

All schedules/appendices referred to in this Contract are attached hereto, are expressly made a part hereof, and are incorporated as if fully set forth herein.

IN WITNESS WHEREOF, SCDHHS and SCDHEC, by their authorized agents, have executed this Contract as of the first day of October 1, 2019.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

"SCDHHS"

BY: Joshua D. Baker/BP
Joshua D. Baker
Director

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

"SCDHEC"

BY: Gwendolyn C. Thompson
Authorized Signature

Gwendolyn C. Thompson
Print Name

WITNESSES:

WITNESSES:

APPENDIX A

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
SURVEY AND CERTIFICATION CONTRACT
TITLE XIX PORTION ONLY (FFP-MATCH)

OCTOBER 1, 2019 - SEPTEMBER 30, 2020

The requested program resources **for the Contract period of October 1, 2019 through September 30, 2020**, are from allocations as follows:

	FFP	State Match	Total
Nursing Long Term Care	$1,661,595	$553,864	$2,215,459
Nurse Aide Registry	$500	$500	$1,000
ICF/IID	$229,349	$95,363	$324,712
MDS	$7,535	$2,512	$10,047
PRTF	$13,896	$4,630	$18,526
Home Health	$30,250	$30,250	$60,500
Non-Long Term Care	$215,075	$215,074	$430,149
Total	$2,158,200	$902,193	$3,060,393

APPENDIX B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL SURVEY AND CERTIFICATION of PRTFs

1. SURVEY PROCESS

The following process for the State of South Carolina indicates the Interagency Agreement between SCDHHS and SCDHEC for the survey of PRTFs:

A. Federal Provider Identification numbers are assigned by SCDHHS and should be shared with SCDHEC.

B. Attestation letters received by SCDHHS from the PRTFs should be shared with SCDHEC by no later than September 1st of each year. Attestations are to include:

1. Facility General Characteristics:
   a. Name
   b. Address
   c. Telephone number
   d. Fax Number
   e. E. Medicaid Provider number and National Provider Identification (NPI)
2. Facility Specific Characteristics:
   a. Bed Size
   b. Number of individuals currently served within the PRTF who are provided services based on their eligibility for the Medicaid inpatient psychiatric services for individuals under age twenty-one (21) benefit.
   c. Number of individuals, if any, whose Medicaid Psych under twenty-one (21) benefit is paid for by any state other than South Carolina.

d. A list of all states from which the PRTF has EVER received Medicaid payment for the providing of Medicaid Psych under twenty-one (21) services.

3. Signature of Facility Director.

4. Date the Attestation was signed.

5. A statement certifying that the facility currently meets all of the requirements under Part 483 Subpart G governing the use of restraint and seclusion.

6. A statement certifying that the facility currently meets the Certification of Need requirements as identified under 42 CFR Part 441, Subpart D – Inpatient Psychiatric Services for individuals under 21 in Psychiatric Facilities or Programs.

7. A statement acknowledging the right of SCDHEC (or its agents) and, if necessary, Centers for Medicare and Medicaid Services to conduct an on-site survey at any time to validate the facility's compliance with the requirements of the rule, to investigate complaints lodged against the facility, or to investigate serious occurrences.

8. A statement that the facility will submit a new attestation of compliance annually and in the event that a new facility director is appointed.

C. SCDHHS should make a recommendation for survey to SCDHEC for 20% of all operating PRTFs within the State based on any data that may be available to SCDHHS including data relevant to all serious occurrences reported to SCDHHS by facilities.

D. SCDHEC will be responsible for selecting the actual 20% of facilities surveyed annually based on SCDHEC budget requirements, facility survey history, survey schedule and scheduling availability, regardless of recommendation from SCDHHS.

E. Because SCDHEC Survey and Certification surveys are generally unannounced, SCDHEC is not required to notify SCDHHS of the actual names of any facility to be surveyed or the date on which the survey will occur.

F. Upon completion of the survey the Statement of Deficiency (CMS Form 2567) will be issued to the PRTF within ten (10) working days of the exit date of the survey.

G. The PRTF will then have ten (10) calendar days from the date of receipt of the Statement of Deficiency (CMS Form 2567) to submit a Plan of Correction (POC) to SCDHEC.

H. Once the PRTF Plan of Correction is reviewed and approved by SCDHEC, a copy of the Statement of Deficiency (CMS Form 2567) and related POC will be released to SCDHHS.

I. Only SCDHEC is authorized to release information related to Survey and Certification Surveys. Unless required by law, SCDHHS is not authorized to release any survey information related to any survey type to any facility, family member, patient or any other outside party. All request for survey results or related information should be referred to SCDHEC. (For additional information related to topic, please refer to SCDHEC FOI policy).

The Secretary shall conduct a special focus facility program for enforcement of requirements for skilled nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirement of this chapter.

(B) Periodic surveys

Under such program the Secretary shall conduct surveys of each facility in the program not less than once every 6 months.

(g) Survey and certification process

(1) State and Federal responsibility

(A) In general

Pursuant to an agreement under section 1395aa of this title, each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d) of this section. The Secretary shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of State skilled nursing facilities with the requirements of such subsections.

(B) Educational program

Each State shall conduct periodic educational programs for the staff and residents (and their representatives) of skilled nursing facilities in order to present current regulations, procedures, and policies under this section.

(C) Investigation of allegations of resident neglect and abuse and misappropriation of resident property

The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide of a resident in a nursing facility or by another individual used by the facility in providing services to such a resident. The State shall, after providing the individual involved with a written notice of the allegations (including a statement of the availability of a hearing for the individual to rebut the allegations) and the opportunity for a hearing on the record, make a written finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. A State shall not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(D) Removal of name from nurse aide registry

(i) In general

In the case of a finding of neglect under subparagraph (C), the State shall establish a procedure to permit a nurse aide to petition the State to have his or her name removed from the registry upon a determination by the State that—

(I) the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect; and

(II) the neglect involved in the original finding was a singular occurrence.

(ii) Timing of determination

In no case shall a determination on a petition submitted under clause (i) be made prior to the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the registry under subparagraph (C).

in permitting individuals adversely affected to appeal such determinations, and shall notify the States of such criteria.

(B) Monitoring compliance

The Secretary shall review, in a sufficient number of cases to allow reasonable inferences, each State's compliance with the requirements of subsection (e)(7)(C)(ii) of this section (relating to discharge and placement for active treatment of certain residents).

(9) Criteria for monitoring State waivers

The Secretary shall develop, by not later than October 1, 1988, criteria and procedures for monitoring State performances in granting waivers pursuant to subsection (b)(4)(C)(ii) of this section.

(10) Special focus facility program

(A) In general

The Secretary shall conduct a special focus facility program for enforcement of requirements for nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirements of this chapter.

(B) Periodic surveys

Under such program the Secretary shall conduct surveys of each facility in the program not less often than once every 6 months.

(g) Survey and certification process

(1) State and Federal responsibility

(A) In general

Under each State plan under this subchapter, the State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d) of this section. The Secretary shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of State nursing facilities with the requirements of such subsections.

(B) Educational program

Each State shall conduct periodic educational programs for the staff and residents (and their representatives) of nursing facilities in order to present current regulations, procedures, and policies under this section.

(C) Investigation of allegations of resident neglect and abuse and misappropriation of resident property

The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide of a resident in a nursing facility or by another individual used by the facility in providing services to such a resident. The State shall, after notice to the individual involved and a reasonable opportunity for a hearing for the individual to rebut allegations, make a finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. A State shall not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(D) Removal of name from nurse aide registry

Code of Federal Regulations
Title 42. Public Health
Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)
Subchapter G. Standards and Certification (Refs & Annos)
Part 483. Requirements for States and Long Term Care Facilities (Refs & Annos)
Subpart B. Requirements for Long Term Care Facilities (Refs & Annos)

42 C.F.R. § 483.12

§ 483.12 Freedom from abuse, neglect, and exploitation.

Effective: November 28, 2016

Currentness

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

(a) The facility must—

(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

(3) Not employ or otherwise engage individuals who—

(i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;

(ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property; or

(iii) Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property.

(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

(b) The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

(2) Establish policies and procedures to investigate any such allegations, and

(3) Include training as required at paragraph § 483.95.

(4) Establish coordination with the QAPI program required under § 483.75.

(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

(i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

(2) Have evidence that all alleged violations are thoroughly investigated.

(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

(4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

Credits

[56 FR 48869, Sept. 26, 1991; 57 FR 43924, Sept. 23, 1992; 68 FR 46072, Aug. 4, 2003; 76 FR 9511, Feb. 18, 2011; 78 FR 16805, March 19, 2013; 81 FR 68855, Oct. 4, 2016]

SOURCE: 53 FR 20496, June 3, 1988; 54 FR 5359, Feb. 2, 1989; 54 FR 29717, July 17, 1989; 54 FR 53611, Dec. 29, 1989; 56 FR 48867, 48918, Sept. 26, 1991; 56 FR 54546, Oct. 22, 1991; 57 FR 7136, Feb. 28, 1992; 57 FR 8202, March 6, 1992; 57 FR 43924, Sept. 23, 1992; 57 FR 56506, Nov. 30, 1992; 59 FR 56237, Nov. 10, 1994; 60 FR 50443, Sept. 29, 1995; 64 FR 66279, Nov. 24, 1999; 71 FR 71334, Dec. 8, 2006; 76 FR 9511, Feb. 18, 2011; 77 FR 29028, May 16, 2012; 78 FR 16805, March 19, 2013; 80 FR 46477, Aug. 4, 2015; 84 FR 34735, July 18, 2019; 84 FR 51824, Sept. 30, 2019, unless otherwise noted.

AUTHORITY: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

Notes of Decisions (41)

Current through August 20, 2020; 85 FR 51629.

End of Document

Code of Federal Regulations
Title 42. Public Health
Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)
Subchapter G. Standards and Certification (Refs & Annos)
Part 488. Survey, Certification, and Enforcement Procedures (Refs & Annos)
Subpart E. Survey and Certification of Long–Term Care Facilities (Refs & Annos)

42 C.F.R. § 488.335

§ 488.335 Action on complaints of resident neglect and abuse, and misappropriation of resident property.

Currentness

(a) Investigation.

(1) The State must review all allegations of resident neglect and abuse, and misappropriation of resident property and follow procedures specified in § 488.332.

(2) If there is reason to believe, either through oral or written evidence that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation.

(3) The State must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property.

(b) Source of complaints. The State must review all allegations regardless of the source.

(c) Notification—

(1) Individuals to be notified. If the State makes a preliminary determination, based on oral or written evidence and its investigation, that the abuse, neglect or misappropriation of property occurred, it must notify in writing—

(i) The individuals implicated in the investigation; and

(ii) The current administrator of the facility in which the incident occurred.

(2) Timing of the notice. The State must notify the individuals specified in paragraph (c)(1) of this section in writing within 10 working days of the State's investigation.

(3) Contents of the notice. The notice must include the—

(i) Nature of the allegation(s);

(ii) Date and time of the occurrence;

(iii) Right to a hearing;

(iv) Intent to report the substantiated findings in writing, once the individual has had the opportunity for a hearing, to the nurse aide registry or appropriate licensure authority;

(v) Fact that the individual's failure to request a hearing in writing within 30 days from the date of the notice will result in reporting the substantiated findings to the nurse aide registry or appropriate licensure authority.

(vi) Consequences of waiving the right to a hearing;

(vii) Consequences of a finding through the hearing process that the alleged resident abuse or neglect, or misappropriation of resident property did occur; and

(viii) Fact that the individual has the right to be represented by an attorney at the individual's own expense.

(d) Conduct of hearing.

(1) The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a

hearing.

(2) The State must hold the hearing at a reasonable place and time convenient for the individual.

(e) Factors beyond the individual's control. A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(f) Report of findings. If the finding is that the individual has neglected or abused a resident or misappropriated resident property or if the individual waives the right to a hearing, the State must report the findings in writing within 10 working days to—

(1) The individual;

(2) The current administrator of the facility in which the incident occurred; and

(3) The administrator of the facility that currently employs the individual, if different than the facility in which the incident occurred;

(4) The licensing authority for individuals used by the facility other than nurse aides, if applicable; and

(5) The nurse aide registry for nurse aides. Only the State survey agency may report the findings to the nurse aide registry, and this must be done within 10 working days of the findings, in accordance with § 483.156(c) of this chapter. The State survey agency may not delegate this responsibility.

(g) Contents and retention of report of finding to the nurse aide registry.

(1) The report of finding must include information in accordance with § 483.156(c) of this chapter.

(2) The survey agency must retain the information as specified in paragraph (g)(1) of this section, in accordance with the procedures specified in § 483.156(c) of this chapter.

(h) Survey agency responsibility.

(1) The survey agency must promptly review the results of all complaint investigations and determine whether or not a facility has violated any requirements in part 483, subpart B of this chapter.

(2) If a facility is not in substantial compliance with the requirements in part 483, subpart B of this chapter, the survey agency initiates appropriate actions, as specified in subpart F of this part.

Credits

[60 FR 50118, Sept. 28, 1995]

SOURCE: 53 FR 22859, 23100, June 17, 1988; 56 FR 48879, Sept. 26, 1991; 57 FR 7137, Feb. 28, 1992; 57 FR 24982, June 12, 1992; 57 FR 34012, July 31, 1992; 57 FR 43925, Sept. 23, 1992; 58 FR 61838, Nov. 23, 1993; 59 FR 56237, Nov. 10, 1994; 59 FR 56238, Nov. 10, 1994; 60 FR 50443, Sept. 29, 1995; 64 FR 3763, Jan. 25, 1999; 64 FR 66279, Nov. 24, 1999; 71 FR 71334, Dec. 8, 2006; 72 FR 53648, Sept. 19, 2007; 72 FR 61545, Oct. 31, 2007; 72 FR 71583, Dec. 18, 2007; 73 FR 3409, Jan. 18, 2008; 73 FR 11048, Feb. 29, 2008; 76 FR 9511, Feb. 18, 2011; 76 FR 15126, March 18, 2011; 77 FR 29028, May 16, 2012; 78 FR 16805, March 19, 2013; 80 FR 29834, May 22, 2015; 82 FR 38516, Aug. 14, 2017; 82 FR 46143, Oct. 4, 2017; 83 FR 56631, Nov. 13, 2018, unless otherwise noted.

AUTHORITY: 42 U.S.C 1302 and 1395hh.

Notes of Decisions (4)

Current through August 20, 2020; 85 FR 51629.

End of Document

HEARING PROCEDURE FOR CERTIFIED NURSE AIDES

I. SCOPE AND APPLICABILITY

Pursuant to 42 U.S.C.A. §§ 1395i-3(g)(1)(C) and -1396r(g)(1)(C), and 42 C.F.R. §§ 483.156, 488.332, and 488.335, a certified nurse aide ("CNA") is entitled to an opportunity for a hearing to dispute a finding by the state survey agency, South Carolina Department of Health and Environmental Control ("Department"), of abuse, neglect, or misappropriation of resident property by the CNA before the Department reports the finding to the South Carolina Nurse Aide Registry. CNA hearings will be governed pursuant to these procedures.

II. REVIEW AND INVESTIGATION

The Department's Bureau of Certification shall review all allegations of resident neglect and abuse, and misappropriation of resident property. A surveyor shall be assigned to conduct an investigation and gather information related to the allegation. Upon completion of the investigation, the assigned surveyor and their supervisor, with the input of an attorney from the Office of General Counsel, shall make a preliminary determination whether to substantiate the allegation.

III. INITIAL STAFF DECISION

The Department's Bureau of Certification shall provide written notification to a CNA that an allegation of abuse, neglect, or misappropriation of resident property has been investigated and substantiated, in accordance with 42 C.F.R. § 488.335. This shall be the initial staff decision, and shall be sent via certified mail and regular U.S. mail within ten (10) working days of the conclusion of the review and investigation.

IV. REQUEST FOR HEARING OF INITIAL STAFF DECISION

A CNA may request a hearing within thirty (30) calendar days from the date the initial staff decision is mailed to the CNA. The request for a hearing shall be in writing and shall be addressed to:

Attention: Chief Counsel for Health Regulation
Office of General Counsel
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201.

The request must be postmarked no later than thirty (30) calendar days from the date the initial staff decision was mailed. The following procedures shall apply to timely requests for a hearing.

A. HEARING OFFICER. Within ten (10) working days after receipt of the request for a hearing, the Department shall appoint a Hearing Officer.

B. TIMING AND LOCATION. The hearing shall be conducted within one hundred and five (105) calendar days of the Department's receipt of the request for a hearing. The hearing shall be held at a reasonable place and time convenient for the CNA, in accordance with 42 C.F.R. § 488.335. The Department shall provide assistance to the appointed Hearing Officer as necessary to schedule the hearing, to include acquisition of a meeting room for the hearing.

C. CONDUCT OF HEARING. The Hearing Officer shall preside at the hearing and shall conduct the proceedings in a fair and impartial manner. The Hearing Officer shall regulate the

conduct of the hearing and of the participants. The Rules of Evidence shall not apply to the hearing. The Department does not have subpoena authority to compel the production of documents or the attendance of witnesses. However, parties may bring other persons to provide information that may be helpful to the Hearing Officer in rendering a report and recommendation.

D. NOTICE OF HEARING. The appointed Hearing Officer shall provide notice of the hearing to all parties at least thirty (30) calendar days prior to the hearing date. The notification to the CNA shall set forth the date, time, place, and purpose of the hearing. Additionally, the notification shall inform the CNA of his/her rights, including the right to: (i) Be accompanied and advised by counsel and/or individuals with special knowledge and training appropriate to the CNA's job; (ii) Present any and all information, including a written statement, disputing the initial staff decision; and (iii) Ask questions of any individuals presenting information on behalf of the Department.

E. ADMINISTRATIVE RECORD. The administrative record shall include any written information offered at the hearing. Any party may submit additional information to the Hearing Officer, with a copy to the other party, within fifteen (15) calendar days following the date of the hearing. The administrative record of the hearing shall close at the end of the fifteenth (15^{th}) day following the hearing.

F. HEARING OFFICER REPORT. The Hearing Officer shall render a written report based on the Hearing Officer's analysis of the information offered at the hearing. The report shall include findings of fact and conclusions and shall make a recommendation as to whether the initial staff decision should be upheld, reversed, or modified. The Hearing Officer shall mail the written report to all parties within sixty (60) calendar days of the date of the hearing.

G. FINAL STAFF DECISION. Within thirty (30) calendar days of receipt of the Hearing Officer's report, the Department's Bureau of Certification shall render a final staff decision, accepting or modifying the Hearing Officer's report and recommendation. The final staff decision shall be made by a manager within the Bureau of Certification who did not participate in the investigation or review of the initial allegation of abuse, neglect or misappropriation of resident property, and who did not participate in the issuance of the initial staff decision or the hearing before the Hearing Officer. The final staff decision shall be sent to the CNA via certified mail, return receipt requested.

V. REQUEST FOR FINAL REVIEW OF FINAL STAFF DECISION

A CNA aggrieved by a final staff decision may file a request for a final review and filing fee with the Board of Health and Environmental Control in accordance with S.C. Code Ann. § 44-1-60. The final staff decision is not the final Department decision until completion of the final review process provided for in Section 44-1-60(F).

VI. APPEAL OF FINAL DEPARTMENT DECISION

S.C. Code Ann. § 44-1-60(G) provides that an applicant, permittee, licensee, or affected person may file a request for a contested case hearing with the S.C. Administrative Law Court challenging a final Department decision.

HEARING PROCEDURE FOR CERTIFIED NURSE AIDES

I. SCOPE AND APPLICABILITY

Pursuant to 42 U.S.C.A. §§ 1395i-3(g)(1)(C) and -1396r(g)(1)(C), and 42 C.F.R. §§ 483.156, 488.332, and 488.335, a certified nurse aide ("CNA") is entitled to an opportunity for a hearing to dispute a finding by the state survey agency, South Carolina Department of Health and Environmental Control ("Department"), of abuse, neglect, or misappropriation of resident property by the CNA before the Department reports the finding to the South Carolina Nurse Aide Registry. CNA hearings will be governed pursuant to these procedures.

II. REVIEW AND INVESTIGATION

The Department shall review all allegations of resident neglect and abuse, and misappropriation of resident property. A surveyor shall be assigned to conduct an investigation and gather information related to the allegation. Upon completion of the investigation, the Department shall make a preliminary determination whether to substantiate the allegation.

III. INITIAL STAFF DECISION

The Department shall provide written notification to a CNA that an allegation of abuse, neglect, or misappropriation of resident property has been investigated and substantiated, in accordance with 42 C.F.R. § 488.335. This shall be the initial staff decision, and shall be sent via certified mail and regular U.S. mail within ten (10) working days of the conclusion of the review and investigation.

IV. REQUEST FOR HEARING OF INITIAL STAFF DECISION

A CNA may request a hearing within thirty (30) calendar days from the date the initial staff decision is mailed to the CNA. The request for a hearing shall be in writing and shall be addressed to:

Attention: Chief Counsel for Healthcare Quality
Office of General Counsel
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201.

The request must be postmarked no later than thirty (30) calendar days from the date the initial staff decision was mailed. The following procedures shall apply to timely requests for a hearing.

A. HEARING OFFICER. Within ten (10) working days after receipt of the request for a hearing, the Department shall appoint a Hearing Officer.

B. TIMING AND LOCATION. The hearing shall be conducted within one hundred and five (105) calendar days of the Department's receipt of the request for a hearing. The hearing shall be held at a reasonable place and time convenient for the CNA, in accordance with 42 C.F.R. § 488.335. The Department shall provide assistance to the appointed Hearing Officer as necessary to schedule the hearing, to include acquisition of a meeting room for the hearing.

C. CONDUCT OF HEARING. The Hearing Officer shall preside at the hearing and shall conduct the proceedings in a fair and impartial manner. The Hearing Officer shall regulate the conduct of the hearing and of the participants. The Rules of Evidence shall not apply to the

hearing. The Department does not have subpoena authority to compel the production of documents or the attendance of witnesses. However, parties may bring other persons to provide information that may be helpful to the Hearing Officer in rendering a report and recommendation.

D. NOTICE OF HEARING. The appointed Hearing Officer shall provide notice of the hearing to all parties at least thirty (30) calendar days prior to the hearing date. The notification to the CNA shall set forth the date, time, place, and purpose of the hearing. Additionally, the notification shall inform the CNA of his/her rights, including the right to: (i) Be accompanied and advised by counsel and/or individuals with special knowledge and training appropriate to the CNA's job; (ii) Present any and all information, including a written statement, disputing the initial staff decision; and (iii) Ask questions of any individuals presenting information on behalf of the Department.

E. ADMINISTRATIVE RECORD. The administrative record shall include any written information offered at the hearing. Any party may submit additional information to the Hearing Officer, with a copy to the other party, within fifteen (15) calendar days following the date of the hearing. The administrative record of the hearing shall close at the end of the fifteenth (15^{th}) day following the hearing.

F. HEARING OFFICER REPORT. The Hearing Officer shall render a written report based on the Hearing Officer's analysis of the information offered at the hearing. The report shall include findings of fact and conclusions and shall make a recommendation as to whether the initial staff decision should be upheld, reversed, or modified. The Hearing Officer shall mail the written report to all parties within sixty (60) calendar days of the date of the hearing.

G. FINAL STAFF DECISION. Within thirty (30) calendar days of receipt of the Hearing Officer's report, the Department shall render a final staff decision, accepting or modifying the Hearing Officer's report and recommendation. The final staff decision shall be made by a Department representative who did not participate in the investigation or review of the initial allegation of abuse, neglect or misappropriation of resident property, and who did not participate in the issuance of the initial staff decision or the hearing before the Hearing Officer. The final staff decision shall be sent to the CNA via certified mail, return receipt requested.

V. REQUEST FOR FINAL REVIEW OF FINAL STAFF DECISION

A CNA aggrieved by a final staff decision may file a request for a final review and filing fee with the Board of Health and Environmental Control in accordance with S.C. Code Ann. § 44-1-60. The final staff decision is not the final Department decision until completion of the final review process provided for in Section 44-1-60(F).

VI. APPEAL OF FINAL DEPARTMENT DECISION

S.C. Code Ann. § 44-1-60(G) provides that an applicant, permittee, licensee, or affected person may file a request for a contested case hearing with the S.C. Administrative Law Court challenging a final Department decision.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 10, 2020

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE:** Request for Placement of Isotonitazene into Schedule I for Controlled Substances in South Carolina.

II. **SUBJECT:** Placement of Isotonitazene 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 Code 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, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The Acting Administrator of the federal Drug Enforcement Administration ("DEA") issued a temporary order to place N,N-diethyl-2-(2-(4 isopropoxybenzyl)- 5-nitro-1H-benzimidazol-1-yl)ethan-1- amine (isotonitazene), 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, in schedule I of the federal Controlled Substances Act ("federal CSA"). The federal CSA allows the DEA to temporarily schedule a substance for two years in order to avoid an imminent hazard to the public safety as defined in the federal CSA. The Attorney General may extend the temporary scheduling for up to one year during the pendency of proceedings to permanently

schedule the substance. The federal order to temporarily schedule isotonitazene in the federal CSA became effective August 20, 2020, in *Federal Register*, Volume 85, Number 162, pages 51342-51346; https://www. https://www.govinfo.gov/content/pkg/FR-2020-08-20/pdf/2020-17951.pdf.

IV. ANALYSIS:

The Acting Administrator of the DEA determined that the temporary scheduling of isotonitazene in schedule I of the federal CSA was necessary to avoid an imminent hazard to the public safety. 21 U.S.C. § 811(h). As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, isotonitazene. 21 U.S.C. § 811(c) requires the Administrator to consider the substances' history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health in making a determination. In addition, 21 U.S.C. 811(h)(3) requires consideration of certain factors including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

1) History and Current Pattern of Abuse

The availability of synthetic opioids in the illicit drug market continues to pose an imminent hazard to the public safety. In recent years, adverse health effects associated with the abuse of synthetic opioids and the continued evolution and increased popularity of these substances have been a serious concern. As the United States continues to experience an unprecedented epidemic of opioid misuse and abuse, the presence of new synthetic opioids with no approved medical use exacerbates the epidemic. Trafficking and abuse of new synthetic opioids are deadly new trends. Beginning April 2019, isotonitazene emerged on the illicit synthetic drug market in the United States, as evidenced by its identification in drug seizures and in biological samples collected and submitted to National Medical Services (NMS) Laboratory. Isotonitazene has been encountered by United States law enforcement primarily in powder form, as well as being identified as a single substance or in combination with other substances. Evidence suggests that individuals are using isotonitazene as a replacement to heroin or other opioids, either knowingly or unknowingly.

2) Scope, Duration, and Significance of Abuse

Isotonitazene, similar to etonitazene, another schedule I drug, has been described as a potent synthetic opioid and evidence suggests it is being abused for its opioidergic effects. The abuse of isotonitazene, similar to other synthetic opioids, has resulted in adverse health effects. Isotonitazene has been positively identified in eighteen death investigations between August 2019 and January 2020. Law enforcement data indicates that isotonitazene has appeared in the United States' illicit drug market. The population likely to abuse isotonitazene appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in isotonitazene fatal overdose cases. Because abusers of isotonitazene are likely to obtain it through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well characterized. This population abusing opioids is likely to be at risk of abusing isotonitazene. Individuals who initiate use of isotonitazene are likely to be at risk of developing substance use disorders, overdoses, and death similar to that of other opioid analgesics.

3) Potential Risks to the Public

The increase in opioid overdose deaths in the United States has been exacerbated by the availability of potent synthetic opioids in the illicit drug market. Data obtained from preclinical studies demonstrates isotonitazene exhibits a pharmacological profile similar to that of etonitazene and other mu-opioid receptor agonists. As with any mu-opioid receptor agonist, the potential health and safety risks for users are high. The public health risks attendant to the abuse of heroin and other mu-opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. The introduction of potent synthetic opioids such as isotonitazene into the illicit market exacerbates problematic opioid use for those seeking these powerful opioids.

V. RECOMMENDATION:

The Acting Administrator of the DEA concludes that N,N-diethyl-2-(2-(4 isopropoxybenzyl)- 5-nitro-1H-benzimidazol-1-yl)ethan-1- amine (isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts meets the criteria for temporary placement in schedule I of the federal CSA. Because isotoniazene has a high potential for abuse, there is no currently accepted medical use for isotoniazene in treatment in the United States, and a lack of accepted safety for use in treatment under medical supervision temporary scheduling was necessary to avoid an imminent hazard to the public safety.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the placement of isotonitazene in Schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act to include:

( ) N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts and salts of isomers, esters and ethers

The Department recommends the Board place isotonitazene in Schedule I of the South Carolina Controlled Substances Act.

Submitted by:

Lisa Thomson
Bureau Director
Drug Control

Gwendolyn C. Thompson
Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 85, Number 162, August 20, 2020

published on March 10, 2020 (85 FR 13741), is adopted as final without change.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–17357 Filed 8–19–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–631]

Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule *N*,*N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as isotonitazene), 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, in schedule I. This action is based on a finding by the Acting Administrator that the placement of isotonitazene in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed 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 isotonitazene.

DATES: This temporary scheduling order is effective August 20, 2020, until August 20, 2022. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling [1] for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator). 28 CFR 0.100.

Background

21 U.S.C. 811(h)(4) requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place isotonitazene in schedule I on a temporary basis to the Assistant Secretary for Health of HHS (Assistant Secretary) by letter dated March 2, 2020. The Assistant Secretary responded to this notice by letter dated March 31, 2020, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for isotonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of isotonitazene in schedule I of the CSA.

The Drug Enforcement Administration (DEA) has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). Isotonitazene is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for isotonitazene under section 505 of the FDCA, 21 U.S.C. 355. DEA has found that the control of isotonitazene in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent to temporarily schedule isotonitazene in the **Federal Register** on June 18, 2020. 85 FR 38619. That notice of intent discussed findings from DEA's three-factor analysis dated May 2020, which DEA made available on *www.regulations.gov* contemporaneously with the publication of the notice of intent. This temporary scheduling order discusses updated findings on isotonitazane for one of the three factors (Factor 5) in DEA's July 2020 analysis related to law enforcement seizures, overdoses, and regulatory status.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for isotonitazene summarized below indicate that it has high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA's May and July 2020 three-factor analyses and the Assistant Secretary's March 31, 2020, letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at *www.regulations.gov*.

[1] Though the Drug Enforcement Administration (DEA) has used the term "final order" with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

[2] 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.

Isotonitazene

The availability of synthetic opioids in the illicit drug market continues to pose an imminent hazard to the public safety. Adverse health effects associated with the abuse of synthetic opioids and the continued evolution and increased popularity of these substances have been a serious concern in recent years. As the United States continues to experience an unprecedented epidemic of opioid misuse and abuse, the presence of new synthetic opioids with no approved medical use exacerbates the epidemic. The trafficking and abuse of new synthetic opioids are deadly new trends.

The identification of isotonitazene, chemically known as *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (other name: *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine), in the illicit drug market has been reported in Canada, Estonia, Germany, Latvia, Sweden, and the United States (see Factor 4 below). Data obtained from preclinical pharmacology studies shows that isotonitazene has a pharmacological profile similar to that of the potent synthetic opioid etonitazene, a schedule I controlled substance. Because of the pharmacological similarities of isotonitazene to etonitazene, the use of isotonitazene presents a high risk of abuse and may negatively affect users and communities. The abuse of isotonitazene has been associated with at least 19 fatalities in the United States (see Factor 5 below). The positive identification of this substance in overdose and post-mortem cases is a serious concern for public safety. Thus, isotonitazene poses an imminent hazard to public safety.

Available data and information for isotonitazene, as summarized below, indicates that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at *www.regulations.gov* under Docket Number DEA–631.

Factor 4. History and Current Pattern of Abuse

The chemical syntheses of isotonitazene (a benzimidazole derivative) and other benzimidazole derivatives (including schedule I substances such as synthetic opioids etonitazene and clonitazene) were first reported in the scientific literature in 1957. Isotonitazene is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. As discussed in the background section, the Assistant Secretary stated in a March 31, 2020, letter to DEA that there are no INDs or FDA-approved NDAs for isotonitazene in the United States. Hence, DEA notes there is no legitimate channel for isotonitazene as a marketed drug product.

Since 2014, numerous synthetic opioids structurally related to fentanyl and several opioids from other structural classes have begun to emerge in the illicit drug market, as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Beginning in April 2019, isotonitazene emerged on the illicit synthetic drug market in the United States, as evidenced by its identification in drug seizures and in biological samples collected and submitted to National Medical Services (NMS) Laboratory [3] in August 2019. In August 2019, isotonitazene was first reported in a drug case in Belgium and in toxicology casework in Canada (a toxicological sample was collected in March 2019). In the United States, the Center for Forensic Science Research and Education (under the novel psychoactive substances discovery program) first reported isotonitazene in November 2019.

According to a report by the European Monitoring Center for Drugs and Drug addiction and Europol,[4] between April 2019 and January 2020, four member-states (Estonia, Latvia, Germany, and Sweden) have reported 24 isotonitazene cases involving 109.6 grams of powder (22 cases) and 4.5 grams of liquid (two cases). Isotonitazene has been encountered by United States law enforcement primarily in powder form. In March 2020, Canada law enforcement also encountered isotonitazene in a tablet form, as a white triangular tablet with 'M' logo on one side and '8' logo on the other side, and as a blue tablet in Dilaudid counterfeit pills. Identification of isotonitazene in counterfeit pills is deeply concerning because the identity, purity, and quantity of isotonitazene in this formulation are uncertain, thus presenting additional safety concerns for unsuspecting users.

In the United States, isotonitazene has been identified as a single substance or in combination with other substances. In April 2019, the United States Customs and Border Protection (CBP) seized 1.6 grams of isotonitazene in California. In addition, Wisconsin State Crime Laboratories identified isotonitazene mixed with heroin and bromazolam, a nonscheduled benzodiazepine, in seized powder. Further, isotonitazene was identified in a substance obtained from the scene of a death investigation in Iowa. Evidence suggests that individuals are using isotonitazene as a replacement to heroin or other opioids, either knowingly or unknowingly.

Factor 5. Scope, Duration, and Significance of Abuse

Isotonitazene, similar to etonitazene (schedule I), has been described as a potent synthetic opioid and evidence suggests it is being abused for its opioidergic effects (see Factor 6). The abuse of isotonitazene, similar to other synthetic opioids, has resulted in adverse health effects. Isotonitazene has been positively identified in 18 death investigations between August 2019 and January 2020. These reports were from four states—Illinois (9), Indiana (7), Minnesota (1), and Wisconsin (1). Most (n = 12) of the decedents were male. The ages ranged from 24 to 66 years old with an average age of 41. Other substances identified in postmortem blood specimens obtained from these decedents include etizolam (6); flualprazolam, a nonscheduled benzodiazepine (7); fentanyl (6); heroin (3); tramadol, a schedule IV narcotic (2); and U–47700, a schedule I synthetic opioid (1). The average concentration of isotonitazene in these biological samples (blood) was 2.2 ± 2.1 nanogram/milliliter (ng/ml) (range 0.4 to 9.5 ng/ml). Isotonitazene was detected as the only opioid in 50 percent (n = 9) of the specimens for these decedents. DEA [5] is aware of another postmortem case that occurred in January 2020 in Pennsylvania where isotonitazene was identified in a biological sample. In total, isotonitazene has been positively identified in 19 postmortem cases.

[3] NMS Labs, in collaboration with the Center for Forensic Science Research and Education at the Fredric Rieders Family Foundation and the Organized Crime Drug Enforcement Task Force at the U.S. Department of Justice, has received funding from the Centers for Disease Control and Prevention to develop systems for the early identification and notification of novel psychoactive substances in the drug supply within the United States.

[4] European Monitoring Centre for Drugs and Drug Addiction and Europol (2020), EMCDDA initial report on the new psychoactive substance *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene). In accordance with Article 5b of Regulation (EC) No 1920/2006 (as amended), Publications Office of the European Union, Luxembourg.

[5] Email communication from DEA Philadelphia Field Division on March 4, 2020.

Recent communication from Minnesota Department of Health [6] reports the positive identification of isotonitazene in two overdose cases.

Law enforcement data indicate that isotonitazene has appeared in the United States' illicit drug market. According to the National Forensic Laboratory Information System (NFLIS) [7] database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State, and local forensic laboratories, there have been 48 encounters of isotonitazene in the United States (queried May 14, 2020). These 48 encounters occurred in 2019 and 2020 in five states: California (1), Iowa (5), Ohio (4), Tennessee (13), and Wisconsin (25). One of these encounters consisted of 1.6 grams of isotonitazene seized by the CBP in California in April 2019.

As of May 2020, Ohio and Wisconsin enacted emergency legislation to control isotonitazene as a schedule I controlled substance. Internationally, isotonitazene is controlled under Estonia, Latvia, Poland, and Sweden drug control legislation. In the United Kingdom, isotonitazene is controlled under the Psychoactive Substances Act 2016. Further, isotonitazene is controlled under the Norwegian Medicines Act and Lithuania medicine legislation.[8]

The population likely to abuse isotonitazene appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in isotonitazene fatal overdose cases. Because abusers of isotonitazene are likely to obtain it through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[9] as of 2018, an estimated 10.3 million people aged 12 years or older had misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, an estimated 2.0 million people had an opioid use disorder which included 1.7 million people with a prescription pain reliever use disorder and 0.5 million people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing isotonitazene. Individuals who initiate (*i.e.,* use a drug for the first time) use of isotonitazene are likely to be at risk of developing substance use disorders, overdoses, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement and toxicology reports demonstrate that isotonitazene is being illicitly distributed and abused.

Factor 6. What, If Any, Risk There Is to the Public Health

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids in the illicit drug market. Data obtained from pre-clinical studies demonstrate that isotonitazene exhibits a pharmacological profile similar to that of etonitazene and other mu-opioid receptor agonists. In an *in vivo* (in mice) study, isotonitazene was 500 times more potent than morphine as an analgesic in a tail-flick assay. The tail-flick assay is useful in evaluating antinociceptive effect. Data from *in vitro* studies showed that isotonitazene activated the mu-opioid receptor and acted as a mu-opioid receptor agonist. Isotonitazene, similar to hydromorphone and fentanyl, activated the mu-opioid receptor and acted as an agonist via interaction at the mu-opioid receptor with β-arrestin-2, a regulatory protein, in a live cell-based receptor assay. Naloxone, an opioid receptor antagonist, blocked isotonitazene's activation of the mu-opioid receptor. Substances that act as an agonist at the mu-opioid receptors have a high potential for addiction and can induce dose-dependent respiratory depression.

As with any mu-opioid receptor agonist, the potential health and safety risks for users are high. The public health risks attendant to the abuse of heroin and other mu-opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. A CDC report shows that from 2013 to 2018,[10] opioid-related overdose deaths in the United States increased from 25,052 to 46,802. Of the drug overdose death data for 2018, opioids were involved in about 69.5 percent of all drug-involved overdose deaths.

In the United States, isotonitazene has been co-identified with other substances in 18 postmortem cases, and DEA is aware of an additional death in January 2020, involving isotonitazene. These deaths associated with isotonitazene occurred in five states: Illinois (9), Indiana (7), Minnesota (1), Pennsylvania (1), and Wisconsin (1). Information gathered from case histories and autopsy findings shows that isotonitazene use is similar to that of classic opioid agonists. Evidence obtained from reported cases of death scenarios suggests that isotonitazene, similar to heroin, can be used intravenously.[11]

The introduction of potent synthetic opioids such as isotonitazene into the illicit market exacerbates problematic opioid use for those seeking these powerful opioids. As documented by a published toxicology report, poly-substance abuse remains common in fatalities associated with the abuse of isotonitazene.[12]

[6] Email communication from Minnesota Department of Health: Biomonitoring and Emerging Contaminants Unit; received May 26, 2020.

[7] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011. NFLIS data was queried on May 14, 2020.

[8] The Medicines Act, LOVDATA, *https://lovdata.no/dokument/NL/lov/1992-12-04-132*, 1992.

[9] The National Survey on Drug Use and Health (NSDUH), formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by HHS' Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population twelve years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.,* ever used), past year, and past month abuse or dependence. The 2018 NSDUH annual report is available at *https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf* (last accessed June 18, 2020).

[10] CDC National Center for Health Statistics (NCHS), National Vital Statistics System, Mortality. NCHS Data Brief, Number 356, January 2020.

[11] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK (2020). Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. *Journal of Analytical Toxicology.* [Epub ahead of print].

[12] *Id.*

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of isotonitazene pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for isotonitazene in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for isotonitazene indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by 21 U.S.C. 811(h)(4), by a letter dated March 2, 2020, the Acting Administrator notified the Assistant Secretary for Health of DEA's intention to temporarily place isotonitazene in schedule I. DEA subsequently published a Notice of Intent in the **Federal Register** on June 18, 2020. 85 FR 38619.

Conclusion

In accordance with the provisions of 21 U.S.C. 811(h), the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as: Isotonitazene) in schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Acting Administrator hereby finds it necessary to temporarily place isotonitazene in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling this substance is effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, isotonitazene will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, isotonitazene 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, as of August 20, 2020. Any person who currently handles isotonitazene, and is not registered with DEA, must submit an application for registration and may not continue to handle isotonitazene as of August 20, 2020, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after August 20, 2020, is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle isotonitazene must surrender all currently held quantities of isotonitazene.

3. *Security.* Isotonitazene is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of August 20, 2020. Non-practitioners handling isotonitazene must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of isotonitazene must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from August 20, 2020, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of isotonitazene on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including isotonitazene) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to isotonitazene pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, 1317, and § 1307.11. Current DEA registrants authorized to handle isotonitazene shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute isotonitazene must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of August 20, 2020.

8. *Order Forms.* All DEA registrants who distribute isotonitazene must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of August 20, 2020.

9. *Importation and Exportation.* All importation and exportation of isotonitazene must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of August 20, 2020.

10. *Quota.* Only DEA registered manufacturers may manufacture isotonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of August 20, 2020.

11. *Liability.* Any activity involving isotonitazene not authorized by, or in violation of the CSA, occurring as of August 20, 2020, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

21 U.S.C. 811(h) provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement of a publication in the **Federal Register** of a Notice of Intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this temporary scheduling order. The APA expressly differentiates between an order and a rule, as it defines an "order" to mean a "final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*" 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in 21 U.S.C. 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this action might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice-and-comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although DEA believes this temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. In addition, because this action is not considered an E.O. 12866 "significant regulatory action," it does not meet the definition of an E.O. 13771 regulatory action. Therefore, the repeal and cost offset requirements of E.O. 13771 have not been triggered.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(48) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(48)	*N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: isotonitazene; *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine)	9614

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–17951 Filed 8–19–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9614]

RIN 1545–AM97

Certain Outbound Property Transfers by Domestic Corporations; Certain Stock Distributions by Domestic Corporations; Correcting Amendment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY SHEET

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 10, 2020

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Deletion of FDA-Approved Drugs that Contain Cannabidiol (CBD) Derived from Cannabis and No More Than 0.1 Percent (w/w) Residual Tetrahydrocannabinols from Schedule V for Controlled Substances in South Carolina

II. SUBJECT: Deletion of FDA-Approved Drugs that Contain Cannabidiol (CBD) Derived from Cannabis and No More Than 0.1 Percent (w/w) Residual Tetrahydrocannabinols from Schedule V for Controlled Substances in South Carolina

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 V substances are listed in Section 44-53-270 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 DHEC. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated. 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, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On June 25, 2018, the Food and Drug Administration ("FDA") approved Cannabidiol 100 mg/ml solution, tradename Epidiolex ("Epidiolex") as a prescription drug for the treatment of seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome. On September 28, 2018, the Acting Administrator of the Drug Enforcement Administration placed FDA-approved drugs that contain cannabidiol derived from cannabis and containing no more than 0.1 percent

tetrahydrocannabinols, including Epidiolex and any future FDA-approved generic versions of such formulation made from cannabis, in Schedule V of the federal Controlled Substances Act ("federal CSA"). On August 21, 2020, the Drug Enforcement Administration ("DEA") issued an interim final rule to remove FDA-approved drugs that contain cannabidiol derived from cannabis and containing no more than 0.1 percent tetrahydrocannabinols from Schedule V of the federal CA, effective August 21, 2020, in *Federal Register*, Volume 85, Number 163, pages 51639-51645; https://www.govinfo.gov/content/pkg/FR-2020-08-21/pdf/2020-17356.pdf .

IV. ANALYSIS:

The Drug Enforcement Administration ("DEA"), pursuant to 21 CFR 1308.15, previously controlled drug products in Schedule V of the federal CSA separately in finished dosage formulations approved by FDA and that, under Controlled Substance Code Number 7367, contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. The FDA-approved substances described under Drug Code 7367 are no longer controlled, by virtue of the Agriculture Improvement Act of 2018 ("AIA"), and as a result, DEA is removing the listing for ''Approved cannabidiol drugs'' under schedule V of the federal CSA.

V. RECOMMENDATION:

The Department recommends the deletion of FDA-approved drugs that contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols from Schedule V for controlled substances in South Carolina the same manner as the federal Drug Enforcement Administration.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends the deletion of FDA approved drugs that contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols from Schedule V for controlled substances in South Carolina in Section 44-53-270 of the South Carolina Code of Laws.

The Department recommends the Board delete FDA-approved drugs that contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols in Schedule V of the South Carolina Controlled Substances Act.

Submitted by:

Lisa Thomson
Bureau Director
Bureau of Drug Control

Gwendolyn C. Thompson
Gwen Thompson
Deputy Director
Healthcare Quality

Attachment: *Federal Register*, Volume 85, Number 163, August 21, 2020

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[in $ Millions 2016 Dollars, Over an Infinite Time Horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs			
Present Value of Cost Savings			
Present Value of Net Costs			
Annualized Costs			
Annualized Cost Savings			
Annualized Net Costs			

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA/Economics Staff, "Elimination of the 21 CFR 610.30 Test for *Mycoplasma* Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," 2018. (Available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*)

List of Subjects in 21 CFR part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 1. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

Subpart D—[Removed and Reserved]

■ 2. Remove and reserve subpart D, consisting of § 610.30.

Dated: July 29, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–17085 Filed 8–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308 and 1312

[Docket No. DEA–500]

RIN 1117–AB53

Implementation of the Agriculture Improvement Act of 2018

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: The purpose of this interim final rule is to codify in the Drug Enforcement Administration (DEA) regulations the statutory amendments to the Controlled Substances Act (CSA) made by the Agriculture Improvement Act of 2018 (AIA), regarding the scope of regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents. This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations.

DATES: Effective August 21, 2020. Electronic comments must be submitted, and written comments must be postmarked, on or before October 20, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "RIN 1117–AB53/Docket No. DEA–500" on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *http://www.regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, Diversion Control Division; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–2596.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and the complete Economic Impact Analysis, to this interim final rule are available in their entirety under the tab "Supporting Documents" of the public docket of this action at *http://www.regulations.gov* under FDMS Docket ID: DEA–500 (RIN 1117–AB53/Docket Number DEA–500) for easy reference.

Executive Summary

The Agriculture Improvement Act of 2018, Public Law 115–334 (the AIA), was signed into law on December 20, 2018. It provided a new statutory definition of "hemp" and amended the definition of marihuana under 21 U.S.C. 802(16) and the listing of tetrahydrocannabinols under 21 U.S.C. 812(c). The AIA thereby amends the regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents in the Controlled Substances Act (CSA).

This rulemaking makes four conforming changes to DEA's existing regulations:

• It modifies 21 CFR 1308.11(d)(31) by adding language stating that the definition of "Tetrahydrocannabinols" does not include "any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*."

• It removes from control in schedule V under 21 CFR 1308.15(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols."

• It also removes the import and export controls described in 21 CFR 1312.30(b) over those same substances.

• It modifies 21 CFR 1308.11(d)(58) by stating that the definition of "Marihuana Extract" is limited to extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis."

This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations. Accordingly, there are no additional costs resulting from these regulatory changes. However, as discussed below, the changes reflected in this interim final rule are expected to result in annual cost savings for affected entities.

Changes to the Definition of Marihuana

The AIA amended the CSA's regulatory controls over marihuana by amending its definition under the CSA. Prior to the AIA, marihuana was defined in 21 U.S.C. 802(16) as follows:

> The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

The AIA modified the foregoing definition by adding that the "term 'marihuana' does not include hemp, as defined in section 1639*o* of Title 7." 21 U.S.C. 802(16)(B). Furthermore, the AIA added a definition of "hemp" to 7 U.S.C. 1639*o*, which reads as follows:

> The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Taken together, these two changes made by the AIA limit the definition of marihuana to only include cannabis or cannabis-derived material that contain more than 0.3% delta-9-tetrahydrocannabinol (also known as Δ^9-THC) on a dry weight basis. Thus, to fall within the current CSA definition of

marihuana, cannabis and cannabis-derived material must both fall within the pre-AIA CSA definition of marihuana and contain more than 0.3 percent Δ^9-THC on a dry weight basis. Pursuant to the AIA, unless specifically controlled elsewhere under the CSA, any material previously controlled under Controlled Substance Code Number 7360 (marihuana) or under Controlled Substance Code Number 7350 (marihuana extract), that contains 0.3% or less of Δ^9-THC on a dry weight basis—*i.e.*, "hemp" as that term defined under the AIA—is not controlled. Conversely, any such material that contains greater than 0.3% of Δ^9-THC on a dry weight basis remains controlled in schedule I.

In order to meet the AIA's definition of hemp, and thus qualify for the exception in the definition of marihuana, a cannabis-derived product must itself contain 0.3% or less Δ^9-THC on a dry weight basis. It is not enough that a product is labeled or advertised as "hemp." The U.S. Food and Drug Administration (FDA) has recently found that many cannabis-derived products do not contain the levels of cannabinoids that they claim to contain on their labels.[1] Cannabis-derived products that exceed the 0.3% Δ^9-THC limit do not meet the statutory definition of "hemp" and are schedule I controlled substances, regardless of claims made to the contrary in the labeling or advertising of the products.

In addition, the definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the Δ^9-THC content of the derivative. In order to meet the definition of "hemp," and thus qualify for the exemption from schedule I, the derivative must not exceed the 0.3% Δ^9-THC limit. The definition of "marihuana" continues to state that "*all* parts of the plant Cannabis sativa L.," and "*every* compound, manufacture, salt, derivative, mixture, or preparation of such plant," are schedule I controlled substances unless they meet the definition of "hemp" (by falling below the 0.3% Δ^9-THC limit on a dry weight basis) or are from exempt parts of the plant (such as mature stalks or non-germinating seeds). *See* 21 U.S.C. 802(16) (emphasis added). As a result, a cannabis derivative, extract, or product that exceeds the 0.3% Δ^9-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ^9-THC on a dry weight basis.

[1] *See* FDA, Warning Letters and Test Results for Cannabidiol-Related Products, *https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.*

Finally, nothing in the AIA or in these implementing regulations affects or alters the requirements of the Food, Drug, & Cosmetic Act (FD&C Act). *See* 7 U.S.C. 1639r(c). Hemp products that fall within the jurisdiction of the FD&C Act must comply with its requirements. FDA has recently issued a statement regarding the agency's regulation of products containing cannabis and cannabis-derived compounds, and DEA refers interested parties to that statement, which can be found at *https://www.fda.gov/newsevents/Newsroom/PressAnnouncements/ucm628988.htm.*

Changes to the Definition of Tetrahydrocannabinols

The AIA also modified the listing for tetrahydrocannabinols under 21 U.S.C. 812(c) by stating that the term tetrahydrocannabinols does not include tetrahydrocannabinols in hemp. Specifically, 21 U.S.C. 812(c) Schedule I now lists as schedule I controlled substances: "Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639*o* of Title 7)."

Therefore, the AIA limits the control of tetrahydrocannabinols (for Controlled Substance Code Number 7370). For tetrahydrocannabinols that are naturally occurring constituents of the plant material, Cannabis sativa L., any material that contains 0.3% or less of Δ^9-THC by dry weight is not controlled, unless specifically controlled elsewhere under the CSA. Conversely, for tetrahydrocannabinols that are naturally occurring constituents of Cannabis sativa L., any such material that contains greater than 0.3% of Δ^9-THC by dry weight remains a controlled substance in schedule I.

The AIA does not impact the control status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) because the statutory definition of "hemp" is limited to materials that are derived from the plant Cannabis sativa L. For synthetically derived tetrahydrocannabinols, the concentration of Δ^9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.

This rulemaking is modifying 21 CFR 1308.11(d)(31) to reflect this statutory change. By this rulemaking, 21 CFR 1308.11(d)(31) is being modified via the addition of subsection (ii), which reads: "Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*."

Removal of Schedule V Control of FDA-Approved Products Containing Cannabidiol

Previously DEA, pursuant to 21 CFR 1308.15, separately controlled in Schedule V drug products in finished dosage formulations that have been approved by FDA and that contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols (under Controlled Substance Code Number 7367). The FDA-approved substances described under Drug Code 7367 are no longer controlled, by virtue of the AIA. As a result, DEA is removing the listing for "Approved cannabidiol drugs" under schedule V in 21 CFR 1308.15.

Note that CBD in a mixture with a Δ^9-THC concentration greater than 0.3% by dry weight is not exempted from the definition of "marihuana" or "tetrahydrocannabinols." Accordingly, all such mixtures exceeding the 0.3% limit remain controlled substances under schedule I.

Removal of Import/Export Provisions Involving FDA-Approved Products Containing CBD

Previously DEA, pursuant to 21 CFR 1312.30, required import and export permits pursuant to 21 U.S.C. 811(d)(1), 952(b)(2), and 953(e)(3) for the import and export of drug products in finished dosage formulations that have been approved by FDA and that contain CBD derived from cannabis and no more than **0.1 percent (w/w) residual** tetrahydrocannabinols. Because such substances are no longer controlled substances, DEA is likewise removing the import and export permit requirement for these substances. The regulation is revised to delete § 1312.30(b).

Drug Code 7350 for Marihuana Extract

The current control status of marihuana-derived constituents depends upon the concentration of Δ^9-THC in the constituent. DEA is amending the scope of substances falling within the Controlled Substances Code Number for marihuana extract (7350) to conform to the amended definition of marihuana in the AIA. As amended, the Drug Code 7350 definition reads:

Marihuana Extract—meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight

basis, other than the separated resin (whether crude or purified) obtained from the plant.

21 CFR 1308.11(d)(58). The drug code 7350 became effective on January 13, 2017. 81 FR 90194.

Regulatory Analysis

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring the publication of a prior notice of proposed rulemaking and the pre-promulgation opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest.

DEA finds there is good cause within the meaning of the APA to issue these amendments as an interim final rule and to delay comment procedures to the post-publication period, because these amendments merely conform the implementing regulations to recent amendments to the CSA that have already taken effect. DEA has no discretion with respect to these amendments. This rule does no more than incorporate the statutory amendments into DEA's regulations, and publishing a notice of proposed rulemaking or soliciting public comment prior to publication is unnecessary. *See* 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). "[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary." *Gray Panthers Advocacy Committee* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); *see also United States* v. *Cain,* 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, "with regulations that merely restate or interpret statutory obligations," which do not); *Komjathy* v. *Nat. Trans. Safety Bd.,* 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule "does no more than repeat, virtually verbatim, the statutory grant of authority" notice-and-comment procedures are not required).

In addition, because the statutory changes at issue have already been in effect since December 20, 2018, DEA finds good cause exists to make this rule effective immediately upon publication. *See* 5 U.S.C. 553(d). Therefore, DEA is issuing these amendments as an interim final rule, effective upon publication in the **Federal Register**.

Although publishing a notice of proposed rulemaking and soliciting public comment prior to publication are unnecessary in this instance because these regulations merely implement statutory changes over which the agency has no discretion, DEA is soliciting public comment on this rule following its publication. For that reason, DEA is publishing this rule as an interim final rule and is establishing a docket to receive public comment on this rule. To the extent required by law, DEA will consider and respond to any relevant comments received.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Cost)

This interim final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

The economic, interagency, budgetary, legal, and policy implications of this interim final rule have been examined and it has been determined that it is not a significant regulatory action under E.O. 12866 because it is a non-discretionary action that is dictated by the statutory amendments to the CSA enacted by the AIA. While not determined to be a significant regulatory action, this action has been reviewed by the OMB.

As explained above, DEA is obligated to issue this interim final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the AIA. In issuing this interim final rule, DEA has not gone beyond the statutory text enacted by Congress. Thus, DEA would have to issue this interim final rule regardless of the outcome of the agency's regulatory analysis. Nonetheless, DEA conducted this analysis as discussed below.

Summary of Benefits and Costs

This analysis is limited to the provisions of the AIA that are being directly implemented by this DEA interim final rule. DEA has reviewed these regulatory changes and their expected costs and benefits. Benefits, in the form of cost savings realized by DEA registrants handling previously controlled substances, will be generated as a direct result of the publication of this interim final rule. DEA does not expect there to be any costs associated with the promulgation of this interim final rule. The following is a summary; a detailed economic analysis of the interim final rule can be found in the rulemaking docket at *http://www.regulations.gov*.

The AIA's revised definitions of marihuana and tetrahydrocannabinols effectively decontrol hemp as defined under the AIA. DEA's regulatory authority over any plant with less than 0.3% THC content on a dry weight basis, and any of the plant's derivatives under the 0.3% THC content limit, is removed as a result. It is important to note, however, that this does not mean that hemp is not under federal regulatory oversight. The AIA directs the U.S. Department of Agriculture (USDA) to review and approve commercial hemp production plans developed by State, territory, and Indian tribal agencies and to develop its own production plan. 7 U.S.C. 1639p, 1639q. Until these regulations are finalized, State commercial hemp pilot programs authorized under the 2014 Farm Bill are still in effect and current participants may proceed with plans to grow hemp while new regulations are drafted.[2] DEA expects the USDA to assess the costs and benefits of this new regulatory apparatus once those rules are finalized. For these reasons, DEA considers any potential costs or benefits broadly related to changes in the domestic industrial hemp market due to the

[2] *See* USDA, Hemp Production Program Questions and Answers, *https://www.ams.usda.gov/publications/content/hemp-production-program-questions-and-answers.*

decontrol of hemp, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.

To determine any cost savings resulting from this decontrol action, DEA analyzed its registration, import, and export data. The removal of DEA's regulatory authority over hemp as defined under the AIA will impact only DEA registrants that currently import viable hemp seed intended for germination. Viable hemp seed was classified as a schedule I controlled substance prior to the amendments to the CSA enacted by the AIA. The importation and exportation of controlled substances requires an importer or exporter to first register with DEA, and then apply and obtain a permit to import or export controlled substances for each shipment.[3] The decontrol of hemp with this interim final rule means that viable hemp seed is no longer subject to those schedule I requirements, as long as the material contains less than the 0.3% limit.

Based on the number of import and export permits issued, DEA estimated the number of import and export permit applications that would no longer be needed. DEA reviewed internal data tracking the number of imports and exports for hemp seed over a three year period beginning January 1, 2016 and ending December 31, 2018.[4] During this three year period, there was an average of 88 import permits issued for hemp seed per year, and no exports. These import permits were issued only to participants in state commercial hemp pilot programs, including state departments of agriculture and higher education institutions, which are considered "fee exempt", and do not pay the $1,523 annual importer registration fee.[5] However, fee-exempt institutions are still required to obtain a DEA registration and renew that registration annually by filling out and submitting DEA form 225a. DEA expects these institutions to relinquish their schedule I importer registrations as a result of the promulgation of this interim final rule.

DEA estimates the average annual cost savings attributable to the elimination of import permits for hemp seed, and the elimination of annual registration renewals for hemp seed importers to be $3,225.[6] This cost savings is realized entirely by DEA registrants. Since the anticipated reduction in import permits and registration renewals being processed is negligible relative to the total amount of permits and renewals processed by DEA annually, DEA is not expected to experience a measurable decrease in workflow or use of resources, and therefore, will incur no cost savings. The results of this analysis are summarized below:

Average Annual Import Permit Application (DEA Form 357) Cost Savings	
Estimated hourly wage ($/hour):[7]	$45.54
Load for benefits (percent of labor rate):[8]	*43%*
Loaded labor rate ($/hour):[9]	$65.06
Average hourly burden, per application:	0.25
Average annual # of import permit applications for hemp seed:	88
Average annual hemp seed import permit application labor costs:[10]	$1,431.32
Average annual mailing cost of hemp seed import permit applications:[11]	$1,579.50
Annual Registration Renewal Application (DEA Form 225a) Cost Savings	
Estimated hourly wage ($/hour):[12]	$59.56
Load for benefits (percent of labor rate):[13]	*43%*
Loaded labor rate ($/hour):[14]	$85.09
# of Importers no longer requiring registration:	21
Average hourly burden, per application:[15]	0.12
Average annual registration renewal application labor cost:[16]	$214.43
Total Annual Cost Savings:	$3,225.25

This interim final rule removes FDA-approved products containing CBD from schedule V control, including controls over the importation and exportation of this class of drugs. There is currently only one drug that meets these criteria for decontrol.[17] To determine any cost savings resulting from this decontrol action, DEA analyzed its registration, import, and export data. DEA believes all entities that currently handle FDA-approved CBD products also handle other controlled substances. This means the decontrol of this product will not allow these DEA registrants to benefit from any registration-related cost savings. However, like importers of viable hemp seed, importers and exporters of FDA-approved CBD products will no longer be required to obtain import and export permits from DEA.

DEA analyzed its internal import and export data to identify the average

[3] *See* 21 CFR 1312.11(a), 1312.21(a).

[4] DEA import data is organized by drug code. Hemp seed falls within drug code "7360—Marihuana".

[5] *See* 21 CFR 1301.21(a)(1).

[6] Rounded down to the nearest whole dollar.

[7] Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2018, 11–3071 Transportation, Storage, and Distribution Managers (*http://www.bls.gov/oes/current/oes_nat.htm*). The DEA considers this occupational category to be representative of the type of employee that is likely to fill out and submit import permits on behalf of a DEA registered importer.

[8] Bureau of Labor Statistics, "Employer Costs for Employee Compensation—March 2019" (ECEC) reports that average benefits for private industry is 30% of total compensation. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

[9] $45.54 × (1 + 0.4286) = $65.06.

[10] ($65.06 × 0.25) × 88 = $1,431.32.

[11] 91% of import permits are submitted via paper form and delivered to DEA by an express carrier with respondent-paid means for return delivery. The estimated cost burden is $19.50 per response: 2 × $9.75 = $19.50. $9.75 is based on a major express carrier's national 3-day flat rate for envelopes. The DEA assumes that 91% of import permits submitted in any given year incur this mailing cost.

[12] Estimates are based on the population of the regulated industry participating in these business activities. The DEA assumes that a general and operations manager (11–1021, 2018 Standard Occupational Classification) will complete the form on behalf of the applicant or registrant.

[13] Bureau of Labor Statistics, "Employer Costs for Employee Compensation—March 2019" (ECEC) reports that average benefits for private industry is 30% of total compensation. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

[14] $59.56 × (1 + 0.4286) = $85.09.

[15] The DEA assumes all forms are submitted online.

[16] ($85.09 × 0.5) × 21 = $214.43.

[17] *See* FDA, Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers, *https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#approved.*

number of permits issued for FDA-approved CBD products over a three year period beginning January 1, 2016 and ending December 31, 2018. During this period there was an average of 52 import permits and one export permit issued per year, the elimination of which will result in an average annual cost savings of $1,814.[18] This cost savings is realized entirely by DEA registrants. Since the anticipated reduction in import and export permits being processed is negligible relative to the total number of permits processed by DEA annually, DEA is not expected to experience a measurable decrease in workflow or use of resources, and therefore, will incur no cost savings. The results of this analysis are summarized below:

Average Annual Import Permit Application (DEA Form 357) Cost Savings	
Estimated hourly wage ($/hour):[7]	$45.54
Load for benefits (percent of labor rate):[8]	*43%*
Loaded labor rate ($/hour):[9]	$65.06
Average hourly burden, per application:	0.25
Average annual # of import permit applications for FDA-approved CBD:	52
Average annual FDA-approved CBD import permit application labor costs:[19]	$845.74
Average annual mailing cost for import permit applications:[11 20]	$916.50
Average Annual Export Permit Application (DEA Form 161) Cost Savings	
Estimated hourly wage ($/hour):[7]	$45.54
Load for benefits (percent of labor rate):[8]	*43%*
Loaded labor rate ($/hour):[9]	$65.06
Average hourly burden, per collection:	0.5
Average annual # of export permit applications for FD-approved CBD:	1
Average annual FDA-approved CBD export permit application labor costs:[21]	$32.53
Average annual mailing cost of export permit applications:[11]	$19.50
Total Annual Cost Savings:	$1,814.27

This interim final rule amends the definition of marihuana extract to conform to the revised definitions of marihuana and tetrahydrocannabinols. This revised definition now includes the 0.3%-THC content limit for the extract, meaning hemp-derived extracts containing less than 0.3%-THC content are also decontrolled along with the plant itself. As discussed previously, the production of hemp and its extracts as defined under the AIA now falls under the same regulatory oversight shared between the States, territories, and Indian tribal agencies, and the USDA. The FDA also affirms its regulatory oversight over cannabis-derived compounds, such as CBD, whether or not these compounds are "classified as hemp under the 2018 Farm Bill."[22] For these reasons, DEA considers any potential costs or benefits broadly related to changes in the markets for domestic hemp extracts due to their decontrol, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.

Like FDA-approved CBD products and viable hemp seeds, entities no longer require a DEA registration or import and export permits to handle hemp extract that does not exceed the statutory 0.3% THC limit. DEA's import and export data does capture a minimal number of instances of the importation and exportation of CBD; however, this data does not detail whether or not the CBD was derived from Cannabis sativa L. plants containing less than 0.3% THC content. For this reason, DEA does not have a good basis to estimate the annual number of imported or exported hemp-derived extracts that no longer require permits as a result of the promulgation of this interim final rule, but after reviewing its data, believes this number to be minimal. Therefore, DEA concludes that this provision of the interim final rule is likely to result in a minimal benefit to DEA registrants, but DEA does not have a good basis to quantify this amount.

As part of its core function, DEA's Diversion Control Division is responsible for managing over 1.8 million DEA registrations, processing new and renewal registration applications, processing registration modification requests, issuing certificates of registration, issuing import and export permits, issuing renewal notifications, conducting due diligence, maintaining and operating supporting information systems, etc. Therefore, DEA does not anticipate it will realize any measurable cost savings to the government as a result of the negligible decreases in registrant services resulting from the promulgation of this interim final rule.

As described above, DEA estimates the average annual benefit in the form of cost savings to DEA registrants as a result of the promulgation of this interim final rule to be $5,039.[23] DEA calculated the present value of this cost savings over a 20 year period at a 3 percent and 7 percent discount rate. At a 3 percent discount rate, the present value of benefits is $74,968, while the present value of costs is $0, making the net present value (NPV) $74,968. At a 7 percent discount rate, the present value of benefits is $53,383, the present value of costs is $0, making the NPV is $53,383.[24] The table below summarizes the present value and annualized benefit calculations.

Discount Rate	3%	7%
Annual benefit ($)	5,039	5,039
Present value of benefits ($)	74,968	53,383
Present value of costs ($)	0	0
Years	20	20

[18] Rounded down to the nearest whole number.

[19] ($65.06 × 0.25) × 52 = $845.74.

[20] 52 × .91 = 47 (rounded down) permits mailed per year; 47 × $19.50 = $916.50.

[21] ($65.06 × 0.5) × 1 = $32.53.

[22] Ibid.

[23] The total average annual cost savings resulting from the decontrol of viable hemp seed ($3,225) and FDA-approved CBD products ($1,814).

[24] *See* Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A–4, Regulatory Analysis (2003).

Net present value ($)	74,968	53,383

Figures are rounded.

E.O. 13771 deregulatory actions are final actions that have totals costs less than zero. Also, under E.O. 13771, regulatory actions that expand production options, which are considered to be "enabling rules," generally qualify as E.O. 13771 deregulatory actions. This interim final rule decontrols hemp, hemp extracts and FDA-approved products containing CBD, and it results in cost savings to the public, as discussed above. Accordingly, DEA has determined that this interim final rule is an E.O. 13771 Deregulatory Action.

Executive Order 12988

This interim final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of E.O. 13132.

Executive Order 13175

This interim final rule is required by statute, and will not have tribal implications or impose substantial direct compliance costs on Indian tribal governments.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553). As explained in the interim final rule, DEA determined that there was good cause to exempt this interim final rule from pre-publication notice and comment. Consequently, the RFA does not apply to this interim final rule.

Paperwork Reduction Act of 1995

This interim final rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–21.

Unfunded Mandates Reform Act of 1995

This interim final rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. 2 U.S.C. 1532.

Congressional Review Act

This interim final rule is not a major rule as defined by the Congressional Review Act (CRA) (5 U.S.C. 804). DEA is submitting the required reports with a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1308

Administrative practice and procedure; Drug traffic control; Reporting and recordkeeping requirements.

21 CFR Part 1312

Administrative practice and procedure; Drug traffic control; Exports; Imports; Reporting and recordkeeping requirements.

For the reasons set forth above, 21 CFR parts 1308 and 1312 are amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b).

■ 2. In § 1308.11, paragraphs (d)(31) and (58) are revised to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(31) Tetrahydrocannabinols 7370

(i) Meaning tetrahydrocannabinols, except as in paragraph (d)(31)(ii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

1 cis or trans tetrahydrocannabinol, and their optical isomers

6 cis or trans tetrahydrocannabinol, and their optical isomers

3, 4 cis or trans tetrahydrocannabinol, and its optical isomers

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(ii) Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.

* * * * *

(58) Marihuana Extract 7350

Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3% delta-9-tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.

* * * * *

§ 1308.15 [Amended]

■ 3. In § 1308.15, paragraph (f) is removed.

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

■ 4. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

§ 1312.30 [Amended]

■ 5. In § 1312.30, paragraph (b) is removed and reserved.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–17356 Filed 8–20–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

32 CFR Part 625

[Docket ID: USA–2020–HQ–0010]

RIN 0702–AA98

Surface Transportation—Administrative Vehicle Management

AGENCY: U.S. Army Corps of Engineers, Department of Defense (DoD).

(x) ACTION/DECISION
( ) INFORMATION

Date: September 10, 2020

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

From: Bureau of Healthcare Professionals

Re: Notice of Proposed Regulation Amending R.61-96, *Athletic Trainers*.

I. Introduction

The Bureau of Healthcare Professionals ("Bureau") proposes the attached Notice of Proposed Regulation amending Regulation 61-96, *Athletic Trainers*, for publication in the September 25, 2020, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-75-10 et seq., which requires the Department of Health and Environmental Control ("Department") to develop standards and prescribe regulations for the improvement of athletic training services in the state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. The Bureau proposes amending R.61-96 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to terminology widely used and understood within the provider community, and revise requirements for obtaining certification, inspections and investigations, continuing education, patient care, documentation, and the incorporation of statutory changes allowing for monetary penalties. The proposed amendments also update the structure of the regulation throughout for consistency with other Department regulations.

2. The Department had a Notice of Drafting published in the February 28, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received eighty-one public comments by the March 30, 2020, close of the public comment period. Attachment C presents a summary of the public comments received and Department responses.

3. The Bureau held a stakeholder meeting on March 16, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

4. Appropriate Department staff conducted an internal review of the proposed amendments on July 28, 2020.

5. Department staff received comments on the proposed amendments from the Athletic Trainers' Advisory Committee on July 31, 2020. Attachment D presents a summary of the comments received and Department responses.

III. Request for Approval

The Bureau of Healthcare Professionals respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 25, 2020, *State Register*.

Arnold Alier for
Robert Wronski
Bureau Director
Healthcare Professionals

Gwen C. Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the February 28, 2020, *State Register*
C. Summary of Public Comments Received and Department Responses
D. Summary of Advisory Council Comments Received and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-96, Athletic Trainers

September 10, 2020

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-75-10 et seq.

61-96. Athletic Trainers.

Preamble:

The Department of Health and Environmental Control ("Department" or "DHEC") proposes amending R.61-96 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to terminology widely used and understood within the provider community, and revise requirements for obtaining certification, inspections and investigations, continuing education, patient care, documentation, and the incorporation of statutory change allowing for monetary penalties. The proposed amendments also update the structure of the regulation throughout for consistency with other DHEC Healthcare Quality regulations.

The Department further proposes revisions for clarity, readability, grammar, references, codification, and overall improvement to the text of the regulation. R.61-96 was last amended in 2015.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the February 28, 2020, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

101. Definitions, title amended for consistency with other Department regulations.
101.A. prior A.3.e. recodified to 101.A and amended for clarity.
101.B. prior A.3.b. amended for consistency with other Department regulations.
101.C. prior A.3.f. amended for clarity.
101.D. prior A.3.d recodified for alphabetizing.
101.E. definition for Consultation added for clarity and consistency with other Department regulations.
101.F. definition for Continuing Education added for clarity.
101.G. prior A.3.c recodified for alphabetizing.
101.H. definition of Inspection added for clarity and consistency with other Department regulations.
101.I. definition of Investigation added for clarity and consistency with other Department regulations.
101.J. definition of Patient added for clarity and consistency with other Department regulations.
101.K. definition added for Physically Active Population for clarity.
101.L. prior A.3.g amended for alphabetizing.

102. prior C. recodified and amended for consistency with other Department regulations.
102.A. prior F. recodified and amended for consistency with other Department regulations.

102.B. added for clarity and consistency with other Department regulations.
102.C. prior C.2.d. recodified and amended for clarity and consistency with other Department regulations.
102.D. added for clarity and consistency with other Department regulations.
102.E. prior D. recodified and amended for clarity and consistency with other Department regulations.
102.F. prior C.4. recodified and amended for clarity and consistency with other Department regulations.
103. section added allowing Athletic Trainers in military to request a temporary hold on his or her certification during deployment.
104. prior E. recodified and amended for clarity.
105. prior G. recodified and amended to reflect statutory requirements.
106. prior H. recodified and amended for clarity.
107. added for consistency with other Department regulations.

200. Enforcing Regulations, added for consistency with other Department regulations and to clarify the Department's enforcing regulations.
201. added for consistency with other Department regulations.
202. added for consistency with other Department regulations.
203. added for consistency with other Department regulations.

300. Enforcement Actions, prior K. recodified and amended for clarity and consistency with other Department regulations.
301. added for clarity and consistency with other Department regulations.
302. added for clarity and consistency with other Department regulations.
303. prior K.1. recodified and amended for clarity.

400. Advisory Committee, prior L. recodified and amended for clarity and to reflect current statutory requirements.

500. Continuing Education, prior J. recodified for consistency with other Department regulations and amended for clarity.

600. Reserved, added and reserved to align regulation sections with other Department regulations.

700. Patient Care and Records, prior B. recodified and amended for clarity regarding patient care and records section. Section title added for consistency with other Department regulations.

800 – 2600. Reserved, added and reserved to align regulation sections with other Department regulations.

2700. Severability, added for consistency with other Department regulations.

2800. General, added for consistency with other Department regulations.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Healthcare Quality; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HealthRegComm@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 26, 2020, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 10, 2020, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their

statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agenda.

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

Preliminary Fiscal Impact Statement

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness

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

DESCRIPTION OF REGULATION: 61-96, Athletic Trainers

Purpose: The Department proposes amending R.61-96 to update provisions in accordance with current practices and standards. The Department further proposes revisions for clarity and readability, grammar, references, codification, and overall improvement to the text of the regulation. The proposed amendments incorporate and revise provisions relating to statutory mandates.

.

Legal Authority: 1976 Code Sections 44-75-10 et seq.

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

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

The proposed amendments are necessary to update provisions in accordance with current practices and standards. The amendments include updated language for Athletic Trainers applying for certification and incorporate provisions delineating requirements in continuing education, documentation, and the incorporation of statutory change allowing for monetary penalties. The amendments revise and incorporate requirements regarding Department inspections and investigations, maintenance of accurate and current contact information, and other requirements for licensure. The proposed amendments also update the structure of the regulation throughout for consistency with other Department regulations.

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. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments to R.61-96 seek to support the Department's goals relating to the protection of public health through implementing updated requirements for Athletic Trainers. There are no anticipated effects on the environment.

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

There is no anticipated detrimental effect on the environment. If the proposed amendments are not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

Statement of Rationale:

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

The Department of Health and Environmental Control proposes amending R.61-96. These amendments are necessary to update provisions in accordance with current practices and standards. The amendments include updated language for Athletic Trainers applying for certification and incorporate provisions delineating new requirements for continuing education, patient care, and documentation requirements, and the incorporation of statutory change allowing for monetary penalties. The amendments revise and incorporate requirements regarding Department inspections and investigations, maintenance of accurate and current contact information, and other requirements for licensure.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-96. Athletic Trainers.

Statutory Authority: S.C. Code Sections 44-75-10 et seq.~~, S.C. Code of Laws, 1976, as amended~~

~~Contents:~~

~~61-96.A. Purpose, Administration and Definitions.~~
~~61-96.B. Description of the Profession.~~
~~61-96.C. Certification.~~
~~61-96.D. Fees.~~
~~61-96.E. Reciprocity.~~
~~61-96.F. Exemption from Certification.~~
~~61-96.G. Grandfather Provision.~~

~~61-96.H. Change of Name and Address.~~
~~61-96.I. Professional Identification.~~
~~61-96.J. Continuing Education.~~
~~61-96.K. Revocation, Suspension and Denial of Certification; Penalties; Appeals Process.~~
~~61-96.L. Athletic Trainers Advisory Committee.~~
~~61-96.M. Responsibilities of the Department.~~

TABLE OF CONTENTS

SECTION 1600 – [RESERVED]

SECTION 1700 – [RESERVED]

SECTION 1800 – [RESERVED]

SECTION 1900 – [RESERVED]

SECTION 2000 – [RESERVED]

SECTION 2100 – [RESERVED]

SECTION 2200 – [RESERVED]

SECTION 2300 – [RESERVED]

SECTION 2400 – [RESERVED]

SECTION 2500 – [RESERVED]

SECTION 2600 – [RESERVED]

SECTION 2700 – SEVERABILITY

SECTION 2800 – GENERAL

SECTION 100 – DEFINITIONS AND CERTIFICATION

~~A. Purpose, Administration and Definitions.~~

~~1. Purpose: The purpose of this regulation is to assure the highest degree of professional conduct by those engaged in offering athletic train services to the public and to safeguard the public's health, safety, and welfare by establishing minimum qualifications for those individuals wishing to offer athletic trainer services to the public.~~

~~2. Administration: All regulations pertaining to the administration of the "Athletic Trainers' Act of South Carolina", Sections 44-75-10 et seq., S.C. Code of Laws, 1976, as amended, shall be administered by the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina.~~

~~3~~**101. Definitions**~~: For the purpose of these Standards, the following definitions shall apply:~~**.**

~~a. "Law" as used in these rules shall mean the "Athletic Trainers' Act of South Carolina", Sections 44-75-10 et seq., S.C. Code of Laws, 1976, as amended.~~

A. Athletic Trainer. An allied healthcare professional with specific qualifications as set forth in South Carolina Code Section 44-75-50 who, upon the advice and consent of a licensed Physician, carries out the practice of care, prevention, and physical rehabilitation of athletic injuries and who, in carrying out these functions, may use physical modalities including, but not limited to, heat, light, sound, cold, electricity, or mechanical devices related to rehabilitation and treatment.

~~b~~B. ~~"Board"~~Board. ~~shall mean the~~The South Carolina Board of ~~the South Carolina Department of~~ Health and Environmental Control.

~~c. "Department" means the South Carolina Department of Health and Environmental Control.~~

~~d. "Committee" shall mean the South Carolina Athletic Trainers' Advisory Committee.~~

~~e. "Athletic Trainer" means a person with specific qualifications as set forth in Section 44-75-50 of the Law who, upon the advice and consent of a licensed physician, carries out the practice of care, prevention, and physical rehabilitation of athletic injuries, and who, in carrying out these functions, may use physical modalities, including, but not limited to, heat, light, sound, cold, electricity, or mechanical devices related to rehabilitation and treatment.~~

~~f~~C. ~~"Certificate"~~Certificate. ~~means o~~Official acknowledgement by the Department that an individual has successfully completed the education and other requirements ~~referred to in the "Athletic Trainers' Act of South Carolina",~~ in accordance with South Carolina Code Sections 44-75-10 et seq. and this regulation, which entitle~~s~~ that individual to perform the functions and duties of an ~~athletic trainer~~Athletic Trainer.

D. Committee. The South Carolina Athletic Trainers' Advisory Committee.

E. Consultation. A meeting with Department representatives who will provide information to the Certificate holder with the goal of facilitating compliance with this regulation.

F. Continuing Education. Education beyond the basic preparation required for entry into the profession that is directly related to the performance and practice of the Athletic Trainer.

G. Department. The South Carolina Department of Health and Environmental Control.

H. Inspection. A visit, in-person meeting, or review of materials by Department representatives for the purpose of determining compliance with this regulation.

I. Investigation. A visit, in-person meeting, or review of materials by Department representatives for the purpose of determining the validity of allegations received by the Department relating to statutory and regulatory compliance.

~~g. "Licensed Physician" means a physician licensed by the South Carolina State Board of Medical Examiners.~~

J. Patient. A person who receives care, treatment, or services from an Athletic Trainer certified by the Department.

K. Physically Active Population. Any individual, entity, group, or organization who participates in an athletic activity, a job function, or a job-related activity that requires physical strength, range of motion, flexibility, control, speed, stamina, or agility.

L. Physician. An individual currently licensed to practice medicine by the South Carolina Board of Medical Examiners.

M. Variance. An alternative method that ensures the equivalent level of compliance with the standards in this regulation.

~~h. "Employment of Athletic Trainer" shall mean a person who is engaged as an athletic trainer if the person is employed on a salary or contractual basis by an educational institution, a hospital, rehabilitation clinic, professional organization, or other bona fide athletic organization and performs the duties of an athletic trainer as a major responsibility of this employment.~~

~~i. "Advice and Consent of a Licensed Physician" shall mean the general written or oral standing orders and/or protocol signed by a licensed physician.~~

~~B. Description of the Profession.~~

~~An athletic trainer is an individua who has successfully completed the college or university undergraduate degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., in association with the National Athletic Trainers' Association (NATA), and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards. The seven domains/standards of athletic training from which these specific tasks are measured in the examination are:~~

~~1. Direction: The athletic trainer renders services or treatment under the advice and consent of a licensed physician.~~

~~2. Prevention: The athletic trainer understands and uses preventative measures to assure the highest quality of care for every patient.~~

~~3. Immediate Care: The athletic trainer provides standard and immediate care procedures used in emergency situations, independent of setting.~~

~~4. Clinical Evaluation and Diagnosis: Prior to treatment the athletic trainer assesses the patient's level of function. The patient's input is considered as an integral part of the initial assessment. The athletic trainer follows the standards of clinical practice in an area of diagnostic reasoning and medical decision making.~~

~~5. Treatment Rehabilitation and Re-Conditioning: The athletic trainer develops the treatment program and determines the appropriate treatment, rehabilitation and/or reconditioning strategies. The treatment program objectives include long and short term goals and appraisal of those that the patient can realistically be expected to achieve from the program. This assessment measure determines effectiveness of the program and is incorporated into the program.~~

~~6. Program Discontinuation: The athletic trainer, in collaboration with the licensed physician, recommends discontinuation of athletic training services when the patient has received optimal benefit of the program. The athletic trainer, at the time of discontinuation, notes the final assessment of the patient's status.~~

~~7. Organization and Administration: All services are documented in writing by the athletic trainer and are part of the patient's permanent records. The athletic trainer accepts responsibility of recording details of the patient's health care status.~~

~~C~~**102. Certification**.

1. Requirements: A person who seeks certification as an athletic trainer in the State of South Carolina must successfully complete the Athletic Trainer Certification Examination as administered by the Board of Certification, Inc., and satisfy the following requirements:

a. Meets the athletic training curriculum requirements of a college or university; and

b. Submits a certified transcript from the college or university along with the completed application.

2. Applications:

a. Each candidate for certification must file a written application on a form furnished upon request from the Department. The application must be completed in its entirety and must include all relative documents and fees.

b. An application must be completed by the applicant and reviewed by the Department within ninety (90) days of the date that the first document has been received by the Department. Any application not completed within this period will become void. Any consideration of certification after this date will require the applicant to submit a new application, new documents and appropriate fees. The applicant will be notified in writing of approval or denial of request for certification.

c. Once an application is reviewed by the Department, no refund of the application fee shall be issued.

d. Certification will remain current for two (2) years from the issue date.

3. Examination: The applicant must pass the Athletic Trainer Certification Examination as administered by the Board of Certification, Inc., in association with the National Athletic Trainers' Association before a certificate for South Carolina certification can be issued from the Department.

4. Renewal: With renewal being every two (2) years, the Department shall send a renewal application form, sixty (60) days prior to the renewal date, to the last address registered with the Department in the South Carolina Credentialing Information System (CIS), to the person to whom the certification was issued or renewed during the preceding renewal period. The athletic trainer shall then:

a. Complete the renewal application form;

b. Submit proof of continuing education credit as detailed in Section J, Continuing Education;

c. Enclose the renewal fee; and

d. File the above with the Department prior to the renewal date.

5. Failure to Renew: An athletic trainer who does not file with the Department his or her renewal application by the renewal date will be deemed to have allowed his or her certification to expire. Such certification may be reinstated by the Department, at its discretion, by the payment of an additional late renewal fee, provided the application is made within six (6) months of the renewal date. After six (6) months, an additional restoration fee will be charged to those individuals who wish to restore certification.

6. Reinstatement: A certificate which is revoked for failure to renew may be reinstated at the direction of the Department and the Committee within two (2) years of its expiration date. Any consideration for recertification will necessitate submission of a new application and will require the applicant to meet the then existing requirements.

~~D. Fees.~~

~~To be certified, athletic trainers practicing in the State of South Carolina must pay the fees according to the fee schedule listed below unless otherwise exempted by law. Appropriate fees must be made payable by credit card, check or money order to the South Carolina Department of Health and Environmental Control.~~

~~1. Fees:~~

~~(a) Application Fee: The application fee shall be fifty dollars ($50) due upon receipt of the application.~~

~~(b) Examination Fee: The examination fee will be the current examination fee of the Board of Certification, Inc. (BOC) in association with the National Athletic Trainers' Association. This fee is in addition to the application fee.~~

~~(c) Re-Examination Fee: The re-examination fee shall be the current BOC in association with the National Athletic Trainers' Association re-examination fee.~~

~~(d) Biennial Renewal Fee: The biennial renewal fee shall be forty dollars ($40) due on the anniversary date of the second year after the applicant is certified. Renewal fees will be due on the anniversary date every two years after that.~~

~~(e) Late Renewal Fees: An additional fifteen ($15) late renewal fee for a total of fifty-five ($55) will be charged to those individuals who renew with a six (6) month period after the biennial renewal date.~~

~~(f) Restoration Fee: An additional one-hundred ($100) restoration fee for a total of one-hundred forty dollars ($140) will be charged to those individuals who fail to renew within the six (6) month late renewal schedule.~~

~~2. Other Fees:~~
~~Duplicate Certificate and ID Certificate Card: Seven dollars ($7).~~
A. Certification.

1. No person may hold himself or herself out as an Athletic Trainer or perform for compensation any activities of an Athletic Trainer as defined in South Carolina Code Section 44-75-20 without first obtaining a Certificate from the Department. When it has been determined by the Department that an individual is engaged as an Athletic Trainer and the individual has not been issued a Certificate from the Department, the individual shall cease engaging as an Athletic Trainer immediately. Current and/or previous violation(s) of the South Carolina Code of Laws or Department regulations may jeopardize the issuance of an Athletic Trainer Certificate. (I)

2. A person is engaged as an Athletic Trainer if the person is employed on a salary or contractual basis by an educational institution, a hospital, a rehabilitation clinic, a Physician's office, an industry, a performing arts group, a professional athletic organization, the military, a governmental agency, or other bona fide organization which employs or serves a Physically Active Population and performs the duties of an Athletic Trainer as a major responsibility of this employment.

3. A person certified by the Department to practice and perform as an Athletic Trainer may use the title "State Certified Athletic Trainer" and/or the abbreviations "S.C.A.T." and "SCAT."

B. Issuance and Terms of Certification.

1. The Athletic Trainer Certificate is issued pursuant to South Carolina Code Sections 44-75-10 et seq. and this regulation. The issuance of a Certificate does not guarantee adequacy of individual care, treatment, personal safety, or well-being of any Patient.

2. The Athletic Trainer Certificate is not assignable or transferable and shall be subject to denial, suspension, or revocation by the Department for failure to comply with the South Carolina Code of Laws and this regulation.

3. The Athletic Trainer Certificate shall be effective for a twenty-four (24) month period following the date of issue by the Department.

4. The Athletic Trainer shall carry the identification Certificate card issued by the Department while performing his or her duties and present the identification Certificate card when requested.

C. Initial Application. Applicants for an initial Athletic Trainer Certificate shall submit to the Department a completed application on a form prescribed, prepared, and furnished by the Department prior to issuance of an initial Certificate. The applicant shall submit, along with the application, documentation that he or she has successfully passed the Athletic Trainer certification exam as administered by the Board of Certification, Inc. or its successors or assigns.

D. Certification Fees. The applicant shall pay a certification fee of fifty dollars ($50.00) prior to issuance of an initial Certificate. The applicant shall pay a biennial certification renewal fee of forty dollars ($40.00) prior to renewal of the certification. The renewal late fee shall be fifteen dollars ($15.00). The Athletic Trainer shall pay one hundred dollars ($100.00) to restore his or her certification. The Athletic Trainer shall pay seven dollars ($7.00) for duplicate Certificates and identification Certificate cards. All fees shall be non-refundable. Athletic Trainers and Athletic Trainer applicants shall submit payment of certification fees with each application to the Department by check, money order, or other means as determined by the Department. (II)

E. Certification Renewal. To renew his or her certification, the Athletic Trainer shall submit a complete and accurate biennial renewal application on a form prescribed and furnished by the Department, shall pay the biennial renewal fee, and shall not have pending enforcement actions by the Department.

1. The Athletic Trainer shall submit the following with the biennial renewal application:

a. Proof of Continuing Education pursuant to Section 500; and

b. Proof of current certification by the Board of Certification, Inc., or its successors or assigns unless the individual is subject to the grandfather provisions of Section 105.

2. The Athletic Trainer who fails to submit his or her renewal application and biennial renewal fee by his or her certification expiration date shall be deemed to have an expired Certification.

3. The Athletic Trainer who submits his or her renewal application, biennial renewal fee, and renewal late fee within three (3) months after his or her certification expired may be reinstated at the Department's discretion. The Athletic Trainer who submits his or her renewal application, biennial renewal fee, and certification restoration fee more than three (3) months after his or her certification expired may be restored at the Department's discretion.

103. Temporary Certification Hold.

The Athletic Trainer who is active duty military service member or spouse may request a temporary hold on his or her certification while actively deployed outside of South Carolina. The Athletic Trainer requesting a temporary certification hold shall submit a written request in a format as determined by the Department including the effective dates of deployment. The Athletic Trainer granted a temporary certification hold shall notify the Department upon return from active duty in a manner determined by the Department.

~~E~~**104. Reciprocity**. (II)

Certification by Reciprocity.~~: A certificate may be issued by the Department to any qualified athletic trainer holding certification in any other state if such other state recognizes the certificate of South Carolina in the same manner. The applicant must meet the following requirements for reciprocal certification~~ Applicants for reciprocal certification shall submit to the Department a completed application, on a form prescribed, prepared, and furnished by the Department prior to certification by reciprocity. Athletic Trainers from other states or territories performing athletic training duties for collegiate and professional organizations or individuals participating in events, camps, tournaments, and other short-term activities shall apply for reciprocal certification. The applicant for reciprocity shall submit documentation with the reciprocity application that he or she is currently credentialed as an Athletic Trainer under the laws of another state or territory. (II)

~~1. The applicant is currently certified to practice athletic training under the laws of another state or territory.~~

~~2. The requirements for said certification are equivalent to those required in South Carolina.~~

~~3. The applicant's certificate has not been, and is not presently, suspended or revoked.~~

~~F. Exemption from Certification.~~

~~No person shall represent him or herself as an athletic trainer unless he or she is certified by the Department, except as otherwise provided in this section. Exemptions apply as follows:~~

~~1. Licensed, registered, or certified professionals such as licensed physicians, nurses, physical therapists, and chiropractors practicing their professions are exempt if they do not assert to the public by any title or description as being athletic trainers.~~

~~2. A person rendering services that are the same as or similar to those within the scope of practice provided for in the Law is exempt as long as he or she is otherwise now employed or employed in the future as a faculty or staff member at the school in question and does not represent him or herself to be an athletic trainer.~~

~~3. Persons employed prior to June 19, 1984 by the State Department of Education, local boards of education, or private secondary or elementary schools for the treatment of injuries received by students participating in school sports activities are exempt.~~

~~4. An person serving as a student-trainer or in any similar position if the service is carried out under the supervision of a licensed physician or certified athletic trainer is exempt.~~

~~G~~**105. Grandfather Provision.**

The Department may issue a ~~c~~Certificate to an applicant who was actively engaged as an ~~a~~Athletic ~~t~~Trainer for a two (2) -year period from June 19, 1979 to June 19, 1984. The applicant shall submit the following for documentation:

~~1~~A. ~~A notarized record~~Verification of employment history in a manner as determined by the Department of being employed on a salaried basis with an educational institute or bona fide athletic organization for the duration of the institution's school year, or the length of the athletic organization's season and performed the duties of an ~~a~~Athletic ~~t~~Trainer as the major responsibility of his or her employment~~.~~;

~~2~~B. A certified oath verifying that the documents submitted to the Department are "true and accurate"~~.~~; and

~~3~~C. Payment of ~~an application~~the initial certification fee ~~as prescribed by the Department~~.

~~H~~**106**. **Change of Name ~~and~~or Address.**

~~1~~A. Change of Name~~:~~. ~~A~~ The Athletic Trainer shall request ~~for~~ a change of name from that under which the original ~~c~~Certificate was issued ~~shall be accompanied~~ by submitting to the Department a certified copy of a marriage certificate, court order, or documentation of legal name change and ~~appropriate~~ payment of the duplicate Certificate fee. ~~See fee schedule.~~

~~2~~B. Change of Address~~:~~. ~~Each person who has a certificate shall keep the Department apprised in writing of any change in his or her current name and address his or her contact information in CIS current at all times.~~The Athletic Trainer shall ensure current information, including name, address, contact information, and other required information by the Department, is maintained in the Department's credentialing information system and submit any changes to the Department within forty-five (45) calendar days of the change.

~~**I. Professional Identification.**~~

~~1. Titles and Abbreviations: A person certified by the Department to practice and perform athletic training in South Carolina may use the title, "State Certified Athletic Trainer and/or the abbreviation S.C.A.T.".~~

~~2. Production and Display of Certificate: A person certified by the Department to practice and perform athletic training in South Carolina shall carry said original card at all times, and show said original card when requested.~~

107. Variance.

The Athletic Trainer may request a Variance to this regulation in a format as determined by the Department. Variances shall be considered on a case-by-case basis by the Department. The Department may revoke issued Variances as it determines appropriate.

SECTION 200 – ENFORCING REGULATIONS

201. General.

The Department shall utilize Inspections, Investigations, Consultations, and other pertinent documentation regarding an Athletic Trainer to enforce this regulation.

202. Inspections and Investigations.

A. The Department may conduct Inspections and Investigations as deemed appropriate by the Department.

B. Athletic Trainers shall be subject to Inspections and Investigations at any time without prior notice by individuals authorized by the Department.

C. The Athletic Trainer shall grant the Department access to all properties and areas, objects, equipment, records, and documentation. The Athletic Trainer shall provide the Department all requested records and documentation in the manner and within the timeframe specified by the Department. The Athletic Trainer shall provide photos and/or electronic copies of documents requested by the Department in the course of Inspections and Investigations. These copies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (I)

D. When there is noncompliance with this regulation, the Athletic Trainer shall submit an acceptable plan of correction in a format determined by the Department. The plan of correction shall be signed by the Athletic Trainer and returned by the date specified by the Department. The plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

203. Consultations.

The Department may provide Consultations as requested by the Athletic Trainer or as deemed appropriate by the Department.

SECTON 300 – ENFORCEMENT ACTIONS

301. General.

A. The Department may suspend or revoke a Certificate at any time it is determined that the Certificate holder no longer meets the prescribed qualifications set forth by the Department or has failed to provide athletic training services of a quality acceptable by the Department.

B. When the Department determines that an Athletic Trainer is in violation of any statutory provision or regulation relating to the duties therein, the Department may, upon proper notice to the individual, impose a monetary penalty, deny, suspend, and/or revoke his or her certification, or authorization or take other actions deemed appropriate by the Department.

302. Violation Classifications.

A. Violations of standards in this regulation are classified as follows:

1. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons being served, other employees, or the general public; or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be a subsequent violation.

2. Class II violations are those that are not classified as Class I or Class III violations the Department determines to have a negative impact on the health, safety, or well-being of those being served, other employees, or the general public. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be a subsequent violation.

3. Class III violations are those that are not classified as Class I or II in this regulation or those that are against the best practices as interpreted by the Department. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be a subsequent violation.

B. The notations "(I)" or "(II)" placed within sections of this regulation indicate those standards are considered Class I or II violations if they are not met respectively. Failure to meet standards not so annotated are Class III violations.

C. Monetary Penalties. When the Department imposes a monetary penalty, the following schedule shall be used as a guide to determine the dollar amount:

FREQUENCY OF VIOLATION	CLASS I	CLASS II	CLASS III
1st	$300-500	$100-300	$50-100
2nd	500-1,500	300-500	100-300
3rd	1,500-5,000	500-1,500	300-800
4th or more	10,000	1,500-5,000	800-1,500

303. Standards of Conduct. (I)

The Department may deny, suspend, or revoke an Athletic Trainer's Certificate and impose a monetary penalty against an Athletic Trainer for the following:

A. Used a false, fraudulent, or forged statement or document or practiced a fraudulent, deceitful, or dishonest act in connection with any of the certification requirements or official documents required by the Department;

B. Convicted of a felony or another crime involving moral turpitude, drugs, or gross immorality;

C. Addicted to alcohol or drugs to such a degree as to render the Certificate holder unfit to perform as an Athletic Trainer;

D. Sustained a physical or mental disability that renders further practice dangerous to the public;

E. Obtained fees or assisted in the obtaining of such fees under dishonorable, false, or fraudulent circumstances;

F. Disregarded an order by a Physician concerning care or treatment;

G. Refused to administer care or treatment on the grounds of the age, gender, race, religion, creed or national origin of the Patient;

H. After initiating care of a Patient, discontinued such care or abandoned the Patient without the Patient's consent or without providing for the further administration of care by an equal or higher medical authority;

I. Revealed confidences entrusted to him or her in the course of medical attendance, unless such revelation is required by law or is necessary in order to protect the welfare of the Patient or the community;

J. By action or omission, and without mitigating circumstance, contributed to or furthered the injury or illness of an Patient under the care of the Athletic Trainer;

K. Performed skills above the level for which the Athletic Trainer is certified or performed skills for which he or she has no training to perform;

L. Observed the administration of substandard care by another Athletic Trainer or other healthcare provider without documenting the event and notifying a supervisor or Physician;

M. By his or her actions, or inactions, created a substantial possibility that death or serious physical harm could result; or

N. Falsified any documentation as required by the Department.

SECTION 400 – ATHLETIC TRAINERS' ADVISORY COMMITTEE

A. Organization. The South Carolina Athletic Trainers' Advisory Committee shall consist of nine (9) members appointed by the Board. The terms of the Committee members are for four (4) years or until successors are appointed. The Committee members appointed by the Board shall consist of the following:

1. Two (2) members shall be representatives from the Department;

2. One (1) member shall be from the State Board of Medical Examiners;

3. Four (4) members shall be Athletic Trainers certified by the Department; and

4. Two (2) members shall be from the general public, not certified or licensed in any healthcare field, and not in any way associated with Athletic Trainers.

B. Meetings. The Committee shall meet at least once a year to review the standards and regulations for improving athletic training services and make recommendations to the Department.

~~J. Continuing Education.~~

SECTION 500 – CONTINUING EDUCATION

~~1. Definition and Philosophy: Each individual certified as an athletic trainer is responsible for service to the consumer and is accountable to the consumer, the employer, and the profession for evidence of maintaining high levels of skill and knowledge. Continuing education is defined as education beyond the basic preparation required for entry into the profession, directly related to the performance and practice of athletic training.~~

2. Requirements: Regulations set the requirement for attending and completing twoAthletic Trainers shall complete the following Continuing Education courses during the two (2) year certification period. These courses are as follows:

a. A course in cardiopulmonary resuscitation (CPR) offered by the American Red Cross or the American Heart Association or any other cardiopulmonary resuscitation (CPR) course approved by the South Carolina Athletic Trainers' Advisory Committee (SCATAC) the Department.; and

bB. A designated professional seminar offered yearly by the SCATA at the Association's annual conference. Two (2) Continuing Education courses approved by the Department in consultation with the Athletic Trainers' Advisory Committee.

c . A seminar shall mean two (2) designated courses within the scope of that year's annual meeting or conference.

d. The development of the course content and the monitoring of the courses will be under the supervision of the Committee.

e. At the completion of the appropriate courses during the seminar, a card will be issued to the athletic trainer by a member of the Committee.

f. Equivalent courses may be approved by the Committee.

g. The Committee will set the continuing education standards on an annual basis.

3. Reporting Procedures for Continuing Education: It is the responsibility of the athletic trainer to submit to the Department, by the renewal date of certification, proof of the completion of the continuing education requirements. Documentation shall include:

a. A photocopy of a current CPR card from either the American Red Cross or the American Heart Association or any other CPR course approved by SCATAC; and

b. A photocopy of the SCATA professional seminar card, signed by a member of the committee.

4. Enforcement: Without documentation of the required continuing education, as outlined in J.2 and J.3 above, an athletic trainer's certification will not be renewed at the two-year renewal date. Documentation for the continuing education units must be current at the time of renewal.

5. Appeals: If the athletic trainer is unable to obtain the proper continuing education units by the time of renewal, he/she may submit a letter of appeal with the renewal application. This letter must document the reason(s) the athletic trainer was unable to obtain the necessary continuing education units. The Committee will recommend the course of action to be taken.

K. Revocation, Suspension and Denial of Certification; Penalties; Appeals Process.

1. Standards of Conduct: At the discretion of the Department, athletic trainers may have their certificates suspended or revoked at any time the Department determines that the holder of the certificate no longer meets the prescribed qualifications set forth by the Department or has committed any of the following acts:

a. Has engaged in any conduct considered by the Board or Department to be detrimental to the profession of athletic training;

b. Has used fraud or deceit in procuring or, attempting to procure, a certificate or renewal of a certificate to practice athletic training;

c. Has violated, aided, or abetted others in violation of any provision of the law, or these regulations;

d. Has practiced athletic training without a valid certificate.

2. Penalties:

Any person violating the provisions of Sections 44-75-10 et seq. is guilty of a misdemeanor and upon conviction must be punished by a fine of not less than twenty-five ($25) nor more than two hundred dollars ($200).

3. Actions: The Committee may recommend revocation or suspension of a certificate. Revocation may be for a period up to two years.

4. Appeals Process: Decisions to deny, suspend or revoke an athletic trainer's certification becomes the final agency decision fifteen (15) days after notice of the Department decision has been mailed to the applicant or holder of the certificate by certified mail, return receipt requested, unless a written request for final review is filed with the DHEC Board by the applicant or holder of the certificate pursuant to Section 44-1-60 of the S.C. Code of Laws, 1976, as amended, and applicable law.

L. Athletic Trainers' Advisory Committee.

1. Organization: The South Carolina Athletic Trainers' Advisory Committee shall consist of nine members appointed by the Board. Two members must be from the Department, one must be from the State Board of Medical Examiners, four must be certified athletic trainers and two must be from the general public who are not certified or licensed in any health care fields and are not in any way associated with athletic trainers.

2. Officers: The Advisory Committee shall annually elect a chairman and vice-chairman from its membership. These two officers shall have all the privileges of re-election.

3. Meetings: The Committee must meet at least once a year. Additional meetings may be held on call of the chairman or at the written request of two Committee members. A record must be kept of all transactions which have been called for by the chairman and a written report shall be submitted for the minutes at the next regularly scheduled meeting. A quorum of two thirds of the Committee membership is required for any meeting of the Committee.

M. Responsibilities of the Department.

The South Carolina Department of Health and Environmental Control, with the advice of the Committee, shall:

1. Coordinate with the Committee chairman to develop and distribute an agenda for committee meetings.

2. Post public notices of upcoming Committee meetings per the Freedom of Information Act and notify the media of the meetings. The following statement shall be read by the chairman of the Committee at the

~~beginning of each public meeting: "Let the minutes reflect that, as required by the provisions of the South Carolina Freedom of Information Act, Section 30-4-80(E) of the S.C. Code of Laws, 1976, as amended, notification of this meeting has been given to all persons, organizations, local news media and other news media which have requested such notification".~~

~~3. Assure that the Committee's address and telephone number is listed in the state telephone directory.~~

~~4. Take Committee meeting minutes, type, and send to the chairman for signature within two weeks after the meeting. The Department will distribute the minutes to committee members within one week after receiving a signature from the chairman.~~

~~5. Receive applications for athletic trainer certification and process for routine action. Unusual applications will be brought before the full Committee. If there is a problem, or if the Department needs additional information, the applicant is notified in writing of the delay by the Department.~~

~~6. Collect application fees, certification renewal fees, and other fees deemed necessary for the certification program. These fees are non-refundable to the applicant.~~

~~7. Maintain a record of each athletic trainer's certification expiration date.~~

~~8. Work with the Committee chairman to develop a formal budget for the Committee.~~

~~9. Develop and maintain an inquiry log to track all correspondence related to the athletic trainer's certification program and record all complaints.~~

~~10. Develop and update a rules and regulations manual for the certification program.~~

~~11. Investigate violations and complaints and follow-up with proper legal procedures.~~

SECTION 600 – [RESERVED]

SECTION 700 – PATIENT CARE AND RECORDS. (II)

A. The Athletic Trainer shall render services and treatment under the advice and consent of a licensed Physician including general written or oral standing orders and/or protocols signed by a licensed Physician. (I)

B. The Athletic Trainer shall be responsible for recording details of the Patient's health care status. The Athletic Trainer shall maintain an organized permanent record for each Patient that contains written documentation of all care, treatment, and services provided to the Patient including:

1. Preventative Care. The Athletic Trainer shall use preventative measures to assure the highest quality of care for every Patient.

2. Immediate Care. The Athletic Trainer shall provide standard and immediate care procedures used in emergency situations, independent of setting.

3. Clinical Evaluation and Diagnosis. The Athletic Trainer shall assess the Patient's level of function prior to treatment. The Athletic Trainer shall consider the Patient's input as an integral part of the initial assessment. The Athletic Trainer shall follow the standards of clinical practice in the areas of diagnostic reasoning and medical decision making.

4. Treatment, Rehabilitation, and Re-Conditioning. The Athletic Trainer shall develop the treatment program and determine the appropriate treatment, rehabilitation, and/or reconditioning strategies. The Athletic Trainer shall ensure the treatment program objectives include long-term and short-term goals and appraisal of those that the Patient can realistically be expected to achieve from the treatment program. The Athletic Trainer shall incorporate and utilize the assessment measure to determine the effectiveness of the treatment program.

C. Program Discontinuation. The Athletic Trainer, with advice and consent of a licensed Physician, shall recommend discontinuation of athletic training services when the Patient has received optimal benefit of the treatment program. The Athletic Trainer shall document and maintain documentation of the final assessment of the Patient's status and the date the Patient was discontinued from the treatment program.

SECTION 800 – [RESERVED]

SECTION 900 – [RESERVED]

SECTION 1000 – [RESERVED]

SECTION 1100 – [RESERVED]

SECTION 1200 – [RESERVED]

SECTION 1300 – [RESERVED]

SECTION 1400 – [RESERVED]

SECTION 1500 – [RESERVED]

SECTION 1600 – [RESERVED]

SECTION 1700 – [RESERVED]

SECTION 1800 – [RESERVED]

SECTION 1900 – [RESERVED]

SECTION 2000 – [RESERVED]

SECTION 2100 – [RESERVED]

SECTION 2200 – [RESERVED]

SECTION 2300 – [RESERVED]

SECTION 2400 – [RESERVED]

SECTION 2500 – [RESERVED]

SECTION 2600 – [RESERVED]

SECTION 2700 – SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of this regulation.

SECTION 2800 – GENERAL

Conditions that have not been addressed in this regulation shall be managed in accordance with the best practices as interpreted by the Department.

ATTACHMENT B

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-96, Athletic Trainers. Interested persons may submit comment(s) on the proposed amendments to the Bureau of EMS and Trauma; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; healthregcomm@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on March 30, 2020, the close of the draft comment period.

Synopsis:

Pursuant to R.61-96, Athletic Trainers, the Department is the central authority that shall establish and regulate minimum qualifications for those individuals wishing to offer athletic trainer services to the public. The Department proposes amending R.61-96 to update and revise definitions and requirements regarding obtaining licensure, inspections, personnel, training, record maintenance and retention, the incorporation of statutory changes allowing for monetary penalties, and licensure standards. The Department may add language to incorporate current provider-wide exceptions to athletic training services.

The Department may also include stylistic changes, which may include corrections for clarity, readability, grammar, punctuation, codification, and overall improvement of the text.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-96, Athletic Trainers

As of the March 30, 2020, close of the Notice of Drafting comment period:

NAME	SECTION	DEPARTMENT RESPONSE
1. Danny Poole, Director of Sports Medicine, Clemson University	General	**Not Adopted.** The department is not increasing fees at this time.
I feel like there needs to be a fee increase. We have not had an increase since the bill was submitted in the 80s. We have gone from 20 members then to over a thousand. Thank you allowing me to make a comment		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
2. Fred Hoover, AT, Retired SCATA, Clemson University	General	**Not Adopted.** The department is not increasing fees at this time.
I am in favor of this bill as written and passed. I am in favor of increasing the fees due to the fact that there has not been an increase since 1986.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
3. Gary Nelson MA, ATC, SCAT, Athletic Trainer, Sumter High School	General	**Not Adopted.** The department is not increasing fees at this time. Changing the term to "licensure" would require statutory change.
I feel there may be a need to have an increase in fees to accommodate the future needs of the organization. I'm adamantly not in favor of the leadership of SCATA to try to leave DHEC in order to just add "Licensure" to our Bill or Law. I'm not in favor of joining the Labor and Licensure Bboard. DHEC has been very good to athletic trainers in this State and have done a great job in getting us to where we are today!		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
4. Jeremy R. Searson, PhD, ATC, Metropolis LLC, South Carolina Athletic Trainers Association Executive Council	General	**Partially Adopted.** The change to using the term "Healthcare" is adopted. Other terms and parameters for the Advisory Committee cannot be changed as they are statutory. Fees are not increasing at this time.
Please make all changes from Health to Healthcare to more accurately reflect the profession. Ensure that the document more aligns with the national standards for verbiage and definitions including but not limited to the utilization of License over Certification. Define roles and term limits for the Advisory Committee so it is more inclusive and relevant to the profession of athletic training in the state of South Carolina. This should include specific term limits and a selection process (external to the committee self nominating.) This should also include a seat for the President of the South Carolina Athletic Trainers Association, the elected representative of athletic		

trainers in the state.

Rates for license/certification should be raised to better allow for enforcement of current legislation as well as support of athletic training throughout SC.

NAME	SECTION	DEPARTMENT RESPONSE
5. Eric Fuchs	General	The Department can provide this guidance in a means other than inclusion in the regulation.

I would like to see more clarity on the ability of AT's to handle, carry, transport and administer medication again below is example language from another state but to be clear this way AT's can carry epi-pens or albuterol, for inhalers or nebulizer of their own and not rely on the patients to have there with them or to have to carry or be responsible or a patients medication which is not really legal, oxygen and numerous other things from IBU to Acetometiphine , also clarifies the ability to administer medication for suturing and ability to travel with all the above as well as clarify ability to dry needle and many other things again all while under the direction or supervision of a physician. Again just spells these things out again to help clarify.

For example language from a state law:

Athletic Trainers' may assist with the appropriate management and use of but shall not prescribe, over-the-counter or prescription medications commonly used in the practice of sports medicine, excluding any controlled substances, only to a patient 18 years of age or older and under the supervision of a physician licensed , and shall maintain accurate records identifying the medication, dose, 9 amount, directions, condition for which the medication is being used, identity of the 10 supervising physician, lot number, and expiration date;

- Shall not provide or administer over-the-counter or prescription medications to a minor without express parental or guardian consent and physician oversight;

- The board shall promulgate administrative regulations, based upon recommendations from the council and in to establish a formulary of legend medications that an athletic trainer may obtain, transport, provide, and administer when providing athletic training services, limited to only those medications that are indicated and approved by the board. This subsection shall not be interpreted to bestow prescriptive authority, and the formulary shall not include Schedule II, III, IV, or V drugs as defined in the Controlled Substances Act, 21 U.S.C. secs. 801 et seq.; 22

Also Clarify invasive procedure ability as well:

Shall not perform invasive procedures, except for those invasive procedures that the board, based on recommendations from the council, determines to be permissible. Any procedures performed under this subsection shall be:
(a) Within the scope of practice for athletic trainers; and

(b) Approved by the supervising physician;

NAME	SECTION	DEPARTMENT RESPONSE
6. Eric Fuchs	Section A	**Partially Adopted.** The term “Athletic Trainer” is defined by statute. The term “Employment of Athletic Trainer” is addressed in other portions of the regulation. 102.D.2.b, 102.F.1.b

First the current Definition of an Athletic Trainer "e. “Athletic Trainer” means a person with specific qualifications as set forth in Section 44-75-50 of the Law who, upon the advice and consent of a licensed physician, carries out the practice of care, prevention, and physical rehabilitation of athletic injuries, and who, in carrying out these functions, may use physical modalities, including, but not limited to, heat, light, sound, cold, electricity, or mechanical devices related to rehabilitation and treatment."

Needs to be changed to add "Athletic Trainer means a healthcare provider with specific qualifications" This change is important for recognition by Third-party payers and others that we are health care providers please note we have been recognized as such by the AMA since 1990.

Addtionally the definition needs updated to include "services provided by ATs include injury and illness prevention, wellness promotion and education, emergent care, examination and clinical diagnosis, therapeutic intervention, and rehabilitation of injuries and medical conditions. " into the definition.

This languages comes from the Strategic Alliance Definition of AT statement published in 2017 see below

"

*This definition is approved by the Inter-Agency Terminology Work Group and the Athletic Trainer Strategic Alliance, January 2017. Athletic Trainers (ATs) are healthcare professionals who render service or treatment, under the direction of or in collaboration with a physician, in accordance with their education and training and the states' statutes, rules and regulations. As a part of the healthcare team, services provided by ATs include injury and illness prevention, wellness promotion and education, emergent care, examination and clinical diagnosis, therapeutic intervention, and rehabilitation of injuries and medical conditions. *Athletic training is recognized by the American Medical Association (AMA) as a healthcare profession. "

The employment definition should be expanded as currently states

"h. “Employment of Athletic Trainer” shall mean a person who is engaged as an athletic trainer if the person is employed on a salary or contractual basis by an educational institution, a hospital, rehabilitation clinic, professional organization, or other bona-fide athletic organization and performs the duties of an athletic trainer as a major responsibility of this employment."

I would like to see other bona-fide organization and performs the duties of an Athletic Trainer and remove athletic organization there, OR needs to be expansion of examples including industrial, first responders/ military settings, performing arts, again or just removing athletic from current as I suggest opens the areas of employment up.

My concern for section B is that you include the 7 domains of the BOC Domains of practice why not just take out and state AT's work withing the domains of practice as defined by the BOC because my question becomes if the BOC updates or changes these will the current statute then have to be readdressed and easier in Section B to keep

"B. Description of the Profession.

An athletic trainer is an individual who has successfully completed the college or university

undergraduate degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., in association with the National Athletic Trainers' Association (NATA), and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards as defined by the BOC, et . and strike this line and the specific domains listed after it " The seven domains/standards of athletic training from which these specific tasks are measured in the examination are:"

NAME	SECTION	DEPARTMENT RESPONSE
7. Aaron Galpert	Section A	**Not adopted.** Definitions do not set forth regulatory requirements or scope of practice. The Scope of Practice for Athletic Trainers does not include medication administration.

Under definition of AT and what they can do maybe consider adding topical medications?

NAME	SECTION	DEPARTMENT RESPONSE
8. Brad Drake, MA, SCAT, Associate Athletic Director for Medical Services and Head Athletic Trainer, Charleston Southern University	Section A	**Adopted.** 101.A

3. Definitions: a. e. "Athletic Trainer" means an allied health healthcare professional with specific qualifications as set forth in Section 44-75- 50 of the Law who, upon the advice and consent of a licensed physician, carries out the practice of care, prevention, and physical rehabilitation of athletic injuries, and who, in carrying out these functions, may use physical modalities, including, but not limited to, heat, light, sound, cold, electricity, or mechanical devices related to rehabilitation and treatment.

Rationale: Update language in line with national definition of the profession.

NAME	SECTION	DEPARTMENT RESPONSE
9. Brad Drake, MA, SCAT, Associate Athletic Director for Medical Services and Head Athletic Trainer, Charleston Southern University	Section B	**Partially Adopted.** 102.D.2.b, 102.F.1.b The description of the profession has been addressed in different portions of the regulation. Definitions are defined by statute.

B. Description of the Profession.

An athletic trainer is an allied health healthcare professional who has successfully completed the college or university degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., or its successor entities, and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc., or its successor entities. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards.

The domains/standards of athletic training from which these specific tasks are measured in the examination are defined by the Board of Certification, Inc., or its successor entities.

Rationale: Update language in line with national definition of the profession.

NAME	SECTION	DEPARTMENT RESPONSE
10. Jane Steinberg	Section B	**Adopted.** 102.D.2.a

"Undergraduate degree" is no longer correct; should include undergraduate degree for us dinosaurs…but Masters for the up-and-coming youngsters….so it needs to state both!

NAME	SECTION	DEPARTMENT RESPONSE
11. Lisa Cummins, Head Athletic Trainer, Augusta University	Section B	**Adopted.** 102.D.2.a

Section B first sentence should be updated to reflex the change from an undergraduate program to graduate level degree.

NAME	SECTION	DEPARTMENT RESPONSE
12. Mike Smith, MA, SCAT	Section F	**Adopted.** 105.B

Section F Exemption from Certification, Item #4 states: "4. A person serving as a student-trainer or in any similar position if the service is carried out under the supervision of a licensed physician or certified athletic trainer is exempt." It is my opinion that in order to be consistent the statement should read as follows: "4. A person serving as a student athletic trainer aide or in any similar position if the service is carried out under the supervision of a licensed physician or certified athletic trainer is exempt." The term "student trainer" is out-dated and not correct terminology now.

NAME	SECTION	DEPARTMENT RESPONSE
13. Mike Smith, MA, SCAT	Section K	**Adopted.** 302.D

The second point that needs addressed is in Section K. Revocation, Suspension and Denial of Certification; Penalties; Appeals Process, 2. Penalties: "Any person violating the provisions of Sections 44-75-10 et seq. is guilty of a misdemeanor and upon conviction must be punished by a fine of not less than twenty-five ($25) nor more than two hundred dollars ($200)." My opinion is that the monetary penalty is too low. I can't reasonably say what is a better amount but I do know that $25-$200 is not enough; it should be higher. As a reference point please see the following information and accompanying links. The first on pertains to practicing medicine without a license. The second one pertains to acting as a physical therapist and disciplinary actions.

https://www.alllaw.com/articles/nolo/medical-malpractice/practicing-without-license-criminal-civil-liability.html
Laws vary by state, but practicing medicine without a license is illegal in all states.
Common sentences range from one to eight years in prison, depending on whether it's a misdemeanor or felony offense. Many judges will also impose fines in addition to prison sentences.

https://www.scstatehouse.gov/code/t40c045.php
SECTION 40-45-120. Board authority to take disciplinary actions and impose civil penalties.
In addition to the sanctions the board may impose against a person pursuant to Section 40-45-110, the board may take disciplinary action against a person as provided in Section 40-1-120 and also may impose a civil penalty of not more than two thousand dollars for each violation of this chapter or of a regulation promulgated under this chapter, the total penalty not to exceed ten thousand dollars.

NAME	SECTION	DEPARTMENT RESPONSE
14. Brian Curless, Manager of Operational Support, Palmetto Health USC Orthopedic Center	Section L	**Not Adopted.** The advisory committee is statutory. 400
There is no description of qualifications needed to be on the Committee. Who nominates candidates? There is no term limits identified for committee members.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
15. Brad Drake, MA, SCAT, Associate Athletic Director for Medical Services and Head Athletic Trainer, Charleston Southern University	Section L	**Partially Adopted.** 400. The advisory committee creates its own bylaws for nomination. That is a process, not a regulation. Regulation regarding investigations was amended in 201 and 202.

1. Organization: The South Carolina Athletic Trainers' Advisory Committee shall consist of nine members appointed by the Board. Two members must be from the Department, one must be from the State Board of Medical Examiners, four must be state certified athletic trainers and two must be from the general public who are not certified or licensed in any health care fields and are not in any way associated with athletic trainers.

2. Officers: The Advisory Committee shall annually elect a chairman and vice-chairman from its membership. These two officers shall have all the privileges of re-election.

Questions: Are the chairman and vice chairman positions only held by the ATs on the board? How are the other ATs (of the four) selected? Elected? How are the elections run? Nothing in the regs stating the process. Any other criteria for ATs on the board? Term limits?

Recommendation: I recommend updating the regulation to more clearly define the criteria, for the committee members, the process of election, and establish term limits. 2. Assure that the Committee's address and telephone number is listed in the state telephone directory.

Questions: Which directory? I cannot find this information on the DHEC website.

Recommendation: I would propose updated the regulation to state that this information will be listed on the DHEC website including emails, phone numbers, and years of service on the committee.

10. Investigate violations and complaints and follow-up with proper legal procedures.

Questions: Is this the job of the committee?

Which member of the SCATAC is responsible for investigation?

Does DHEC provide resources to investigate?

How does the public submit a formal complaint?

Recommendation: I recommend DHEC provide a phone number and email link on the athletic trainer’s page of the DHEC website for the public to submit formal complaints. I recommend updating the regulation to more clearly define the parties that will investigate violations and complaints.

NAME	SECTION	DEPARTMENT RESPONSE
16. Kevin Ennis	A.3.e	**Adopted.**
Suggested: e. "Athletic Trainer" means an allied health professional with specific qualifications …		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
17. Kevin Ennis	K.2	**Adopted.** 303
Additional comments regarding the suggested items for K.2: for f: May need to reword this. Observed being under the influence while providing care. for g: If they are disabled, this would not fall under conduct. for l. Did not adhere to HIPAA laws		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
18. Kevin Ennis	L.1	**Adopted.** 400.
Suggested: ...four must be state certified athletic trainers and two must be from the general public...		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
19. Kevin Ennis	B	**Not Adopted.** The definition is in statute.
Suggested: An athletic trainer is an allied health professional who has successfully completed the college or university degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., or its successor entities, and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc., or its successor entities. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards. The domains/standards of athletic training from which these specific tasks are measured in the examination are defined by the Board of Certification, Inc., or its successor entities.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
20. Kevin Ennis and Zachary K. Winkelmann	A.3	**Adopted**. This regulation does not prohibit this.
Suggested adding: j. This Regulation shall not be misconstrued to prohibit an athletic trainer who holds additional valid credential(s) from providing services allowed under his/her additional area(s) of credentialing.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
21. Kevin Ennis and Zachary K. Winkelmann	A.3.c	**Adopted.**
Suggested: c. "Department" shall mean the South Carolina Department of Health and Environmental Control.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
22. Kevin Ennis and Zachary K. Winkelmann	A.3.h	**Adopted.** 102.A.2
Suggested: h. "Employment of Athletic Trainer" shall mean a person who is engaged as an athletic trainer if the person is employed on a salary or contractual basis by an educational institution, a hospital, rehabilitation clinic, a physician's office, an industry, a performing arts group, professional athletic organization, the military, governmental agency or other bona-fide organization which employs or		

serves a physically active population and performs the duties of an athletic trainer as a major responsibility of this employment.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
23. Kevin Ennis and Zachary K. Winkelmann	C.1	**Adopted.** 102.D.2.b
Suggested: 1. Requirements: A person who seeks certification as an athletic trainer in the State of South Carolina must pass the Athletic Trainer Certification Examination as administered by the Board of Certification, Inc., or its successor entities, and satisfy the following requirements:		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
24. Kevin Ennis and Zachary K. Winkelmann	C.1.a	**Adopted.** 102.D.1.b.1
Suggested: a. Complete the athletic training curriculum requirements of an accredited professional athletic training program at the college or university level; and		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
25. Kevin Ennis and Zachary K. Winkelmann	C.1.b	**Adopted.** 102.D.1.b.1
Suggested: b. Submit a certified transcript from the college or university along with the completed application and submit to a criminal background check.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
26. Kevin Ennis and Zachary K. Winkelmann	C.3	**Adopted** 102.D.2.b
Suggested: 3. Examination: The applicant must pass the Athletic Trainer Certification Examination as administered by the Board of Certification, Inc., or its successor entities, before a certificate for South Carolina certification can be issued from the Department.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
27. Kevin Ennis and Zachary K. Winkelmann	C.4	**Not Adopted.** The comment pertains to Departmental Standard Operation Procedure, not regulatory items.
Suggested: 4. Renewal: With renewal being every two (2) years, the Department shall send a renewal application form, sixty (60) days prior to the renewal date, to the last address registered with the Department in Continuum, or its successor entities, to the person to whom the certification was issued or renewed during the preceding renewal period. The athletic trainer shall then:		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
28. Kevin Ennis and Zachary K. Winkelmann	C.4	**Adopted.** 102.F.1.b
Suggested adding c. Submit proof of active BOC, Inc. certification(or certification with BOC's successor entities) (unless the athletic trainer submits proof of retirement prior to July 2025).		

NAME	SECTION	DEPARTMENT RESPONSE
29. Kevin Ennis and Zachary K. Winkelmann	C.4	**Not Adopted.** There is no statutory authority to require a criminal background check.
Suggested: recodify the current C.4.c and C.4.d to C.4.d and C.4.e and amend the current C.4.c as follows: d. Enclose the renewal fee and submit to a criminal background check;		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
30. Kevin Ennis and Zachary K. Winkelmann	C.5	**Adopted.** 102.F
Suggested: ...provided the application is made within three (3) months of the renewal date. After three (3) months, yet prior to the anniversary of the biennial renewal date, an additional restoration fee will be charged to those individuals who wish to restore certification.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
31. Kevin Ennis and Zachary K. Winkelmann	C.6	**Partially Adopted.** This comment pertains more to Department Standard Operating Procedure than a regulatory item.
Suggested: 6. Reinstatement: A certificate which is revoked for failure to renew may be reinstated at the direction of the Department and the Committee within two (2) years of its expiration date. Any consideration for recertification after that two year period will necessitate submission of a new application and will require the applicant to meet the then existing requirements.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
32. Kevin Ennis and Zachary K. Winkelmann	D.1	Adopted. 103
Suggested adding D.1.g to read as follows: g. Upon prior notification to the Department, active duty military personnel and spouses may be granted a temporary hold on their certification while actively deployed outside the state.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
33. Kevin Ennis and Zachary K. Winkelmann	D.1.a	**Not Adopted.** The Department is not changing the licensure fees at this time.
Suggested: Change fee from $50 to $150		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
34. Kevin Ennis and Zachary K. Winkelmann	D.1.b	**Not Adopted.** The examination is not administered by the Department.
Suggested: b. Examination Fee: The examination fee will be the current examination fee of the Board of Certification, Inc. (BOC), or its successor entities. This fee is in addition to the application fee.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
35. Kevin Ennis and Zachary K. Winkelmann	D.1.c	**Not Adopted.** The examination is not administered by the Department.
Suggested: c. Re-Examination Fee: The re-examination fee shall be the current Board of Certification, Inc., or its successor entities, re-examination fee.		

NAME	SECTION	DEPARTMENT RESPONSE
36. Kevin Ennis and Zachary K. Winkelmann	D.1.d	**Not Adopted.**
Suggested: Change biennial renewal fee to $75		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
37. Kevin Ennis and Zachary K. Winkelmann	D.1.e	**Not Adopted.**
Suggested: e. Late Renewal Fees: An additional twenty five dollar ($25) late renewal fee for a total of one hundred dollars ($100) will be charged to those individuals who renew within a three (3) month period after the biennial renewal date.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
38. Kevin Ennis and Zachary K. Winkelmann	D.1.f	**Not Adopted.**
Suggested: f. Reinstatement Fee: An additional one hundred twenty five dollar ($125) restoration fee for a total of two hundred dollars ($200) will be charged to those individuals who fail to renew within the three (3) month late renewal schedule but prior to the biennial renewal anniversary date. After the biennial renewal anniversary date the individual must apply as a new applicant.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
39. Kevin Ennis and Zachary K. Winkelmann	D.2	**Not Adopted.**
Suggested the cost be changed to $20.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
40. Kevin Ennis and Zachary K. Winkelmann	E	**Adopted.** 104.A
Suggested changing E to E.1 and amending as follows: 1. Certification by Reciprocity: A certificate may be issued by the Department to any qualified athletic trainer holding credentials in any other state (state, the District of Columbia, and each commonwealth, territory, or possession of the United States) if such other state recognizes the certificate of South Carolina in the same manner. The applicant must meet the following requirements for reciprocal certification: a. The applicant is currently credentialed as an athletic trainer under the laws of another state. b. The requirements for said credential are substantially similar to those required in South Carolina. c. The applicant's credential has not been, and is not presently, suspended or revoked.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
41. Kevin Ennis and Zachary K. Winkelmann	E	**Adopted.** 104.B
Suggested adding E.2 to read as follows: 2. Temporary Reciprocal Certification: A temporary reciprocal certification will be allowed to address the need of credentialed athletic trainers from other states traveling to South Carolina for the purpose of caring for the individuals with whom they are traveling. Examples include, but are not limited to, athletic trainers traveling with scholastic, collegiate and professional organizations or individuals participating in competitions, tournaments, etc. The athletic trainer must meet the following requirements for temporary reciprocal certification: a. The athletic trainer is credentialed to practice athletic training under the laws of another state. b. The athletic trainer's credential has not been, and is not presently, suspended or revoked. c. The athletic trainer must show proof of credential upon request.		

Individuals meeting these criteria need not apply for Temporary Reciprocal Certification but will be granted such during short term visits to South Carolina. When granted temporary reciprocity the athletic trainer's scope of practice shall not exceed the scope of practice of their credential in their primary state. Athletic trainers desiring to work events, camps, tournaments, etc. in South Carolina for the organizer must be State Certified Athletic Trainers.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
42. Kevin Ennis and Zachary K. Winkelmann	F.2	**Adopted.** This section was unnecessary for the regulation since it is already statutory. This is covered in 102.A.
Suggested: ...or staff member at the school /organization in question ...		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
43. Kevin Ennis and Zachary K. Winkelmann	F.4	**Adopted.** 105.B
Suggested: 4. A person serving as an athletic training student or student aide or in any similar position if the service is carried out under the supervision of a licensed physician and/or certified athletic trainer is exempt.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
44. Kevin Ennis and Zachary K. Winkelmann	G	**Not Adopted.** There is no statutory authority to require a criminal background check.
Suggested: Adding "Submit to a criminal background check." as G.3 and recodifying the remainder of Section G for consistency.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
45. Kevin Ennis and Zachary K. Winkelmann	H.2	**Adopted.** 107
Suggested: 2. Change of Address: Each person who has a certificate shall keep the Department apprised in writing of his or her current name and address his or her contact information in Continuum, or its successor entities, current at all times.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
46. Kevin Ennis and Zachary K. Winkelmann	I.1	**Adopted.** 101.A
Suggested: 1. Titles and Abbreviations: An athletic trainer certified by the Department may use the title, "State Certified Athletic Trainer and/or the abbreviation "S.C.A.T." or "SCAT".		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
47. Kevin Ennis and Zachary K. Winkelmann	K.1	**Not Adopted.** The Department may consider this in regards to its operating procedures.
Suggest Section K.1 be amended to read: 1. The Department shall, upon receiving a complaint of misconduct as herein defined, initiate an investigation to determine whether or not suitable cause exists to take action against the holder of an athletic trainer certificate, a. The initial complaint shall be in the form of a brief statement, dated and signed by the person making the complaint, which shall identify the person that is the subject of the complaint and contain		

a summary as to the nature of the complaint. The Department is also authorized to initiate an investigation based on information acquired from other sources.
b. Information received by the Department through inspection, complaint, or otherwise authorized under S.C. Code Sections ?????????? et. seq. shall not be disclosed publicly except in a proceeding involving the questioning of certification or revocation of a certificate.

NAME	SECTION	DEPARTMENT RESPONSE
48. Kevin Ennis and Zachary K. Winkelmann	General	**Adopted.** A section titled "Enforcing Regulations was created. 200

Suggested adding an additional Section "N. ENFORCING REGULATIONS"

NAME	SECTION	DEPARTMENT RESPONSE
49. Kevin Ennis and Zachary K. Winkelmann	K.2	**Adopted.** 301 and 303

Suggested:
2. Standards of Conduct: At the discretion of the Department, athletic trainers may have their certificates suspended or revoked or assessed a monetary penalty at any time the Department determines that the holder of the certificate no longer meets the prescribed qualifications set forth by the Department or has committed any of the following acts considered to be misconduct:

NAME	SECTION	DEPARTMENT RESPONSE
50. Kevin Ennis and Zachary K. Winkelmann	K.2	**Partially Adopted.** **303**

Suggested to add the following items under K.2:
a. Has engaged in any conduct considered by the Board or Department to be detrimental to the profession of athletic training;
b. Has used fraud or deceit in procuring or, attempting to procure, a certificate or renewal of a certificate to practice athletic training;
c. Has violated, aided, or abetted others in violation of any provision of the law, or these regulations;
d. Has practiced athletic training without a valid certificate;
e. Has been convicted of a felony or another crime involving moral turpitude, drugs, or gross immorality;
f. Has been addicted to alcohol or drugs to such a degree as to render the holder unfit to perform as an athletic trainer;
g. Sustained a physical or mental disability that renders further practice by the certificate holder dangerous to the public;
h. Obtained fees or assisted in the obtaining of fees under dishonorable, false or fraudulent circumstances;
i. Disregarded an appropriate order by a physician concerning care and treatment;
j. Refused to administer care on the grounds of age, sex, race, religion, creed or national origin of the athlete;
k. After initiating care, discontinued such care or abandoned the athlete without the athlete's consent or without providing for the further administration of care by an equal or higher medical authority;
l. Revealed confidences entrusted to him in the course of medical attendance, unless such revelation is required by law or is necessary in order to protect the welfare of the individual or the community;
m. By action or omission and without mitigating circumstance, contributed to or furthered the injury or illness of an athlete under care;
n. Performed skills above the level for which the certificate holder was certified;
o. Observed the administration of sub-standard care provided by another athletic trainer or other medical provider without documenting the event and notifying the proper individual or authority;
p. By the certificate holder's action, or inactions created a substantial possibility that death or serious

physical harm could result;
q. Did not take or complete remedial training or other courses of action as directed by the Department;
r. Has been found guilty of the falsification of any documentation as required by the Department;
s. Breached a section of the Athletic Trainers Act of South Carolina or a subsequent amendment of the Act or any rules or regulations published pursuant to the Act;
t. Failed to provide an athlete with care of a quality deemed acceptable by the Department.
u. Breached the Code of Ethics as established by the Board of Certification, Inc., or its successor entities.

NAME	SECTION	DEPARTMENT RESPONSE
51. Kevin Ennis and Zachary K. Winkelmann	K.4	**Adopted.** 301.B

Suggested:
4. Actions: The Committee may recommend revocation or suspension of a certificate or assessment of a monetary penalty. Revocation may be for a period up to two years.

NAME	SECTION	DEPARTMENT RESPONSE
52. Kevin Ennis and Zachary K. Winkelmann	N	**Adopted.** Comment Suggestion 1.a was added to 201. Comment suggestion 2.b and 2.c can be found in 202

Suggested adding an additional Section "N. ENFORCING REGULATIONS" with the following subtext:
1. General.
a. The Department may utilize investigations, consultations, and other pertinent documentation regarding an athletic trainer in order to enforce these regulations. b. The Department reserves the right to make exceptions to these regulations where it is determined that the health and welfare of those being served would be compromised.
2. Inspections and Investigations. a. An investigation may be conducted of an athletic trainer and subsequent investigations conducted as deemed appropriate by the Department.
b. All athletic trainers are subject to investigation at any time without prior notice by individuals authorized by the Department. c. Individuals authorized by the Department shall be granted access to all properties and areas, objects, equipment, and records, and have the authority to require that entity to make photo and/or electronic copies of those documents required in the course of investigations. These copies shall be used for purposes of enforcement of regulations
and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings.

NAME	SECTION	DEPARTMENT RESPONSE
53. Kevin Ennis and Zachary K. Winkelmann	N	**Adopted.** 300

Suggested adding the following additional items under section "N. ENFORCING REGULATIONS with the following subtext.
3. Enforcement Actions. When the Department determines that an athletic trainer is in violation of any statutory provision, rule, or regulation relating to the duties therein, the Department may, upon proper notice to that entity, impose a monetary penalty and/or deny, suspend, and/or revoke its certification, or authorization or take other actions deemed appropriate by the Department and/or recommended by the Committee. Disciplinary actions taken will be published on the SC DHEC Website and Board of Certification, Inc. Disciplinary Action Exchange.
4. Violation Classifications. Violations of standards in this regulation are classified as follows:
a. Class III violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons being served, other employees, or the general public; or a

substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.
b. Class II violations are those that are not classified as Class I or Class III violations the Department determines to have a negative impact on the health, safety or well-being of those being served, other employees, or the general public. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.
c. Class I violations are those that are not classified as Class II or III in these regulations or those that are against the best practices as interpreted by the Department. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.
d. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on the health, safety, or well-being of those being served, other employees and the general public, efforts by the Athletic Trainer to correct cited violations; behavior of the entity in violation that reflects negatively on that entity's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.
5. Monetary Penalties When a decision is made to impose monetary penalties, the following schedule shall be used as a guide to determine the dollar amount:

NAME	SECTION	DEPARTMENT RESPONSE
54. Kevin Ennis and Zachary K. Winkelmann	N.5	**Adopted.** 302.D
Suggested adding a chart titled "Monetary Penalty Ranges" beneath the proposed Section N.5 to reflect Class III Enforcments of $300-500 for 1st infraction, $500-1500 for 2nd, $1,000-5,000 for 3rd, $10,000 for four or more; Class II Enforcments of $100-300 for 1st infraction, $300-500 for 2nd, $500-1,500 for 3rd, and $1,500-5,000 for four or more; Class I Enforcements of $50-100 for 1st infraction, $100-300 for 2nd, $300-800 for 3rd, $800-1,500 for four or more.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
55. Kevin Ennis and Zachary K. Winkelmann	I.2	**Adopted.** 107
Suggested: 2. Production and Display of Certificate: An athletic trainer certified by the Department shall carry said original card/badge at all times, and show said original card/badge when requested.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
56. Kevin Ennis and Zachary K. Winkelmann	J.1	**Adopted.** 101.F
Suggested: ...directly related to the performance and practice of the athletic trainer.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
57. Kevin Ennis and Zachary K. Winkelmann	J.2.a	**Not Adopted.** Course approval is determined by the Department.
Suggested: ...by the South Carolina Athletic Trainers' Advisory Committee (SCATAC) and		

NAME	SECTION	DEPARTMENT RESPONSE
58. Kevin Ennis and Zachary K. Winkelmann	J.2.d	**Not Adopted.** This is an operating process rather than a regulatory item.
Suggested: d. At the completion of the appropriate courses during the symposium/meeting/conference, a SC DHEC CEU card or SC DHEC Proof of Attendance will be issued to the athletic trainer by a member of the Committee.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
59. Kevin Ennis and Zachary K. Winkelmann	J.3	**Not Adopted.** This would require statutory change
Suggested adding J.3.c to read as follows: "c. A photocopy of the BOC, Inc. (or its successor entities) certification card (unless the athletic trainer submits proof of retirement prior to July 2025)."		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
60. Kevin Ennis and Zachary K. Winkelmann	J.3.a	**Not Adopted.** This section was amended, so the suggested change is no longer necessary.
Suggested: Change SCATA to SCATAC		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
61. Kevin Ennis and Zachary K. Winkelmann	J.3.b	**Not Adopted.** The Department approves the documentation required for evidence of continuing education.
Suggested: b. A photocopy of the SC DHEC CEU card or SC DHEC Proof of Attendance, signed by a member of the committee.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
62. Kevin Ennis and Zachary K. Winkelmann	J2.b	**Partially Adopted.** 501.A.2
Suggested: b. A designated professional seminar offered yearly by the South Carolina Athletic Trainers' Association, or its successor entities, at the Association's annual symposium/meeting/conference. A seminar shall mean two (2) designated courses within the scope of that year's symposium meeting/conference.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
63. Kevin Ennis and Zachary K. Winkelmann	A.1	**Not Adopted.** This section was removed as it was not regulatory language.
Suggested: Purpose: The purpose of this regulation is to assure the highest degree of professional conduct by those engaged in offering athletic training services to the public and to safeguard the public's health, safety, and welfare by establishing minimum qualifications for those individuals wishing to offer athletic training services to the public.		

NAME	SECTION	DEPARTMENT RESPONSE
64. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	A.3	**Adopted.** 101.J
Suggested adding the following term and definition: f.“Physically active” population means any individual who participates in an athletic activity, a job function, or a job-related activity that requires physical strength, range of motion, flexibility, control, speed, stamina, or agility.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
65. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	A.3.e	**Adopted.** 101.A
Suggested: "Athletic Trainer" means an healthcare professional with specific qualifications as set forth in Section 44-75- 50 of the Law who, upon the advice and consent of a licensed physician, carries out the practice of care, prevention, and physical rehabilitation for injuries and illnesses of the physically active, and who, in carrying out these functions, may use physical modalities, including, but not limited to, heat, light, sound, cold, electricity, or mechanical devices related to rehabilitation and treatment.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
66. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	C.2.b	**Adopted.** 102.D.3
Suggested: ...within ninety (90) days of the date that the Department has received the first document. ...		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
67. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	F	**Adopted.** 102.A.1
The following wording under Section F is Confusing wording with three negatives "no", "unless" and "except - consider revising. Current regulation reads, "No person shall represent him or herself as an athletic trainer unless he or she is certified by the Department, except as otherwise provided in this section. Exemptions apply as follows:"		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
68. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	G	**Not Adopted.** This is statutory. The language was updated.
Regarding the text directly under Section G, does this need to stay? If removed, how many Ats would it impact? May be okay to remove at this point. Current regulation reads, "The Department may issue a certificate to an applicant who was actively engaged as an athletic trainer for a two-year period from June 19, 1979 to June 19, 1984. The applicant shall submit the following for documentation:"		

NAME	SECTION	DEPARTMENT RESPONSE
69. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	G.1	**Not Adopted.** This does not match statute.
Suggested: 1. A notarized record of being employed on a salary or contractual basis by an educational institution, a hospital, rehabilitation clinic, a physician's office, an industry, a performing arts group, professional athletic organization, the military, governmental agency, or other bona-fide organization which employs or serves a physically active population and performs the duties of an athletic trainer as a major responsibility of this employment.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
70. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	K.2	**Not Adopted.** T**h**e Department has statutory authority to take an enforcement action.
Agreed with Kevin Ennis' suggestions for K.2 items escept K.2.t. Suggests K.2.t reading as follows: t.Failed to provide an athlete with care of a quality deemed acceptable by the Department.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
71. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	L	**Not Adopted.** This would require statutory change.
Suggests adding an L.2 item to read as follows and recodify the remainder of L to maintain numerical consistence. "2. The Board may appoint athletic trainer members from a list of qualified individuals submitted to the Board by the South Carolina Athletic Trainers Association with special attention given to those from diverse job settings."		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
72. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	L	**Not Adopted.** This would require statutory change.
Suggest Adding: 5. Term Limits: The Committee members should serve a term of 3 years. a. The terms for members are staggered b. At the end of a term, a member can reappointed for one additional term for a maximum of 6 years c. At the end of a term, a member will continue to serve until a successor is appointed		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
73. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	L.1	**Not Adopted.** This would require statutory change. This could possibly be added to bylaws.
Suggested:1. Organization: The South Carolina Athletic Trainers' Advisory Committee shall consist of nine members appointed by the Board. a.Two members must be from the Department: b. One member must be a licensed physician from the State Board of Medical Examiners: • Whom previously or currently have partnered with or directed an athletic trainer c. Four must be state certified athletic trainers: • Reside in the state of South Carolina; and		

• That are certified by a national certifying board; and • Have a minimum of 5 years of clinical experience, and • In active status and in good standing with the Department d. Two must be from the public who are not certified or licensed in any healthcare fields and are not in any way associated with athletic trainers including training to be an athletic trainer or other health professional. • Participate or ever have participated in a commercial or professional field related to athletic training • No financial interest in the last 2 years with any person regulated by the Board; or • No financial interest in the last 2 years in the provision of good or services to athletic trainers or the field of athletic training		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
74. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	L.2	**Not Adopted.** This would require statutory change. This could possibly be added to bylaws.
Suggest: 3. Officers: The Advisory Committee shall annually elect a chairperson and vice-chairperson from its membership. a. These two officers shall have all the privileges of re-election after their first term as an officer for a total of 6 years .		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
75. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	L.3	**Not Adopted.** This would require statutory change. This could possibly be added to bylaws.
Suggest: 4.Meetings: The Committee must meet at least once a year. Additional meetings may be held on call of the chairperson or at the written request of two Committee members. A record must be kept of all transactions which have been called for by the chairperson and a written report shall be submitted for the minutes at the next regularly scheduled meeting. A quorum of two thirds of the Committee membership is required for any meeting of the Committee.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
76. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	M	**Adopted.** This term will no longer be used.
Change the "chairman" to "chairperson" throughout		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
77. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	M.10	**Not Adopted.** These are the Department's responsibilities that are not part of regulation.
This process should be defined as to how the public and/or athletic trainers can file a complaint. Additionally, the process should be delineated as to how this process will work Section 40 of the Medical Examiner Board is a great example. Could reference a document similar to this in this regulation so the reader is aware but not include in the document Currently this reads as DHEC job – is this going to stay the way? Is this within the scope of DHEC?		

NAME	SECTION	DEPARTMENT RESPONSE
78. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	B	**Not Adopted.** This section was removed from the regulation.
Suggested: An athletic trainer is an healthcare professional who has successfully completed the college or university degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., or its successor entities, and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc., or its successor entities. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards. The domains/standards of athletic training from which these specific tasks are measured in the examination are defined by the Board of Certification, Inc., or its successor entities.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
79. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	J.2.e	**Adopted.** 501.A.2
Suggested: e. The Committee may approve equivalent courses.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
80. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	B	**Not Adopted.** This section was removed from the regulation.
Suggested: An athletic trainer is an healthcare professional who has successfully completed the college or university degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., or its successor entities, and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc., or its successor entities. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards. The domains/standards of athletic training from which these specific tasks are measured in the examination are defined by the Board of Certification, Inc., or its successor entities.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
81. Zachary K. Winkelmann, Clinical Assistant Professor in the Arnold School of Public Health at USC	J.2.d	**Not Adopted.** This is a process rather than a regulatory item.
Can this be transitioned to an online model to save money/time? Does the card or proof of attendance need to be a paper – could be included in the SCATA CEU report that is already provided.		

ATTACHMENT D

SUMMARY OF ATHLETIC TRAINERS' ADVISORY COMMITTEE COMMENTS AND DEPARTMENT RESPONSES

R.61-96, Athletic Trainers

Comments received from the committee on July 31, 2020:

SECTION	COMMENT	DEPARTMENT RESPONSE
Table of Contents	Remove Section 108. Professional identification	**Adopted.** Updated Table of Contents to reflect correct sections.
	Comment. The above change to the Table of Contents Section 100 – Definitions and Certification is necessary due to changes in the body of the document explained below Section 108. Professional Identification. and Section 109. Variance.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102.A.4	4. A person certified by the Department to practice and perform as an Athletic Trainer may use the title, "State Certified Athletic Trainer" and/or the abbreviations "S.C.A.T." and "SCAT".	**Adopted.**
	The above statement, Section 102, A. Certification, 4. is recommended for inclusion by The Committee.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102.B	B. Compliance. The Athletic Trainer shall not be issued an initial Certificate until ~~the~~ he or she demonstrates to the Department substantial compliance with the standards of this regulation. Current and/or previous violation of the South Carolina Code of Laws or Department regulations may jeopardize the issuance of an Athletic Trainer Certification	**Adopted.**
	Comment. The Committee recommends the above correction.	

SECTION	COMMENT	DEPARTMENT RESPONSE
102.E	Change certification fee to $100, renewal to $75, late fee to $25, restoration fee to $125, $20 for duplication certificates and cards.	**Not Adopted.** The Department does not need a fee increase at this time.
	Comments. The Committee recommends the above increase in Certification Fees for the financial well-being of the program and to sustain the Department's ability to administer the program relying on the stakeholders to fund the program and not becoming a burden to the tax payer. Justifications for an increase include; the number of Athletic Trainers in South Carolina has grown to over 1000 at the present time, technology is more readily available to assist with activities, credentialing, tracking, etc. and needs to be purchased, the program now has staff assigned spending a greater amount of time administering the program and increased human resource costs, and the cost of doing business is significantly greater than it was 36 years ago. This increase is designed to allow for the continued promotion of Athletic Training in South Carolina through education and regulation for many years to come and is the first request for an increase in fees since the inception of the Act in 1984.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102.F.1.b	Add "unless the individual is subject to inclusion via Section 106. Grandfather Provision."	**Adopted.**
	Comment. The Committee recommends including the above wording in Section 102. Certification Requirements. F. Certification Renewal. B.	

SECTION	COMMENT	DEPARTMENT RESPONSE
104	A. Applicants for reciprocal Certification shall submit to the Department a completed application, on a form prescribed, prepared, and furnished by the Department prior to Certification by reciprocity. ~~Athletic Trainers from other states or territories performing athletic training duties for collegiate and professional organizations or individuals participating in events, camps, tournaments, and other short term activities shall apply for reciprocal Certification~~. Athletic Trainers desiring to work camps, events, tournaments and caring for the general population of said activity(s) must apply for reciprocal certification. The applicant for reciprocity shall submit documentation that ~~her~~he or she is currently credentialed as an Athletic Trainer under the laws of another state or territory with the reciprocal application. B.Temporary Reciprocal Certification Athletic Trainers from other states or territories performing athletic training duties assigned by their employer for collegiate and professional organizations or individuals participating in events, tournaments, and other short term activities need not apply for reciprocal certification in caring for only those athletes to which they are assigned. The visiting Athletic Trainer must provide current proof of credentialing from his/her home state when requested.	**Partially Adopted.** 104.A Adopted Change (only) 15 U.S.C. § 8601. Protections for covered sports medicine professionals provides person who meet the federal statute to go into other states with the sports teams they treat and treat them in those states without having to seek an actual license from the other state. It gives a deemed as, or treated as, status to them.
	Comments. The Committee recommends the above changes for Section 104. Reciprocity. A. and the inclusion of Section 104. Reciprocity. B. Temporary Reciprocal Certification. This is intended to clarify who is and who is not required to apply for Reciprocal Certification.	

SECTION	COMMENT	DEPARTMENT RESPONSE
105.A	Strike section. A. ~~An individual employed by the South Carolina Department of Education, local boards of education, or private secondary or elementary schools for the treatment of injuries received by students participating in school sports activities prior to June 19, 1984 are exempt from Certification provided he or she submits proof of continued employment to the Department.~~	**Adopted.**
	Comments. The Committee recommends striking Section 105. Exemption from Certification. A. as it is not an accurate statement. These individuals are not exempt, they are eligible for inclusion in Section 106. Grandfather Provision.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
105	B. An individual serving as ~~a~~an Athletic Trainer student or student aide or in any similar position if the service is carried out under the supervision of a Physician oran Athletic Trainer is exempt from Certification.	**Not adopted.** This entire section was struck through as it was the language from statute and therefore not necessary for the regulation.
	Comments. The Committee recommends the above change to Section 105. Exemption from Certification. B. These individuals must work under the supervision of an Athletic Trainer.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
108	Remove.	**Adopted.**
	Comments. The Committee recommends doing away with Section 108. Professional Identification. The previous content is recommended to be included Section 102. Certification Requirements. A. Certification. 4.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
109	Renumber to 108	**Adopted.**
	Comment. With the deletion of Section 108. Professional Identification. This Section number should be changed.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
109	Change "the facility" to "the Athletic Trainer"	**Adopted.**
	Comment. The Committee recommends the change to Section 108. Variance. The Department does not regulate the facilities that employ Athletic Trainers.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
201	Change "licensed facility" to "certified individual, or individual"	**Adopted**
	Comment. The Committee recommends the above change to Section 200 - Enforcing Regulations 201. General. The Department does not regulate Facilities that employ proposed or certified individuals or individual.	

SECTION	COMMENT	DEPARTMENT RESPONSE
302.A.3	Change "II or III" to "I or II"	**Adopted.**
	Comment. The Committee recommends correcting the typo in the above paragraph to reflect correct class of violations.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
302.D	3rd ~~1000~~1500-5,000	**Adopted.**
	Comment. The Committee recommends the changes to Section 302. Violation Classifications. D. Monetary Penalties. Frequency of Violation (chart).	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
303	Remove the past tense in the opening paragraph.	**Adopted.**
	Comment. The Committee recommends the above changes to correct tense.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
500.B	Change to read "B. Two continuing education course(s) approved by the Department in consultation with the Athletic Trainers' Advisory Committee must be obtained and submitted for each renewal period."	**Adopted.**
	Comment. The Committee recommends specifying the number of continuing education courses that must be obtained and submitted for each renewal period.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
700	Comment. The Committee applauds the DHEC Healthcare Quality Team for the inclusion of Section 700 in the document.	**Thank you.**
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
700.B.4	Comment. The Committee recommends adding punctuation(comma) following the word "Treatment" in Section 700. Patient Care and Records. B. 4. Treatment Rehabilitation and Re-Conditioning.	**Adopted.**
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
700.C	Add the word "treatment" before each occurance of the word "program"	**Adopted.**
	The Committee recommends the inclusion of the term "treatment" in Section 700 Patient Care and Records. C. Program Discontinuation. This is to distinguish the treatment program from Preventative Care and Immediate Care Programs.	

(x) ACTION/DECISION
( ) INFORMATION

Date: September 10, 2020

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

From: Bureau of Water

Re: Notice of Proposed Regulation Amending R.61-43, *Standards for the Permitting of Agricultural Animal Facilities.*

I. Introduction

The Bureau of Water ("Bureau") proposes the attached Notice of Proposed Regulation amending R.61-43, *Standards for the Permitting of Agricultural Animal Facilities*, for publication in the September 25, 2020, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-1-60, 44-1-65, 46-45-80, and 48-1-10 *et seq*., which authorizes the South Carolina Department of Health and Environmental Control ("Department") to promulgate applicable regulations, procedures, or standards as may be necessary to protect human health and the environment. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these amendments.

II. Facts

1. The Bureau proposes amending R.61-43 to incorporate Act 139 of 2018, which amended S.C. Code Sections 44-1-60 and 46-45-80 and added Section 44-1-65. S.C. Code Section 44-44-1-65 establishes specific requirements for review and appeal of decisions by the Department regarding the permitting, licensing, certification, or other approval of poultry and other animal facilities, except for swine facilities. Section 44-1-60 sets procedures for reviewing permits for poultry and other animal facilities, except swine facilities, relating to appeals from Department decisions giving rise to contested cases. Section 46-45-80 includes provisions regarding setback distances for poultry and other animal facilities, except swine facilities, so as to prohibit requiring additional setback distances if established distances are achieved, allow waiver of the established setback distances in certain circumstances, and other purposes. Since the above-referenced statutory provisions added and removed requirements currently contained in R.61-43, the Department proposes further amendments to reflect these changes.

2. The Bureau also proposes amendments to correct typographical errors, citation errors, and other errors and omissions that have come to the Department's attention. These include correcting form references and regulation references, updating definitions, adding and/or omitting language and punctuation, clarification, reorganizing sections for consistency, and other such changes.

3. The Bureau held five stakeholder meetings between March 28, 2019 and August 25, 2020 to solicit stakeholder input, including open-invitation meetings, in person and virtually, and individual interest groups. The Bureau utilized the Department's website and agency calendar to advertise these meetings and emailed invitations to identified stakeholders. Bureau received feedback from the stakeholders and personnel considered their comments and suggestions regarding the proposed changes to the regulation.

4. The Department had a Notice of Drafting published in the June 26, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the July 27, 2020, close of the public comment period.

5. Appropriate Department staff conducted an internal review of the proposed amendments on August 3, 2020.

III. Request for Approval

The Bureau of Water respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 25, 2020, *State Register*.

Dr. Michael Marcus
Bureau Chief

Myra Reece
Director

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the June 26, 2020, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-43, *Standards for the Permitting of Agricultural Animal Facilities*

September 10, 2020

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-60, 44-1-65, 46-45-80, and 48-1-10 et seq.

61-43. Standards for the Permitting of Agricultural Animal Facilities.

Preamble:

The Department of Health and Environmental Control ("Department") proposes amending R.61-43, Standards for the Permitting of Agricultural Animal Facilities, to incorporate Act 139 of 2018, which amended S.C. Code Sections 44-1-60 and 46-45-80 and added Section 44-1-65. S.C. Code Section 44-1-65 establishes specific requirements for review and appeal of decisions by the Department regarding the permitting, licensing, certification, or other approval of poultry and other animal facilities, except for swine facilities. Section 44-1-60 sets procedures for reviewing permits for poultry and other animal facilities, except swine facilities, relating to appeals from Department decisions giving rise to contested cases. Section 46-45-80 includes provisions regarding setback distances for poultry and other animal facilities, except swine facilities, so as to prohibit requiring additional setback distances if established distances are achieved, allow waiver of the established setback distances in certain circumstances, and other purposes.

The Department also proposes amendments to correct typographical errors, citation errors, and other errors and omissions that have come to the Department's attention. These include correcting form references and regulation references, updating definitions, adding and/or omitting language and punctuation, clarification, reorganizing sections for consistency, and other such changes. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these amendments.

The Department published a Notice of Drafting in the June 26, 2020, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Table of Contents – amended to reflect proposed changes in Text.
Part 50 – general definitions, adding, deleting, updating, clarifying, deleted codification throughout the definitions.
Section 100.10 – amended title and language throughout for clarity and consistency.
Section 100.20 – recodified to reflect proposed changes. Amended for clarity and consistency.
Section 100.30 – amended for clarity and consistency.
Section 100.40 – recodified to reflect proposed amendments and removed references to repealed regulations.
Section 100.50 – amended for clarity and consistency.
Section 100.60 – amended method and time requirements of public notice. Amended public hearing requirement. Amended for clarity and consistency.
Section 100.70 – recodified to reflect proposed changes. Amended for clarity and consistency and removed variability of setbacks for consistency throughout the regulations. Removed language for stayed permits.
Section 100.80 – recodified to reflect proposed changes. Re-organized for clarity and consistency.

Section 100.90 – amended for clarity and consistency.
Section 100.100 – amended for clarity and consistency. Added language for ease of use. Amended for clarity and consistency and removed variability of setbacks for consistency throughout the regulations.
Section 100.110 – amended for clarity and consistency.
Section 100.120 – amended for clarity and consistency.
Section 100.130 – added language for phasing out option for burial. Amended for clarity.
Section 100.140 – amended for clarity and consistency. Relocated 100.140.J to 100.100.B.23 for clarity and consistency.
Section 100.150 – removed limitations of odor interpretation. Amended for clarity and consistency. Recodified.
Section 100.160 – amended for clarity and consistency.
Section 100.170 – amended for clarity.
Section 100.180 – amended for consistency.
Section 100.190 – amended for clarity, consistency and content.
Section 100.200 – amended for consistency.
Section 200.10 – amended for clarity, consistency and content.
Section 200.20 – amended for consistency.
Section 200.30 – amended for clarity.
Section 200.40 – content removed due to statute. Amended for content and consistency. Recodified.
Section 200.50 – amended for clarity, consistency and content.
Section 200.60 – amended for clarity, consistency and content. Amended for cost savings.
Section 200.70 – amended due to statute. Amended for clarity, consistency and content. Removed language for stayed permits.
Section 200.80 – amended for clarity, consistency and content. Removed due to statute. Recodified.
Section 200.90 – amended for clarity, consistency and content.
Section 200.100 – amended for clarity, consistency and content.
Section 200.110 – amended for clarity.
Section 200.120 – amended for clarity and content.
Section 200.130 – amended for clarity and content. Recodified.
Section 200.140 – amended for consistency. Relocated 200.140.J to 200.100.B.23 for consistency.
Section 200.150 – amended for clarity, consistency and content. Recodified.
Section 200.160 – amended for clarity, consistency and content.
Section 200.180 – amended for consistency.
Section 200.190 – amended due to statute. Amended clarity and consistency.
Section 300.30 – amended for consistency.
Section 300.40 – amended for clarity, consistency and content.
Section 300.50 – amended for clarity and consistency.
Section 400.10 – amended for clarity, consistency and content.
Section 400.20 – amended for clarity and consistency.
Section 400.30 – amended due to regulation no longer exist. Amended for content. Recodified.
Section 400.40 – amended for clarity, consistency and content.
Section 400.50 – amended for clarity, consistency and cost savings. Removed language for stayed permits.
Section 400.60 – amended for clarity, consistency and content. Recodified.
Section 400.70 – amended for consistency.
Section 400.80 – amended for clarity, consistency and content. Recodified.
Section 400.90 – amended for clarity and consistency.
Section 400.100 – amended for clarity, consistency and content.
Section 400.110 – amended for consistency.
Section 400.120 – amended for consistency and content. Recodified.
Section 500.10 – amended for content.
Section 500.20 – amended for content. Recodified.

Section 500.50 – amended for consistency and content.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendment to Chuck Williams of the Bureau of Water; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; williacj@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 26, 2020, the close of the comment period.

The Board will conduct a public hearing on the proposed amendments during its December 10, 2020, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agenda.

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

Preliminary Fiscal Impact Statement

The proposed amendments have no substantial fiscal or economic impact on the state or its political subdivisions. There are no anticipated additional costs 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.61-43, Standards for the Permitting of Agricultural Animal Facilities.

Purpose: The Department proposes amending R.61-43 to incorporate statutory changes made by the General Assembly's passage of Act 139 of 2018 and to correct typographical errors, citation errors, and other errors and omissions. These amendments expand and clarify definitions applicable to agricultural animal facility regulations and standards, streamline permitting options, clarify reporting requirements, identify the Department's consistent noticing method, improve the regulation's organizational structure, and provide corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of R.61-43.

Legal Authority: 1976 Code Sections 44-1-60, 44-1-65, 46-45-80, and 48-1-10 et seq.

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

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

The Department proposes amending R.61-43 to adopt the changes of Act 139 that amended S.C. Code Sections 44-1-60 and 46-45-80 and added Section 44-1-65. S.C. Code Section 44-1-65 establishes specific requirements for review and appeal of decisions by the Department regarding the permitting, licensing, certification, or other approval of poultry and other animal facilities, except for swine facilities. Section 44-1-60 sets procedures for reviewing permits for poultry and other animal facilities, except swine facilities, relating to appeals from Department decisions giving rise to contested cases. Section 46-45-80 includes provisions regarding setback distances for poultry and other animal facilities, except swine facilities, so as to prohibit requiring additional setback distances if established distances are achieved, allow waiver of the established setback distances in certain circumstances, and other purposes. Since the above-referenced statutory provisions added and removed requirements currently contained in R.61-43, the regulation is amended to reflect these changes.

The Department also proposes amendments to correct typographical errors, citation errors, and other errors and omissions that have come to the Department's attention. These include correcting form references and regulation references, updating definitions, adding and/or omitting language and punctuation, clarification, reorganizing sections for consistency, and other such changes.

The proposed amendments seek to simplify, clarify, and correct elements of the Department's agriculture animal facility permitting regulations while supporting the Department's goal of promoting and protecting the health of the public and the environment in an efficient and effective manner.

DETERMINATION OF COSTS AND BENEFITS:

The Department does not anticipate an increase in costs to the state, its political subdivisions, or the regulated community resulting from these proposed revisions. Proposed changes to the public notice process will be a cost saving measure to the applicants and the Department, public notices will be available on the Department website, decreasing the cost of publishing the notices in the local newspapers. The proposed changes are meant to create a more usable and functional regulation that will assist the regulated community and the citizens of South Carolina.

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:

These proposed amendments seek to provide continued state-focused protection of the environment and public health.

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

If these proposed revisions are not implemented, R.61-43 will not include the policy initiatives advanced by Act 139.

Statement of Rationale:

The Department proposes amending R.61-43, Standards for the Permitting of Agricultural Animal Facilities, to incorporate statutory changes made by the General Assembly's passage of Act 139 of 2018 and to correct typographical errors, citation errors, and other errors and omissions. These amendments expand and clarify definitions applicable to agricultural animal facility regulations and standards, streamline permitting options, clarify reporting requirements, identify the Department's consistent noticing method, improve the regulation's organizational structure, and provide corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of R.61-43.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-43. Standards for the Permitting of Agricultural Animal Facilities.

Statutory Authority: ~~1976~~ S.C. Code Sections ~~48-1-30, 47-20-40, 47-20-60, and 47-20-160 et seq.~~44-1-60, 44-1-65, 46-45-80, and 48-1-10 *et seq*.

Table of Contents

~~Part 50. General Definitions.~~

PART 50
GENERAL DEFINITIONS

For purposes of this regulation, the following definitions apply:

"Active Animal Facility" means a facility with a minimum of 30,000 pounds normal production animal live weight and in production.

"Affected Person" means a property owner with standing within a one (1)-mile radius of the proposed building footprint or permitted poultry facility or other animal facility, except a swine facility, who is challenging on his own behalf the permit, license, certificate, or other approval for the failure to comply with the specific grounds set forth in the applicable Department regulations governing the permitting of poultry facilities and other animal facilities, other than swine facilities.

~~A.~~"Agricultural animal" means an animal confined in an agricultural facility.

~~B.~~"Agricultural facility" means a lot, building, or structure, which is used for the commercial production of animals in an animal facility.

~~C.~~"Agronomic rate" ~~is~~means the animal manure and other animal by-products' application rate designed: (1) to provide the amount of nitrogen needed by the food crop, feed crop, fiber crop, cover crop, or vegetation grown on the land ~~and~~; (2) to minimize the amount of nitrogen in the animal manure that passes below the root zone of the crop or vegetation grown on the land to ~~the~~ groundwater ~~and~~; (3) to provide the amount of other organic and inorganic plant nutrients which promote crop or vegetative growth, such as calcium-carbonate equivalency; and (4) to provide the amount of phosphorus needed by the crop or vegetation grown on the land without causing an excessive buildup of phosphorus in the soil.

~~D.~~"Animal" means any domesticated animal.

~~E.~~"Animal by-product" means a secondary or incidental product of animal production that may include bedding, spilled feed, water or soil, milking center washwater, contaminated milk, hair, feathers, dead animals or other debris. This definition may also refer to dead animal or animal manure compost.

~~F.~~"Animal facility" means an agricultural facility where animals are confined and fed or maintained for a total of forty-five (45) calendar days or more in a twelve (12)-month period and crops, vegetative, forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. Structures used for the storage of animal manure and other animal by-products from animals in the operation also are part of the animal facility. Two (2) or more animal facilities under common ownership or management are considered to be a single animal facility if they are adjacent ~~or utilize a common system for animal manure storage~~.

~~G.~~"Animal Facility Management Plan" means a plan prepared by the United States Department of Agriculture's Natural Resources Conservation Service (USDA-NRCS) or a professional engineer detailing the management, handling, treatment, storage, or utilization of manure generated in an animal facility. This plan shall include facility management details and a detailed map of each manure utilization area showing all buffer zones and setbacks, a description of the land use, the crops grown on the site, the timing for application of ~~swine~~ manure to the land and a land use agreement if the site is not owned by the permittee.

"Animal Feeding Operation" means a lot or facility where animals have been, are, or will be stabled or confined and fed for a total of forty-five (45) calendar days or more in any twelve (12)-month period.

~~H.~~"Animal manure" means animal excreta or other commonly associated organic animal manures including, but not limited to, bedding, litter, feed losses, or water mixed with the manure.

~~I.~~"Annual animal manure application rate" ~~is~~means the maximum amount of animal manure that can be agronomically applied to a unit area of land during any 365-day period.

~~J.~~"Annual constituent loading rate" means the maximum amount of a constituent that can be applied to a unit area of a manure utilization area during any 365-day period.

"Application rate" means the amount of manure applied at any one time based on agronomic rates.

"Approval to Operate (ATO)" means a letter from the Department granting approval to place the facility into operation.

~~K.~~"Average animal live weight" means the sum of the average exit weight of the animal from the facility and the average entry weight divided by two, as shown by the following formula:

Average animal live weight = (Average Exit Weight + Average Entry Weight)/2

~~L.~~"Broker" means a person who accepts or purchases ~~dry~~ animal manure or other animal by-products from agricultural facilities and transfers this product to a third party for land application.

"Certification of Construction" means a document, certified by the consultant, PE, or NRCS staff, that a certain construction project has been completed in accordance with the terms, conditions, and specifications contained in the permit of applicable regulations.

~~M.~~"Closed facility" means an animal facility that has ceased operations (no confined animals at the facility) and is no longer in production, and all lagoons and waste storage ponds have been properly closed out and cannot be placed back into operation without a new permit.

~~N.~~"Commercial Facility" means an animal facility that produces animals or animal by-products for commercial sale, boards animals, rents animals, or provides a service utilizing the animals for a fee.~~The facility is considered commercial if the owner earned at least one thousand dollars gross farm income in at least three of the first five years.~~

~~O.~~"Compost" ~~is~~means an organic soil conditioner that has been stabilized to a humus-like product, is free of viable human and plant pathogens and plant seeds, does not attract insects or vectors, can be handled and stored without nuisance, and is beneficial to the growth of plants.

~~P.~~"Composting" ~~is~~means the biological decomposition and stabilization of organic substrates, under conditions that allow development of thermophilic temperatures as a result of biologically produced heat, to produce a final product that is stable, free of pathogens and plant seeds, and can be beneficially applied to land. Composting requires special conditions of moisture and aeration to produce thermophilic temperatures.

"Concentrated Animal Feeding Operation (CAFO)" means as defined by the Environmental Protection Agency (EPA).

"Confined Animal Manure Management (CAMM) Certification" means an operator, manager, or owner of an animal facility or manure utilization area, has received certification by completing a class and passing

an exam that is provided by Clemson University, Clemson Extension, the South Carolina Department of Health and Environmental Control, and the USDA Natural Resource Conservation Service.

~~Q.~~"Constituent limit" ~~is~~means a numerical value that describes the amount of a constituent allowed per unit amount of animal manure (e. g., milligrams per kilogram of total solids); the amount of a constituent that can be applied to a unit area of land (e. g., pounds per acre); or the volume of a material that can be applied to a unit area of land (e.g., gallons per acre).

~~R.~~"Cover crop" ~~is~~means a small grain crop, including, but not limited to, oats, wheat, or barley; grasses; or other crop grown for agronomic use or to maintain topsoil and prevent soil erosion.

"Critical Habitat" means the term used to define those areas of habitat containing physical and biological features that are essential for an endangered or threatened species to recover and that require special management or protection.

~~S.~~"Cumulative constituent loading rate" means the maximum amount of a constituent that can be applied to an area of land.

~~T.~~"Cumulative impacts" means an increase or enlarging of impact to the environment or community by the successive addition or accumulation of animal facilities in an area.

~~U.~~"CWA" means the Clean Water Act (formerly referred to as the Federal Water Pollution Control Act or Federal Water Pollution Control Act Amendments of 1972) Pub. L. 92-500, as amended by Pub. L. 95-217, Pub. L. 95-576, Pub. L. 96-483, and Pub. L. 97-117, 33 U.S.C. 1251 et seq. Specific references to sections within the CWA shall be according to Pub. L. 92-500 notation.

~~V.~~"Deemed Permitted Facility" means an agricultural animal facility that held a valid permit from the Department for their swine facility prior to July 1, 1996, or for their animal facility prior to June 26, 1998.

~~W.~~"Department" means the South Carolina Department of Health and Environmental Control.

"Discharge" means any release, emission or dismissal of sewage, industrial waste, agriculture waste, or other waste into any Waters of the State, whether treated or not.

"Downwind Receptors" means virtual three-dimensional coordinates placed off site where the concentrations of emissions would be measured for comparison to air quality standards.

~~X.~~"Dry manure" means manure, bedding, litter, feed losses, or composted animal material (animal manure or dead animals) that is not in a liquid form. Dry animal manure can normally be easily handled with a shovel or other similar equipment and it can be placed in piles without liquid manure or leachate drainage occurring.

~~Y.~~"Dry weight basis" means calculated on the basis of having been dried at 105 degrees Celsius until reaching a constant mass (i.e., essentially 100 percent solids content).

~~Z.~~"EPA" means the United States Environmental Protection Agency.

~~AA.~~"Ephemeral stream" means a stream that flows only in direct response to rainfall or snowmelt in which discrete periods of flow persist no more than twenty-nine (29) consecutive days per event.

"Evergreen Buffer" means trees that have foliage remaining green and functional through at least more than one growing season and are not considered deciduous.

~~BB.~~"Excessive Mortality" means total animal mortality in any one twenty-four (24)-hour period that exceeds the design capacity of the normal method of dead animal disposal. This may include utilizing the barns to compost the excessive mortality.

~~CC.~~"Expansion" means an increase in the permitted number of animals or normal production animal live weight ~~at the facility~~ that will result in physical construction at the facility. ~~For facilities with a lagoon, treatment system or manure storage pond, expansion means an increase due to construction in the maximum capacity of the existing lagoon, treatment system or manure storage pond as determined using the appropriate design standards of the United States Department of Agriculture's Natural Resource Conservation Service.~~ An animal manure treatment lagoon that is converted to an animal manure storage pond is considered an expansion of the facility. For facilities permitted prior to 1998, where the treatment/storage design function was not clearly specified, the Department shall review the facility's operation records and compliance history to determine the current function and condition of the manure handling structures. If the existing structure can handle additional animals, without physical alteration, significant changes in the original function of the structure, or any significant increase in odor, the Department may allow this increase in animals without classifying the change as an expansion.

"Feedlot" means an animal feeding operation (AFO) which is used in intensive animal farming for finishing livestock.

~~DD.~~"FEMA" means the Federal Emergency Management Agency.

~~EE.~~"Feed crops" ~~are~~means crops produced primarily for consumption by animals. These include, but are not limited to~~:~~ corn, grains, and grasses.

~~FF.~~"Fiber crops" ~~are~~means crops including, but not limited to, flax and cotton.

~~GG.~~"Floodplain" means land adjacent to water bodies that periodically becomes temporarily inundated with water during or after rainfall events. The land inundated from a flood whose peak magnitude would be experienced on an average of once every 100 years is the 100-year floodplain. The 100-year flood has a ~~1%~~one percent (1%) probability of occurring in one given year.

~~HH.~~"Food crops" ~~are~~means crops produced primarily for human consumption. These include, but are not limited to, fruits, vegetables, and grains~~. and tobacco~~.

"Footprint" means the area of ground covered by an agricultural facility (i.e., the part of the property where the animal facility is constructed).

"Freeboard" means additional capacity in a storage/treatment structure designed to provide a safety margin of storage in the event that a rainfall occurs when the structure is full. The design storm is normally a twenty-five (25) year storm of twenty-four (24) hours duration.

~~II.~~"Groundwater" ~~is~~means water below the land surface in the saturated zone.

"Inactive Facility" means an animal facility that is not considered in production, but the facility and/or lagoon(s)/waste pond(s) have not been properly closed out. The owner/operator/permittee will continue to pay the annual fees throughout the inactive period of the permit, will be required to maintain the facility and/or lagoon(s)/waste storage pond(s), and will be inspected by the Department on a routine basis.

~~JJ.~~"Integrator" or "Integrating company" means any entity or person(s) who contracts with agricultural animal producers to grow animals to be supplied to this person(s) at the time of removal from the animal growing houses or facilities and exercises substantial operational control over an animal facility, along with the owner/operator of the facility. Substantial operational control includes, but is not limited to, the following: directs the activities of persons working at the animal facility either through a contract, direct supervision, or on-site participation; owns the animals; or specifies how the animals are grown, fed, or medicated. This definition does not include independent producers that contract with other independent producers to accomplish a portion of the animal growing process under contract.

~~KK.~~"Intermittent stream" means a stream that generally has a defined natural watercourse, which does not flow year-round but flows beyond periods of rainfall or snowmelt.

~~LL.~~"Lagoon" means an impoundment used in conjunction with an animal facility, the primary function of which is to store or stabilize, or both, manure, organic wastes, wastewater, and contaminated runoff.

~~MM.~~"Land application" ~~is~~means the spraying or spreading of manure or other animal by-products onto the land surface; the injection of manure below the land surface into the root zone; or the incorporation of manure into the soil so that the manure can either condition the soil or fertilize crops or vegetation grown in the soil.

"Land Applier" means any person who accepts or purchases manure or other animal by-products from agricultural facilities for use as a fertilizer or soil enhancer on land either owned, leased, or managed by the land applier.

~~NN.~~"Large Animal Facility" means an animal facility (excluding swine facilities) that has a capacity for more than 500,000 pounds and less than 1,000,000 pounds of normal production animal live weight at any one time.

~~OO.~~"Large Swine Facility" means a swine facility with a capacity for greater than 500,000 pounds and less than 1,000,000 pounds of normal production animal live weight at any one time.

~~PP.~~"Liquid manure" means manure that by its nature, or after being diluted with water, can be pumped easily and ~~which~~ is removed, either intermittently or continuously, from an animal lagoon, manure storage pond, or treated effluent from other types of animal manure treatment systems.

~~QQ.~~"Manure" means the fecal and urinary excretion of livestock and poultry. This material may also contain bedding, spilled feed, water, or soil. It may also include wastes not associated with livestock excreta, such as milking center washwater, contaminated milk, hair, feathers, or other debris. Manure may be described in different categories as related to solids and moisture content, such as dry manure and liquid manure.

"Manure Application Rate" means managing manure to optimize its beneficial returns while minimizing its potential environmental impact by land applying at agronomic rates.

~~RR.~~"Manure storage pond" means a structure used for impounding or storing manure, wastewater, and contaminated runoff as a component of an agricultural manure management system. Manure is stored for a specified period of time, one (1) year or not less than ninety (90) calendar days, and then the pond is emptied. This definition does not include tanks or other similar vessels.

~~SS.~~"Manure utilization area" means land on which animal manure (including swine manure) is spread as a fertilizer and is synonymous with land application site or land application area

"Mass Burial Site" means a section of land approved by the Department designated to handle excessive mortality.

~~TT."mg/l" means milligrams per liter.~~

~~UU.~~"NRCS" ~~is~~means the Natural Resources Conservation Service of the United States Department of Agriculture.

~~VV.~~"NRCS-CPS" ~~is~~means the Natural Resources Conservation Service's Conservation Practice Standards as given in the USDA-NRCS, SC Handbook of Conservation Practices.

~~WW.~~"Normal production animal live weight at any one time" means the maximum number of animals at the facility at any one time multiplied by the average animal live weight of those animals.

"Notice of Intent (NOI)" means a document provided by the Department used by an applicant to notify the surrounding property owners of the applicant's intent to construct a permitted animal facility.

~~XX.~~"Nuisance" means a condition causing annoyance or danger ~~or annoyance~~ to a limited number of persons or to the general public as determined by the Department.

"Operator" means the person(s) who manage(s) a permitted animal facility and may be CAMM certified.

"Outstanding Recreational or Ecological Resource Waters (ORW)" means waters which are of exceptional recreational, ecological importance, or of unusual value. Such waters may include, but are not limited to: waters in national or state parks or wildlife refuges; waters supporting threatened or endangered species; waters under the National Wild and Scenic Rivers Act or South Carolina Scenic Rivers Act; waters known to be significant nursery areas for commercially important species or known to contain significant commercial or public shellfish resources; or waters used for or having significant value for scientific research and study.

"Owner" means the owner or operator of any facility of activity subject to this regulation.

~~YY.~~"Pasture" ~~is~~means land on which animals feed directly on feed crops including, but not limited to, legumes, grasses, grain stubble, or stover.

"Permit" means any license, certificate, registration, variance, or other approval issued by or required by the Department or any of its divisions, pursuant to any statute or regulation.

"Permit Extension" means a one (1)-year extension with justification that must be applied for in writing ten (10) calendar days prior to the permit expiration date.

"Permit Modification" means a minor or moderate change to a facility's permit that is considered, as determined by the Department, to not change the general operations of the permitted site but is necessary to continue the regulated operation of the facility. Permit Modifications are not required to be Public Noticed.

"Permittee" means any person authorized to conduct any activity or business pursuant to a valid permit issued by or filed with the Department.

"Permitting Decision" means any decision by the Department to issue, modify, deny, or withdraw the permit.

~~ZZ.~~"Person" means any individual, public or private corporation, political subdivision, association, partnership, corporation, municipality, ~~S~~state or ~~F~~federal agency, industry, co-partnership, firm, trust, estate, any other legal entity whatsoever, or an agent or employee thereof.

"Plant Available Nitrogen (PAN)" means the quantity of nitrogen made available during the growing season after fertilizing materials are applied. A certain amount of the nitrogen is immobilized, and the remaining nitrogen is available to the plant.

~~AAA.~~"Potable water well" means any well designed and/or constructed to produce potable water for consumption by humans or animals.

~~BBB.~~"Producer" ~~is~~means a person who grows or confines animals; a person responsible for the manure produced at an animal facility; a person processing manure; and/or a person responsible for the land application of manure.

"Production" means a facility that meets the permit requirements based on 30,000 pounds of Normal Production Animal Live Weight.

~~CCC.~~"Professional Engineer" or "Engineer" ~~is~~means a person who, by reason of his or her special knowledge of the mathematical and physical sciences and the principles and methods of engineering analysis and design, acquired by professional education and practical experience, is qualified to practice engineering, all as attested by his or her legal registration as a professional engineer in ~~this State~~South Carolina.

"Public Hearing" means a proceeding, properly noticed in accordance with applicable state and federal laws, during which comments are received and testimony is taken to establish a record of concern prior to an administrative action by the Department.

"Public Notice" means the notice of an application or of proposed agency action published in accordance with applicable statutes and regulations.

~~DDD.~~"Range land" ~~is~~means open land with indigenous vegetation.

"Ranged Animal Facility" means the size of the range area is sufficient to allow for the natural degradation or utilization of the manure with no adverse impact to the environment. Ranged facilities shall also maintain adequate vegetative buffers between the animal range and the adjacent property lines and/or Waters of the State to mitigate runoff from reaching adjacent property and/or Waters of the State.

"Replacement in Kind" means construction of the same size or less of animal growing barn(s), and the same number or less of animal live weight, at the same location as the barn(s) being replaced.

~~EEE.~~"Residence" means a permanent inhabited dwelling, any existing church, school, hospital, or any other structure which is routinely occupied by the same person or persons more than twelve (12) hours per day or by the same person or persons under the age of eighteen (18) for more than two (2) hours per day, except those owned by the applicant.

"Rolling Average" means the laboratory results from the most recent analysis averaged with the previous manure analysis for a particular form of manure. The rolling average analysis sequence should be restarted after any major modification or changes to the lagoon/waste storage pond.

"Routinely" means a regular course of procedure.

~~FFF.~~"Runoff" ~~is~~means rainwater or other liquid that drains overland on any part of a land surface and runs off of the land surface.

~~GGG.~~"Seasonal High Water Table" ~~is~~means the surface between the zone of saturation and the zone of aeration, where the pore water pressure is equal to atmospheric pressure, and which exhibits the shallowest average water depth in relation to the surface during the wettest season.

~~HHH.~~"Small Animal Facility" means an animal facility (other than swine) that has a capacity for 500,000 pounds of normal production animal live weight or less at any one time.

~~III.~~"Small Swine Facility" means a swine facility with a capacity for 500,000 pounds of normal production animal live weight or less at any one time.

~~JJJ.~~"Source Water Protection Area" means an area either above and/or below ground that is the source of water for a public drinking water system via a surface water intake or a water supply well that is designated by the State for increased protection.

"South Carolina National Heritage Corridor" means a National Heritage Area, federally designated in 1996, spanning seventeen (17) counties and 320 miles across South Carolina, and committed to promoting and preserving the cultural, natural, and historic resources of South Carolina.

~~KKK.~~"State" means ~~the State of~~ South Carolina.

"Surface Water Runoff" means the flow of water that occurs when excess stormwater, meltwater, or other sources flows over the Earth's surface.

~~LLL.~~"Swine" means a domesticated animal belonging to the porcine species.

~~MMM.~~"Swine by-product" means a secondary or incidental product of swine production that may include bedding, spilled feed, water or soil,~~milking center washwater, contaminated milk~~ hair, ~~feathers,~~ dead swine, or other debris. This definition may also refer to dead swine or swine manure compost.

~~NNN.~~"Swine facility" means an agricultural facility where swine are confined and fed or maintained for a total of forty-five (45) calendar days or more in a twelve (12)-month period and crops, vegetative, forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. Structures used for the storage of swine manure from swine in the operation are also ~~are~~ part of the swine facility. Two or more swine facilities under common ownership or management are considered ~~to be~~ a single swine facility if they are adjacent or utilize a common system for swine manure treatment and/or storage. For any new or expanding swine facility, the combined normal production of all swine facilities owned by the producer, and of all swine facilities owned by corporations having a common majority shareholder in common with the producer, within ~~twenty-five~~ 25 miles of the new or expanding facility shall be used to determine the normal production of the new or expanding facility. For example, when a new facility has a proposed capacity of 300,000 pounds of normal production and the producer owns two (2) other swine facilities within ~~twenty-five~~ 25 miles of the new or expanding swine facility and

the normal production of each facility is 400,000 pounds, the proposed swine facility's normal production is 1,100,000 (300,000 + 400,000 + 400,000) pounds.

~~OOO.~~"Swine manure" means swine excreta or other commonly associated organic animal manures including, but not limited to, bedding, litter, feed losses, or water mixed with the manure.

~~PPP.~~~~"µg/l" means microgram per liter.~~

~~QQQ.~~"Vector" means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

"Waiver" means a document recording the deferral of a right, claim, or privilege.

"Waste Storage Pond" means an earthen waste impoundment that temporarily stores organic wastes such as manure and wastewater.

~~RRR.~~"Wastewater" means any water ~~which~~that, during the confinement of animals or the handling, storage, or treatment of manure, dead animals, and litter, ~~etc.~~ comes into contact with the animals, manure, litter, or spilled feed~~, etc~~. Wastewater includes, but is not limited to, wash waters, contaminated milk, and storm water (except storm water runoff from land application areas where the application of manure has been properly applied) that comes into contact with manure.

~~SSS.~~"Watershed" means a drainage area contributing to a river, lake, or stream.

~~TTT.~~"Waters of the State" means lakes, bays, sounds, ponds, impounding reservoirs, springs, artesian wells, rivers, perennial and navigable streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within the territorial limits of the State, and all other bodies of water, natural or artificial, public or private, inland or coastal, fresh or salt, which are wholly or partially within or bordering the State or within its jurisdiction. This definition does not include ephemeral or intermittent streams. This definition includes wetlands as defined in this section.

~~UUU.~~"Wetlands" means lands that have a predominance of hydric soil, are inundated or saturated by water or groundwater at a frequency and duration sufficient to support a prevalence of hydrophytic vegetation typically adapted for life in saturated soil conditions, and, under normal circumstances, do support a prevalence of hydrophytic vegetation. Normal circumstances refer to the soil and hydrologic conditions that are normally present without regard to whether the vegetation has been removed. Wetlands shall be identified through the confirmation of the three wetlands criteria: hydric soil, hydrology, and hydrophytic vegetation. All three criteria shall be met for an area to be identified as wetlands. Wetlands generally include swamps, marshes, and bogs.

"X-Large Animal Facility" means an animal facility (excluding swine) with 1,000,000 pounds or more of normal production animal live weight at any one time.

"X-Large Swine Facility" means a swine facility with 1,000,000 pounds or more of normal production animal live weight at any one time.

PART 100
SWINE FACILITIES

100.10. Purpose, Applicability, Inactive Facilities, and Facilities Permitted Prior to the Effective Date of the Regulation.

A. Purpose.

1. To establish standards for the growing or confining of swine, processing of swine manure and other swine by-products, and land application of swine manure and other swine by-products in such a manner as to protect the environment, and the health and welfare of citizens of the State from pollutants generated by this process.

2. To establish standards, which consist of general requirements, constituent limits, management practices, and operational standards, for the utilization of swine manure and other swine by-products generated at swine facilities. Standards included in this part are for swine manure and other swine by-products applied to the land.

3. To establish standards for the frequency of monitoring and record keeping requirements for producers who operate swine facilities.

4. To establish standards for the proper operation and maintenance of swine facilities.

5. To establish criteria for swine facilities' and manure utilization areas' location as they relate to protection of the environment and public health ~~and welfare as outlined by statute~~. The location of swine facilities and manure utilization areas as they relate to zoning in an area is not covered in this regulation. Local county or municipal governments may have zoning requirements and ~~these~~this regulation~~s~~ neither interferes with nor restricts such zoning requirements. Permit applicants should contact local municipal and county authorities to determine any local requirements that may be applicable.

B. Applicability.

1. This part applies to:

a. All new swine facilities;

b. All expansions of existing swine facilities;~~and~~

c. New manure utilization areas for existing swine facilities~~.~~;

d. All inactive facilities; and

e. All facilities and lagoon closures.

2. This part applies to all swine manure and other swine by-products applied to the land.

3. This part applies to all land where swine manure and other swine by-products are applied.

C. Inactive Facilities.

1. If a swine facility is ~~closed~~inactive for two (2) years or less, a producer may resume operations of the facility under the same conditions by which it was previously permitted by notifying the Department in writing that the facility is being operated again.

2. For swine facilities that have been ~~closed~~inactive for more than two (2) years but less than five (5) years, the Department shall review the existing permit and modify its operating conditions as necessary prior to the facility being placed back into operation.

3. For swine facilities that have been ~~closed~~inactive for more than five (5) years, the producer shall properly close out any lagoon, treatment system, or manure storage pond associated with the facility. The closeout shall be accomplished in accordance with ~~Regulation~~R.61-82, Proper Closeout of Wastewater Treatment Facilities. The permittee shall submit a closeout plan that meets at a minimum NRCS-CPS within a time frame prescribed by the Department. Additional time may be granted by the Department to comply with the closeout requirement or to allow a producer to apply for a new permit under this regulation, as appropriate.

4. If a swine facility is ~~closes~~inactive for more than five (5) years, the permit is considered expired and the producer shall apply for a new permit. All requirements under this regulation ~~R.61-43~~ shall be met before the facility can resume operations.

5. During the closeout of the facilities and/or lagoons/waste storage ponds, annual fees are required to be paid until proper closeout is certified and approved.

D. Facilities Permitted Prior to the Effective Date of the Regulation.

1. All existing swine facilities with permits issued by the Department before July 1, 1996, do not need to apply for a permit as they are deemed permitted ~~(deemed permitted swine facilities)~~swine facilities unless they have been ~~closed~~ inactive for more than two (2) years or expand operations. These facilities shall meet the following sections of Part 100: Section 100.20 (Permits and Compliance Period); Section 100.90 items A, G, and N~~.~~–T (General Requirements for Lagoons, Treatment Systems, and Manure Storage Ponds); Section 100.100 ~~items B.1. 22.~~ (Manure Utilization Area Requirements); Section 100.110.G.-J. (Spray Application System Requirements); Section 100.120 A, C, and D (Frequency of Monitoring for Swine Manure); Section 100.130 A, B, C items 2-3 (Dead Swine Disposal Requirements); Section 100.140 A, C-J (Other Requirements); Section 100.150 B-G (Odor Control Requirements); Section 100.160 B-D (Vector Control Requirements); Section 100.170 (Record Keeping); Section 100.180 (Reporting); Section 100.190 A~~.~~–F~~.~~ (Training Requirements); and Section 100.2~~1~~00 (Violations). The capacity of a deemed permitted facility is the maximum capacity of the existing lagoon, treatment system, or manure storage pond as determined using swine lagoon, treatment system, or manure storage pond capacity design standards of the United States Department of Agriculture's Natural Resource Conservation Service.

2. All existing swine facilities with permits issued by the Department between July 1, 1996, and the effective date of ~~these~~this regulation~~s~~ do not need to apply for a new permit if they hold a valid permit from the Department, unless they have been ~~closed~~inactive for more than two (2) years. These facilities shall meet all the requirements of ~~these~~this regulation~~s~~.

3. All existing swine facilities that were constructed and placed into operation prior to July 1, 1996, but have never received an agricultural permit from the Department, shall apply for a permit from the Department. These facilities shall meet all the requirements of this regulation, as the Department determines appropriate. The Department shall review the site and make a determination on a case-by-case basis on which requirements are applicable.

4. An existing facility may be required to submit for approval an updated Animal Facility Management Plan on a case-by-case basis by the Department. The Department shall notify the permittee in writing of this requirement. The permittee ~~shall submit this updated plan within a time frame prescribed by the Department~~has six (6) months or an agreed upon time frame from the date of notification to submit an

updated Animal Facility Management Plan. Failure to submit the updated plan within this time frame is a violation of the South Carolina Pollution Control Act and ~~these~~this regulation~~s~~, and may result in permit revocation.

5. Both the setbacks and other requirements for manure utilization areas shall be met when a new manure utilization area (MUA) is added by the owner of any swine facility regardless of when the facility was permitted.

6. If an existing facility regulated under Part 200 of ~~these~~this regulation~~s~~ proposes to convert to a swine facility, it shall be considered a new swine facility under ~~these~~this regulation~~s~~. Converted facilities shall be permitted as new swine facilities and meet all criteria for new swine facilities before they begin operation as a swine facility.

7. If an existing swine facility proposes to expand operations or increase the number of permitted swine such that it falls into a new size classification, the facility shall be considered a new swine facility in that size classification under ~~these~~this regulation~~s~~. The facility shall meet all the requirements for the new classification.

100.20. Permits and Compliance Period.

A. Permit Requirement. Swine manure and other swine by-products from a new or expanded swine facility can only be generated, handled, stored, treated, processed, or land applied in the State in accordance with a permit issued by the Department under the provisions of this part. Existing producers that are required by the Department to update their Animal Facility Management Plan shall meet the requirements of this part to the extent practical as determined by the Department.

~~B. Large Swine Facilities with 1,000,000 pounds or more normal production live weight must also apply for an individual National Pollutant Discharge Elimination System (NPDES) permit for Confined Animal Feeding Operations (CAFO)in accordance with the provisions of Regulation 61-9.~~

~~C~~B. Permits issued under this regulation are no-discharge permits.

~~D~~C. The requirements in this part shall be implemented through a permit issued to any producer who operates a swine facility where swine manure and other swine by-products are generated, handled, treated, stored, processed, or land applied.

~~E~~D. The requirements under this part may be addressed in permits issued to producers who only land apply swine manure and other swine by-products.

~~F~~E. Notification Requirements. The permittee shall notify the Department in writing and receive written Departmental approval, except as otherwise noted, prior to any change in operations at a permitted facility, including, but not limited to, the following:

1. Change in ownership and control of the facility. The Department has thirty (30) calendar days from the receipt of a complete and accurate notification of transfer of ownership to either: request additional information regarding the transfer or the new owner; deny the transfer; or approve the transfer ~~of ownership~~. If the Department does not act within thirty (30) calendar days, the transfer is automatically approved. If additional information is requested by the Department in a timely manner, the Department shall act on this additional information, when it is received, within the same time period as the initial notification.

2. Increase in the permitted number of swine.

3. Increase in the normal production animal live weight of the existing permitted swine facility.

4. Addition of manure utilization areas.

5. Change in swine manure and other swine by-products treatment, handling, storage, processing, or utilization.

6. Change in method of dead swine disposal.

~~G~~F. ~~Permit Modification.~~Permit modifications for items 100.20.~~F~~FE.3 and 100.20.~~F~~FE.5 for facilities regulated under this part, which shall result in expansions, shall adhere to the requirements of this part and other applicable statutes, regulations, or guidelines.

~~H~~G. Permit modification for items 100.20.~~F~~FE.2-3 which result in an expansion may be required to obtain new written waivers or agreements for reduction of setbacks from adjoining property owners (if applicable).

100.30. Exclusions.

The following do not require permits from this part unless specifically required by the Department under Section 100.30.G.

A. Existing swine facilities that are deemed permitted under Section 100.10.D.1. are excluded from applying for a new permit unless an expansion is proposed, ~~a~~ new manure utilization areas ~~is~~are added, or ~~it is~~as required by the Department. New manure utilization areas added to an existing facility shall meet the appropriate requirements in this part. However, deemed permitted facilities shall meet the requirements of this regulation as outlined in Section 100.10.D~~.1.~~ (Purpose, Applicability, Inactive Facilities, and Facilities Permitted Prior to the Effective Date of the Regulation).

B. Except as given in Section 100.30.G, swine facilities that do not have a lagoon, manure storage pond, or liquid manure treatment system, having 10,000 pounds or less of normal production animal live weight at any one time, are excluded from obtaining a permit from the Department. However, these facilities shall have and implement an Animal Facility Management Plan for their facility that meets the requirements of this regulation.

C. Except as given in Section 100.30.G, swine facilities that do not have a lagoon, manure storage pond, or liquid manure treatment system, having more than 10,000 pounds of normal production animal live weight at any one time and less than 30,000 pounds of normal production animal live weight at any one time, are excluded from obtaining a permit from the Department. However, these facilities shall submit an Animal Facility Management Plan to the Department and implement an Animal Facility Management Plan for their facility that meets the requirements of this regulation.

D. Except as given in Section 100.30.G, ranged swine facilities where the size of the range area is sufficient to allow for natural degradation or utilization of the swine manure with no adverse impact to the environment are excluded from obtaining a permit from the Department. Ranged facilities shall also maintain adequate vegetative buffers between the swine range and Waters of the State.

E. Except as given in Section 100.30.G, swine facilities that ~~do~~are not ~~produce~~classified as swine for commercial purposes are excluded from obtaining a permit from the Department.

F. Except as given in Section 100.30.G, swine facilities that hold valid permits issued by the Department are not required to obtain a new permit if they decide to replace in kind any of the swine growing houses. ~~If the permittee chooses to leave the old swine houses in place to utilize for another purpose other than housing animals, the Department shall perform a preliminary site inspection for the proposed location of the replacement houses and approve the site prior to construction.~~

G. Swine ~~F~~ffacilities exempted under Sections 100.30.A, B, C, D, E, and F may be required by the Department to obtain a permit. The Department shall visit the site before requiring any of these facilities to obtain a permit.

100.40. Relationship to Other Regulations.

The following regulations are referenced throughout this part and may apply to facilities covered under this regulation.

~~A.Nuisances are addressed in Regulation 61-46.~~

~~B.~~A. Applications, application fees, and the time schedules governing the review of applications, and annual operating fees are addressed in ~~Regulation~~R.61-30, Environmental Protection Fees.

~~C.~~B. The proper closeout of wastewater treatment facilities ~~is~~are addressed in ~~Regulation~~R.61-82, Proper Closeout of Wastewater Treatment Facilities. This includes swine lagoons and manure storage ponds.

~~D.Permitting requirements for concentrated animal feeding operations as defined by Regulation 61-9 are contained in Regulation 61-9.~~

~~E.~~C. Setbacks and construction specifications for potable water wells and monitoring wells shall be in accordance with ~~Regulation~~R.61-71, Well Standards.

~~F.~~D. Permits for air emissions from incinerators are addressed in ~~Regulation~~R.61-62, Air Pollution Control Regulations and Standards.

~~G.~~E. Disposal of swine lagoon sludge in a municipal solid waste landfill unit is addressed in ~~Regulation~~ R.61-107.~~258~~19, Solid Waste Management: Solid Waste Landfills and Structural Fill.

~~H.~~F. Disposal of swine manure with domestic or industrial sludge is addressed in ~~Regulation~~ R.61-9, Water Pollution Control Permits, and permitted under R.61-9.

~~I. Procedures for contested cases are addressed in Regulation 61-72 and Rules of the State's Administrative Law Judge Division.~~

~~J.~~ G. Laboratory ~~C~~ccertification is addressed in ~~Regulation~~R.61-81, State Environmental Laboratory Certification Program.

~~K.~~H. Water Classifications and Standards are addressed in ~~Regulation~~R.61-68.

100.50. Permit Application Procedures (Animal Facility Management Plan Submission Requirements).

A. Preliminary Site Evaluations. The Department shall perform a preliminary evaluation of the proposed site at the request of the applicant. Written requests for a preliminary site inspection shall be made using a

form~~, as designated~~ provided by the Department. The Department shall not schedule a preliminary site inspection until all required information specified in the form has been submitted to the Department. This evaluation should be performed prior to preparation of the Animal Facility Management Plan. Once the preliminary site inspection is performed, the Department shall issue an approval or disapproval letter for the proposed site.

B. A producer who proposes to build a new swine facility or expand an existing swine facility shall make application for a permit under this part using an application form ~~as designated~~provided by the Department. The following information shall be included in the application package.

1. A completed and accurate application form.

2. An Animal Facility Management Plan prepared by qualified Natural Resources Conservation Service (NRCS) personnel or a S.C. registered professional engineer (PE). Other qualified individuals, such as certified soil scientists~~, etc.,~~ or S.C. registered professional geologists (PG), may prepare the land application component of an Animal Facility Management Plan. The Animal Facility Management Plan shall, at a minimum, contain:

a. Facility name, address, telephone numbers, email address (if applicable), county, and National Pollutant Discharge Elimination System Permit or other permit number (if applicable);

b. Facility location description and the zoning or land use restrictions in this area (this information is available from the county);

c. Applicant's name, address, email, and telephone number (if different from above);

d. Operator's name and CAMM number;

e. Facility capacity;

i. Number of swine;

ii. Pounds of normal production animal live weight at any one time;

iii. Amount in gallons of swine manure generated per year;

iv. Description of swine manure storage and storage capacity of lagoon, treatment system, or manure storage pond (if applicable); and

v. Description of swine manure and other swine by-products treatment (if any).

f. Concentration of constituents in swine manure including, but not limited to, the constituents given below:

i. Nutrients.

(a) Nitrate. (Only needed for aerobic treatment systems)

(b) Ammonium-Nitrogen.

(c) Total Kjeldahl Nitrogen (TKN).

(d) Organic Nitrogen (Organic Nitrogen = TKN - Ammonium Nitrogen)

(e) P_2O_5

(f) K_2O (potash).

ii. Constituents.

(a) Copper.

(b) Zinc.

iii. Name, address, S.C. lab certification number, and telephone number of the laboratory conducting the analyses.

~~iii~~iv. For new swine facilities, swine manure analysis information does not have to be initially submitted as the Department shall use swine manure analysis from similar sites or published data (such as: Clemson University, American Society of Agricultural Engineers, Midwest Planning Service Document, NRCS Technical Guide or equivalent) in the review of the application. Analysis of the actual swine manure generated shall be submitted to the Department six (6) months after a new swine facility starts operation or prior to the first application of swine manure to a manure utilization area, whichever occurs first. If this analysis is significantly different from the estimated analysis used in the permitting decision, the Department may require a permit modification as necessary to address the situation. Analysis shall be conducted by Clemson University Extension Service or a laboratory certified by the Department. This laboratory shall have and maintain certification for the constituents to be analyzed.

g. Swine manure and other swine by-products handling and application information shall be included as follows:

i. A crop management plan which includes the time of year of the swine manure and other swine by-products application and how it relates to crop type, crop planting, and harvesting schedule (if applicable) for all manure utilization areas;

ii. Name, address, email, and telephone number of the producer(s) that will land apply the swine manure and other swine by-products if different from the permittee;

iii. Type of equipment used to transport and/or spread the swine manure and other swine by-products (if applicable); and

iv. For spray application systems, plans and specifications with supporting details and design calculations for the spray application system.

h. Facility and manure utilization area information shall be included (as appropriate):

i. Name, ~~and~~ address, and tax map number of landowner and location of manure utilization area(s);

ii. List previous calendar years that swine manure and/or dry manure and other swine by-products were applied and application amounts, where available;

iii. Facility and manure utilization area location(s) on maps drawn to approximate scale including:

(a) Topography (7.5' minutes or equivalent) and drainage characteristics (including ditches);

(b) Adjacent land usage (within 1/4 mile of property line minimum) and location of inhabited dwellings and public places showing property lines and tax map number;

(c) All known water supply wells on the applicant's property and within 500 feet of the facility's footprint of construction or within 200 feet of any manure utilization areas;

(d) Adjacent ~~Waters of the State~~surface water bodies (including ephemeral and intermittent streams)~~ or the nearest waterbody~~;

(e) Swine manure utilization area boundaries and buffer zones;

(f) ~~R~~right-of-~~W~~ways (Utilities, roads, etc.);

(g) Soil types as given by soil tests or soil maps, a description of soil types, and boring locations (as applicable);

(h) Recorded Pplats, ~~S~~surveys, or other acceptable maps that include property boundaries; and

(i) Information showing the 100-year and 500-year floodplain as determined by FEMA.

iv. For manure utilization areas not owned by the permit applicant, a signed agreement between the permit applicant and the landowner acceptable to the Department detailing the liability for the land application. The agreement shall include, at a minimum, the following:

(a) Producer's name, farm name, farm address, CAMM number, and county in which the farm is located;

(b) Landowner's name, address, email, phone number;

(c) Location (map with road names, tax map numbers, and county identified) of the land to receive manure application;

(d) Field acreage, acreage less setbacks, and crops grown;

(e) Name of manure hauler;

(f) Name of manure applier;

(g) A statement that land is not included in any other management plans and manure or compost from another farm is not being applied on this land; and any manure utilization areas that are included in multiple Animal Facility Management Plans, identify the names of all facilities that include this manure utilization area in their plan; and

(h) A signed statement which informs the landowner that he is responsible for spreading and utilizing this manure in accordance with the requirements of the Department and ~~Regulation~~R.~~61-43~~this regulation.

~~v. For other manure utilization areas that are included in multiple Animal Facility Management Plans identify the names of all facilities that include this manure utilization area in their plan.~~

3. Groundwater monitoring well details and proposed groundwater monitoring program (if applicable).

4. The Animal Facility Management Plan shall contain an odor abatement plan for the swine facility, lagoon, treatment system, manure storage pond, and manure utilization areas. For more specific details, see Section 100.150 (Odor Control Requirements).

5. A Vector Abatement Plan shall be included for the swine facility, lagoon, treatment system, manure storage pond, and manure utilization areas. For more specific details, see Section 100.160 (Vector Control Requirements).

6. The Dead Swine Disposal Plan~~. The plan~~ shall include written details for the handling and disposal of dead swine. Plans should include method of disposal, any construction specifications necessary, and management practices. See Section 100.130 (Dead Swine Disposal Requirements) for ~~specific requirements on dead swine disposal~~more detailed information.

7. A Soil Monitoring Plan~~. A soil monitoring plan~~ shall be developed for all manure utilization areas~~,~~. ~~s~~See Section 100.100 (Manure Utilization Area Requirements) for more detailed information.

8. Plans and specifications for all other manure treatment or storage structures, such as holding tanks or manure storage sheds.

9. All "Notice of Intent to Build or Expand a Swine Facility" forms as provided by the Department and a tax map (or equivalent) to scale showing all neighboring property owners and identifying which property has inhabited dwellings that are required to be notified. See Section 100.60 (Public Notice Requirements) for more detailed information.

10. An Emergency Plan. The emergency plan shall, at a minimum, contain a list of entities or agencies the producer shall contact in the event of ~~a structural failure (such as a dike/dam breach)~~lagoon, treatment system, or manure storage pond breach, ~~major~~mass animal mortality, fire, flood, or other similar type problem. For facilities in the coastal areas of the State, the emergency plan shall address actions to be taken by a producer during hurricane season (such as providing additional freeboard during that time) and when advance warning is given on any extreme weather condition.

11. All waivers as specified in Section 100.80 (Facility, Lagoon, Treatment System, and Manure Storage Pond Siting Requirements), if applicable.

12. Application fee and the first year's operating fee as established by ~~Regulation~~R.61-30.

C. The Department may request an applicant to provide any additional information deemed necessary to complete or correct deficiencies in the swine facility permit application prior to processing the application or issuing, modifying, or denying a permit.

D. Applicants shall submit all required information in a format acceptable to the Department.

E. An application package for a permit is complete when the Department receives all of the required information which has been completed to its satisfaction. Incomplete submittal packages may be returned to the applicant by the Department.

F. Application packages for permit modifications ~~only need to~~must contain the information applicable to the requested modification or any additional information the Department deems necessary.

100.60. Public Notice Requirements.

A. Small Swine Facilities~~(500,000 pounds or less of normal production live weight)~~.

~~1. For persons seeking to construct a new small swine facility, the Department shall have the applicant notify all adjoining property owners and people residing on property within 1/4 mile (1320 feet) of the proposed location of the facility (footprint of construction) of the applicants intent to build a swine facility. The applicant shall use a notice of intent form provided by the Department. The Department shall also post up to four notices on the perimeter of the property or in close proximity to the property, in visible locations as determined by the Department. The notice of intent shall advise adjoining property owners that they can send comments on the proposed animal facility directly to the Department.~~

1. For persons seeking to construct a new small swine facility, the applicant shall:

a. Notify all adjoining property owners and people residing on property within 1/4 mile (1,320 feet) of the proposed location of the facility (footprint of construction and manure storage pond) of the applicant's intent to build a swine facility.

b. Notify the parties listed in A.1.a. of this section using an NOI form provided by the Department. The NOI shall advise the adjoining property owners that they may send comments on the proposed animal facility directly to the Department.

~~2. For existing small swine facilities seeking to expand their current operations, the Department shall post up to four notices of intent to expand a swine facility on the perimeter of the property or in close proximity to the property, in visible locations as determined by the Department.~~

2. For persons seeking to construct a new small swine facility or expand an established small swine facility, the Department shall post a Public Notice of application received, for fifteen (15) business days, on the Department's website. The Department may also post up to four (4) notices, in the four (4) cardinal directions around the perimeter of the property or in close proximity to the property, in visible locations as determined by the Department.

3. For small swine facilities, the Department shall review all comments received. If the Department receives twenty (20) or more letters from different people living in a 2-mile radius of the proposed facility requesting a meeting or the Department determines significant comment exists, a meeting shall be held to discuss and seek resolution to the concerns prior to a permit decision being made. All persons who have submitted written comments shall be invited in writing to the meeting. First Class US mail service, email, or hand delivery to the address of the interested party shall be used by the Department for the meeting invitation. However, if the Department determines that the number of persons who submitted written comments is significant, the Department shall publish a notice of the public meeting in a local newspaper of general circulation instead of notifying each individual by ~~f~~First ~~c~~Class mail. In addition, the Department shall notify all group leaders and petition organizers in writing or email. Agreement of the parties is not required for the Department to make a permit decision.

B. Large Swine Facilities~~(greater than 500,000 pounds normal production live weight)~~.

1. For persons seeking to construct a new large swine facility or expand an established large swine facility, the applicant shall:

~~a. Notify all property owners within 1/4 mile (1320 feet) of the proposed location of the facility (footprint of construction) utilizing a form provided by the Department; and~~

a. Notify all adjoining property owners and people residing on property within 1/4 mile (1,320 feet) of the proposed location of the facility (footprint of construction and manure storage pond) of the applicant's intent to build a swine facility.

~~b. Notify persons residing on adjoining property;~~

b. Notify the parties listed in B.1.a. of this section using an NOI form provided by the Department. The NOI shall advise the adjoining property owners that they may send comments on the proposed animal facility directly to the Department.

2. For persons seeking to construct a new large swine facility or expand an established large swine facility, the Department shall~~at the expense of the applicant~~:

a.~~Publish a notice of intent to construct or expand an established swine facility in a local newspaper of general circulation~~ Post a Public Notice of application received, for fifteen (15) business days, on the Department's website. The Department may also post up to four (4) notices, in the four (4) cardinal directions around the perimeter of the property or in close proximity to the property, in visible locations as determined by the Department;

b. Notify the appropriate county commission;

c. Notify the appropriate water supply district (owners or operators of any potable surface water treatment plant located downstream from the proposed swine facility that could reasonably be expected to be adversely impacted if a significant problem arose); and

d. Notify any person who asked to be notified~~;~~.

3. First Class US mail service, email, or hand delivery to the address of a person to be notified shall be used by the Department for the notifications in Section 100.60.B.2.b-d. If the Department determines that members of the same group or organization have submitted comments or a petition, the Department shall only notify all groups, organization leaders, and petition organizers in writing or email. The Department shall ask these leaders and organizers to notify their groups or any concerned citizens who signed the petitions.

4. The notice shall contain instructions for public review and comment to the Department on the proposed construction and operation of the swine facility. The notice shall allow for a minimum ~~thirty~~ fifteen (15) business-day comment period.

5. ~~When~~If the Department receives twenty (20) or more letters or emails from different people living in a 2-mile radius of the proposed facility requesting a ~~hearing~~public meeting or the Department determines there is significant public interest, the Department shall conduct a public ~~hearing~~meeting and shall provide notice of the public ~~hearing~~meeting in accordance with the notice requirements provided for in Section 100.60.B.2.a-d. The initial public notice and ~~hearing~~meeting notice can be combined into one (1) notice.~~The Department shall provide at least thirty days (30) notice of the hearing.~~

C. Additional requirements for X-large swine facilities~~with 1,000,000 pounds or more normal production live weight~~.

1. For persons seeking to construct a new X-large swine facility or expand an established X-large swine facility~~with 1,000,000 pounds or more normal production live weight~~, the applicant shall notify all property owners and person(s) residing on property within one mile (5,280 feet) of the proposed location of the X-large swine facility (footprint of construction and manure storage pond) by certified mail. The notification must include the following information:

a. Name and address of the person proposing to construct an X-large swine facility;

b. The type of swine facility, the design capacity, and a description of the proposed swine manure management system;

c. The name and address of the preparer of the Animal Facility Management Plan;

d. The address of the local Natural Resources Conservation Service (NRCS) office; and

e. A statement, approved by the Department, informing the adjoining property owners and property owners within ~~one~~ 1 mile of the proposed facility, that they may submit written comments or questions to the Department.

2. The applicant shall conduct a minimum of one public meeting to present to the public the proposed project, its purpose, design, and environmental impacts. The applicant shall provide at least thirty (30) calendar days ~~(30)~~ notice of the meeting date and time by advertisement in a local newspaper of general circulation in the area of the proposed facility. The public meeting notice can be combined into one (1) notice in combination with the notice run by the Department. However, the applicant must provide information concerning the date, time, and location of the public meeting at the time of application. The minutes of the public meeting, proof of advertisement, and opinions derived from the meeting must be submitted to the Department.

3. The Department shall conduct a public ~~hearing~~meeting and shall provide notice of the public ~~hearing~~meeting in accordance with the notice requirements provided for in Section 100.60.~~C~~B.2.a-d. The initial public notice and ~~hearing~~meeting notice can be combined into one (1) notice. The Department shall provide at least thirty (30) calendar days ~~(30)~~notice of the ~~hearing~~meeting.

D. For properties that have multiple owners or properties that are in an estate with multiple heirs, the ~~Department, at the expense of the~~ applicant~~,~~ shall ~~publish~~send an ~~notice of intent~~NOI to construct an animal facility ~~in a local paper of general circulation in the area of the facility~~by certified mail to each individual. This notice ~~in the newspaper~~ shall serve as notice to these multiple property owners of the ~~producer's~~applicant's intent to build a swine facility.~~The cost to run this notice is not included in the application fee, and therefore shall be billed directly to the permit applicant for payment. This notice fee shall be paid prior to the issuance of the permit.~~

E. When comments are received by ~~electronic~~ email, the Department shall acknowledge receipt of the comment by ~~electronic~~ email. These comments shall be handled in the same manner as written comments received by postal mail.

F. The Department shall consider all relevant comments received in determining a final permit decision.

G. The Department shall send notice of the permit decision to issue or deny the permit to the applicant, all persons who commented in writing to the Department, and all persons who attended the public ~~hearing or~~meeting, if held. First Class US mail service, email, or hand delivery to the address of a person to be

notified shall be used by the Department for the decision notification. However, if the Department determines that members of the same group or organization have submitted comments or a petition, the Department shall only notify all group leaders and petition organizers in writing or email. The Department shall ask these leaders and organizers to notify members of their groups or any concerned citizens who signed the petitions.

H. For permit issuances, the Department shall publish a notice of issuance of a permit to construct or expand a swine facility ~~in a local newspaper of general circulation in the area of the facility~~on the Department's website.

I. For permit denials, the Department shall give the permit applicant a written explanation which outlines the specific reasons for the permit denial.

J. For permit denials, the Department may publish a notice of decision ~~in a local newspaper of general circulation in the area of the facility. If the number of concerned citizens who submitted written comments is small, the department may send each concerned citizen a letter by first class mail in lieu of the newspaper notice~~on the Department's website.

K. The Department shall include, at a minimum, the following information in the public notices: the name and location of the facility, a description of the operation and the method of manure and other swine by-products handling, instructions on how to appeal the Department's decision, the time frame for filing an appeal, the date of the decision, and the date upon which the permit becomes effective.

100.70. Permit Decision Making Process.

A. No permit shall be issued before the Department receives a complete application package.

B. The agricultural program of the Department is not involved in local zoning and land use planning. Local government(s) may have more stringent requirements for agricultural animal facilities. The permittee is responsible for contacting the appropriate local government(s) to ensure that the proposed facility meets all the local requirements.

C. After the Department has received a complete application package, a technical review shall be conducted by the Department. The Department may request any additional information or clarification from the applicant or the preparer of the Animal Facility Management Plan to help with the determination on whether a permit should be issued or denied. If a permit application package meets all applicable requirements of this part, a permit may be issued.

D. A preliminary site inspection shall be made by the Department before a ~~permit decision is made~~complete application package is received by the Department.

E. The Department shall consider the cumulative impacts including, but not limited to~~;~~, impacts from evaporation; storm water; and other potential and actual point and nonpoint sources of pollution runoff; levels of nutrients or other elements in the soils and nearby waterways; groundwater or aquifer contamination; pathogens or other elements; and the pollution assimilative capacity of the receiving waterbody. These cumulative impacts will be considered prior to permitting new or expanded swine facilities. Alternative manure and other swine by-products treatment and utilization methods may be required in watersheds which are nutrient-sensitive waters, or impaired by pathogens.

F. The Department shall act on all permits to prevent, ~~so~~as far as reasonably possible considering relevant standards under state and federal laws, an increase in pollution of the waters and air of the State from any new or enlarged sources.

G. The Department also shall act on all permits so as to prevent degradation of water quality due to the cumulative and secondary effects of permit decisions. Cumulative and secondary effects are impacts attributable to the collective effects of a number of swine facilities in a defined area and include the effects of additional projects similar to the requested permit proposed on sites in the vicinity. All permit decisions shall ensure that the swine facility and manure treatment and utilization alternative with the least adverse impact on the environment will be utilized. To accomplish this, new and expanding facilities, except X-large swine facilities~~with 1,000,000 pounds or more normal production live weight~~, shall use the best available technology economically achievable for the handling, storage, processing, treatment, and utilization of manure. New and expanding X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall use the best available technology for the handling, storage, processing, treatment, and utilization of manure. Cumulative and secondary effects shall include, but are not limited to~~;~~, runoff from land application of swine manure and a swine facility; evaporation and atmospheric deposition of elements; ground-water or aquifer contamination; the buildup of elements in the soil; and other potential and actual point and nonpoint sources of pollution in the vicinity.

H. The ~~S~~setback limits given in ~~this part~~Part 100 are ~~minimum~~ siting requirements ~~(with exception to those that are not labeled as minimum requirements, which are absolutes). On a case-by-case basis the Department may require additional separation distances applicable to swine facilities~~. The Department shall evaluate the ~~proposed site including, but not limited to, the following factors when determining if additional distances are necessary~~following factors to determine if any special conditions are necessary:

1.~~Proximity to 100-year floodplain~~ Latitude and Longitude;

2.~~Geography and soil types on the site~~ Down-wind receptors; and

3.~~ Location in a watershed~~ Nutrient Management Plan~~;~~.

~~4.Classification or impairment of adjacent waters;~~

~~5.Proximity to a State Designated Focus Area; Outstanding Resource Water; Heritage Corridor; Historic Preservation District; State Approved Source Water Protection Area; state or national park or forest; state or federal research area; and privately-owned wildlife refuge, park, or trust property;~~

~~6. Proximity to other known point source discharges and potential nonpoint sources;~~

~~7. Slope of the land;~~

~~8. Swine manure application method and aerosols;~~

~~9. Runoff prevention;~~

~~10. Adjacent groundwater usage;~~

~~11. Down-wind receptors; and~~

~~12. Aquifer vulnerability~~.

~~I. The appeal of a permit decision is governed by the SC Administrative Procedures Act, Regulation 61-72, and the Rules of the State's Administrative Law Judge Division.~~

~~J.~~I. When a permit is issued it shall contain an issue date, an effective date, and, when applicable, a construction expiration date. The effective date shall be at least ~~twenty (20)~~fifteen (15) calendar days after the issue date to allow for any appeals. If a timely appeal is not received, the permit shall be effective on the effective date.

~~K.~~J. The swine facility, lagoon, treatment system, or manure storage pond can be built only when the permit is effective ~~with no appeals pending~~. The facility cannot be placed into operation until the Department grants a written ~~authorization~~Approval to ~~begin operations~~Operate (ATO).

~~L.~~K. To receive ~~authorization to begin operations~~an ATO, the producer shall have the preparer of the Animal Facility Management Plan submit in writing, to the Department, the following information:

1. Certification that the construction of the structural components (such as the facility footprint, the lagoon, treatment system and/or manure storage pond) has been completed in accordance with the approved Animal Facility Management Plan and the requirements of this regulation;

2. Certification that no portion of the facility has been ~~construction~~constructed in the 100-year floodplain;

3. Certification for containment of structural failures, if applicable; and

4. Certification for lagoon or manure storage pond lining, if applicable.

~~M.~~L. The Department shall conduct a final inspection before granting ~~authorization~~approval to a producer to begin operations.

~~N.~~M. The Department shall grant written ~~authorization~~approval for the producer to begin operations after it has received the information in 100.70.~~L~~K and the satisfactory results of a final inspection ~~are satisfactory~~.

~~O.~~N. Swine Facility Permit Construction Expiration and Extensions.

1. Construction permits issued by the Department for agricultural animal facilities shall be given two (2) years from the effective date of the permit to start construction and three (3) years from the effective date of the permit to complete construction.

2. If the proposed construction as outlined in the permit is not started prior to the construction start expiration date, the construction permit is invalid unless an extension in accordance with this regulation is granted.

3. If construction is not completed and the facility is not placed into operation prior to the construction completion expiration date, the construction permit is invalid unless an extension in accordance with this regulation is granted.

4. If only a portion of the permitted facility (animal growing houses and associated manure treatment and/or storage structures are completely constructed, but not all houses originally permitted were constructed) is completed prior to the construction completion expiration date, the construction for the remainder of the permit may be utilized within the permit life. The permittee shall obtain Departmental

approval prior to utilizing the permit in this manner. The Department may require that the permittee submit additional information or update the Animal Facility Management Plan prior to approval.

5. Extensions of the construction permit start and completion dates may be granted by the Department. The permittee shall submit a written request explaining the delay and detailing any changes to the proposed construction. This request shall be received not later than ~~60 days prior to~~ the expiration date that the permittee proposes to extend. The maximum extension period shall not exceed one (1) year. There shall be no more than two (2), one (1)-year extension periods per permit to construct, granted.

~~P.~~O. Permits issued under this regulation for all swine facilities shall be renewed at least every seven (7) years. ~~However, if a facility is classified as a CAFO under the NPDES Regulations in R.61-9, the expiration date shall be no more than five years after the issue date.~~

~~Q.~~P. An expired permit (final expiration date for renewal) issued under this part continues in effect until a new permit is effective if the permittee submits a complete application, to the satisfaction of the Department, at least one hundred eighty (180) calendar days before the existing permit expires. The Department may grant permission to submit an application later than the deadline for submission stated above, but no later than the permit expiration date. If the facility has been closed for any two (2) consecutive years since the last permit was issued, the provision for the expiring permit remaining in effect does not apply since the permit is no longer valid. Permittees shall notify the Department in writing within thirty (30) calendar days ~~of when they go~~ before going out of business.

~~R.~~Q. Permit renewal applications shall meet all the requirements of this regulation as the Department determines appropriate. The Department shall review the site and make a determination on a case-by-case basis on which requirements are applicable.

~~S.~~R. No permit will be issued to an applicant who contracts with an integrator or integrating company unless the permit is in accordance with the approved cumulative environmental and public health impact assessment plan as required in part 500.20 (~~Integrator~~ Submittal Requirements) of this regulation.

100.80. Swine Facility, Lagoon, Treatment System, and Manure Storage Pond Siting Requirements.

A. Siting Requirements applicable to all small ~~(500,000 pounds or less of normal production live weight)~~ swine facilities and the lagoons, treatment systems, and/or manure storage ponds associated with them.

1. The minimum separation distance between a swine facility (not including a lagoon, treatment system, manure storage pond, or manure utilization area~~s~~) and a potable water well (excluding the applicant's well) is 200 feet. The minimum separation distance between a swine facility (not including a lagoon, treatment system, manure storage pond, or manure utilization area~~s~~) and a potable water well owned by the applicant is 50 feet (as required by R.61-71).

2. The minimum separation distance between a lagoon, treatment system, or a manure storage pond and a public or private human drinking water well (excluding the applicant's well) is 500 feet. The minimum separation distance between a lagoon, treatment system, or manure storage pond and a potable water well owned by the applicant is 100 feet.

3. Except for site drainage, the minimum separation distance required between a ditch or swale, which drains directly into Waters of the State (~~excluding~~including ephemeral and intermittent streams) and a swine facility, swine lagoon, treatment system, or manure storage pond is 100 feet. ~~The setback from ditches may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

~~4. Except for site drainage, the minimum separation distance required between a ditch or swale, which drains directly into an ephemeral or intermittent stream, and a swine facility, swine lagoon, treatment system, or manure storage pond is 50 feet. The setback from ditches may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

~~5.~~4. The minimum separation distance required between a swine facility, lagoon, treatment system, or manure storage pond and ephemeral or intermittent streams is 100 feet. ~~The setback from ephemeral or intermittent streams may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

~~6.~~5. The minimum separation distance required between a small swine facility (not including the lagoon, treatment system, or manure storage pond) and Waters of the State (excluding ephemeral and intermittent streams) is 100 feet.

~~7.~~6. The minimum separation distance required between a small swine lagoon, treatment system, or manure storage pond and Waters of the State (excluding ephemeral and intermittent streams) is 500 feet.

~~8.~~7. If the Waters of the State (not including ephemeral and intermittent streams) are designated Outstanding Resource Waters, Critical Habitat Waters of federally endangered species, or Shellfish Harvesting Waters, the minimum separation distance required between a small swine lagoon, treatment system, or a manure storage pond and Waters of the State (not including ephemeral and intermittent streams) is 1,320 feet (1/4 mile).

~~9. The distance required between a small swine lagoon, treatment system, or manure storage pond and Waters of the State (not including ephemeral and intermittent streams) can be reduced to 200 feet if the permittee implements a design to control the discharge from a failed lagoon, treatment system or manure storage pond so that it never enters Waters of the State (not including ephemeral and intermittent streams) and the designer, either a NRCS employee or a registered engineer, certifies that the system has been constructed as specified. The distance shall not be reduced if the Waters of the State are designated Outstanding Resource Waters, Critical Habitat Waters of federally endangered species, or Shellfish Harvesting Waters.~~

~~10. For small facilities with a capacity of 250,000 pounds or less of normal production animal live weight at any one time, the separation distance required between a swine growing area (pens or barns not including range areas) and the distance to lot line of real property owned by another person is 200 feet or 1000 feet from the nearest residence, whichever is greater.~~

~~11.~~8. For small swine facilities ~~with a capacity of more than 250,000 pounds and less than 500,001 pounds of normal production animal live weight at any one time,~~ the separation distance required between a swine growing area (pens or barns not including range areas) and the lot line of real property owned by another person is 400 feet ~~or~~and 1,000 feet from the nearest residence~~, whichever is greater~~.

~~12. For small facilities with a capacity of 250,000 pounds or less of normal production animal live weight at any one time, the separation distance required between a lagoon, treatment system, and/or manure storage pond and the lot line of real property owned by another person is 300 feet or 1000 feet from the nearest residence, whichever is greater.~~

~~13.~~9. For small swine facilities ~~with a capacity of more than 250,000 pounds and less than 500,001 pounds of normal production animal live weight at any one time,~~ the separation distance required between

a lagoon, treatment system, or manure storage pond and the lot line of real property owned by another person is 600 feet ~~or~~and 1,000 feet from the nearest residence~~, whichever is greater~~.

~~14.~~10. The distances in items ~~10-13~~8 and 9 above can be reduced by written consent of the adjoining property owner, unless a swine facility is located on the adjacent property or within 1,000 feet of the property line. Written consent is not needed when the Department reduces the distances under the requirements of Part 300.

B. Siting Requirements applicable to all large swine facilities, ~~with less than 1,000,000 pounds normal production live weight,~~ and the lagoons, treatment systems, and manure storage ponds associated with the facility.

1. The minimum separation distance between a large swine facility ~~with less than 1,000,000 pounds normal production live weight~~ (not including a lagoon, treatment system, manure storage pond, or manure utilization area~~s~~) and a potable water well (excluding the applicant's well) is 200 feet. The minimum separation distance between a swine facility (not including a lagoon, treatment system, manure storage pond, or manure utilization area~~s~~) and a potable water well owned by the applicant is 50 feet (as required by R.61-71).

2. The minimum separation distance between a lagoon, treatment system, or a manure storage pond, ~~with less than 1,000,000 pounds normal production live weight~~ and a public or private human drinking water well (excluding the applicant's well) is 500 feet. The minimum separation distance between a lagoon, treatment system, or manure storage pond and a potable water well owned by the applicant is 100 feet.

3. Except for site drainage, the minimum separation distance required between a ditch or swale, which drains directly into Waters of the State (~~excluding~~including ephemeral and intermittent streams) and a swine facility, swine lagoon, treatment system, or manure storage pond~~, with less than 1,000,000 pounds normal production live weight,~~ associated with a large swine facility is 100 feet.~~The setback from ditches may be reduced by the Department, if a permanent vegetative water quality buffer at least 50 feet wide, that meets NRCS standards at a minimum, is installed and maintained.~~

~~4.Except for site drainage, the minimum separation distance required between a ditch or swale, which drains directly into an ephemeral or intermittent stream, and a swine facility, swine lagoon, treatment system, or manure storage pond, with less than 1,000,000 pounds normal production live weight, is 50 feet.~~

~~5~~4. The minimum separation distance required between a large swine facility, lagoon, treatment system, or manure storage pond, ~~with less than 1,000,000 pounds normal production live weight, and ephemeral or intermittent is 100 feet. The setback from ephemeral or intermittent streams may be reduced by the Department, if a permanent vegetative water quality buffer at least 50 feet wide, that meets NRCS standards at a minimum, is installed and maintained.~~ associated with the facility and ephemeral or intermittent streams is 200 feet.

~~6~~5. The minimum separation distance required between a large swine facility ~~with less than 1,000,000 pounds normal production live weight~~ (not including the lagoon, treatment system, or manure storage pond) and Waters of the State (~~excluding~~including ephemeral and intermittent streams) is 200 feet.

~~7~~6. The minimum separation distance required between a large swine lagoon, treatment system, or manure storage pond~~, with less than 1,000,000 pounds normal production live weight,~~ and Waters of the State (not including ephemeral and intermittent streams) is 1,320 feet (1/4 mile). If the Waters of the State (not including ephemeral and intermittent streams) are designated Outstanding Resource Waters, Critical Habitat Waters of federally endangered species, or Shellfish Harvesting Waters, the minimum separation

distance required between a lagoon, treatment system, or manure storage pond and Waters of the State (not including ephemeral and intermittent streams) is 2,640 feet (½ mile). A minimum 100-foot wide vegetative water quality buffer of plants and trees is required to be installed and maintained on the site between the facility and any down slope Waters of the State. Sites with existing vegetation may qualify to utilize the existing vegetation for a buffer, if the vegetation is deemed sufficient. For new facilities constructed in areas where natural vegetation is not present, the Department shall evaluate these sites on a case-by-case basis to determine the amount of vegetative buffer that shall be planted. However, each site shall be required at a minimum to provide a vegetative buffer that meets the current NRCS standards.

~~8. The distance required between a large swine lagoon, treatment system, or manure storage pond, with less than 1,000,000 pounds normal production live weight, and Waters of the State (not including ephemeral and intermittent streams) can be reduced to 500 feet if the permittee implements a design to control the discharge from a failed lagoon, treatment system, or manure storage pond so that it never enters Waters of the State (not including ephemeral and intermittent streams) and the designer, either a NRCS employee or a professional engineer, certifies that the plan has been implemented as specified. The distance shall not be reduced if the Waters of the State are designated Outstanding Resource Waters, Critical Habitat Waters of federally endangered species, or Shellfish Harvesting Waters.~~

~~9.~~7. The minimum separation distance required between a large swine facility ~~with less than 1,000,000 pounds normal production live weight~~ (growing area, pens or barns not including range areas) and real property owned by another person is 1,000 feet.

~~10. For swine facilities with a capacity of 500,001 to 750,000 pounds of normal production animal live weight at any one time, the minimum separation distance required between a lagoon, treatment system, or manure storage pond and real property owned by another person is 1,000 feet.~~

~~11.~~8. For large swine facilities ~~with a capacity of 750,001 to 1,000,000 pounds of normal production animal live weight at any one time~~, the minimum separation distance required between a lagoon, treatment system, ~~and/~~or a ~~waste~~manure storage pond and real property owned by another person is 1,250 feet.

~~12.~~9. The minimum separation distance required between large swine facilities ~~with less than 1,000,000 pounds normal production live weight~~ is ~~two~~ 2 miles.

~~13.~~10. A separation distance to adjacent land as provided in ~~9-11~~items 7 and 8 above does not apply to a swine facility, lagoon, treatment system, or manure storage pond which is constructed or expanded, if the titleholder of adjoining land to the concentrated swine operation executes a written waiver with the title holder of the land where the swine facility is established or proposed to be located, under terms and conditions that the parties negotiate. The written waiver becomes effective only upon the recording of the waiver in the office of the Register of Deeds of the county in which the benefited land is located. The filed waiver precludes enforcement of 100.80.B.~~9-11~~7 and 8 as it relates to the swine facility and to real property owned by another person. The permittee shall submit a copy of the document with the recording stamp to the Department. The separation distances shall not be reduced or waived if a swine facility is located on the adjacent property or within 1,000 feet of the property line.

C. Siting requirements applicable to X-large swine facilities~~, with 1,000,000 pounds or more normal production live weight,~~ and the lagoons, treatment systems, and manure storage ponds associated with the facility are as follows:

1. The minimum separation distance required between an X-large swine facility ~~with 1,000,000 pounds or more normal production live weight~~ and Waters of the State (~~excluding~~including ephemeral and intermittent streams) is 2,640 feet (½ mile).

2. The minimum separation distance required between an X-large swine lagoon, treatment system, or manure storage pond~~, with 1,000,000 pounds or more normal production live weight,~~ and Waters of the State (~~not~~ including ephemeral and intermittent streams) is 2,640 feet (½ mile). If the Waters of the State (not including ephemeral and intermittent streams) are designated Outstanding Resource Waters, Critical Habitat Waters of federally endangered species, or Shellfish Harvesting Waters, the minimum separation distance required between a lagoon, treatment system, or manure storage pond and Waters of the State (not including ephemeral and intermittent streams) is 3,960 feet (3/4 mile). A minimum 100-foot wide vegetative water quality buffer of plants and trees is required to be installed and maintained on the site between the facility and any down slope Waters of the State. Sites with existing vegetation may qualify to utilize the existing vegetation for a buffer, if the vegetation is deemed sufficient. For new facilities constructed in areas where natural vegetation is not present, the Department shall evaluate these sites on a case-by-case basis to determine the amount of vegetative buffer that shall be planted. However, each site shall be required, at a minimum, to provide a vegetative buffer that meets the current NRCS standards.

3. The minimum separation distance required between an X-large swine facility ~~with 1,000,000 pounds or more normal production live weight~~ (including the lagoon, treatment system, and manure storage pond) and real property owned by another person or a residence (excluding the applicant's residence) is 1,750 feet.

4. The minimum separation distance between an X-large swine facility ~~with1,000,000 pounds or more normal production live weight~~ (including a lagoon, treatment system, or manure storage pond) and a potable water well (excluding the applicant's well) is 1,750 feet. The minimum separation distance between a swine facility (including a lagoon, treatment system, or manure storage pond) and a potable water well owned by the applicant is 100 feet (as required by R.61-71).

5. The minimum separation distance required between X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ is ~~twenty-five~~ 25 miles.

D. A new swine facility or an expansion of an established swine facility may not be located in the 100-year floodplain.

E. Water (a pond) that is completely surrounded by land owned by the permit applicant and has no connection to other water is excluded from the setback requirements outlined in this part.

F. All lagoon and manure storage pond setbacks contained in this part shall be measured from the outside toe of the dike.

G. Setback limits given in this part are minimum siting requirements, except those not labeled as minimum requirements, which are absolutes. On a case-by-case basis the Department may require additional separation distances to the minimum setbacks applicable to swine facilities. See Section 100.70.H. for specific criteria evaluated for determining if greater setbacks should be required.

100.90. General Requirements for Swine Manure Lagoons, Treatment Systems, and Swine Manure Storage Ponds.

A. The lagoon, treatment system, or manure storage pond shall be designed by a professional engineer or an NRCS engineer and the construction shall be certified by the design engineer or professional engineer licensed in S.C. It is a violation of ~~these~~this regulations and the South Carolina Pollution Control Act for the owner or operator of the facility to make modifications or physical changes to the lagoon, treatment system, or manure storage pond without the prior approval of the Department and supervision of NRCS or

a professional engineer. Plans and specifications for lagoon, treatment system, or manure storage pond modifications shall be designed and certified by NRCS or a professional engineer and submitted to the Department for approval prior to the modification.

B. Swine manure lagoons and manure storage ponds shall be designed at a minimum to NRCS-CPS. The ~~manure storage pond or~~ lagoon or manure storage pond shall be designed to provide a minimum storage capacity for manure, wastewater, normal precipitation less evaporation, normal runoff, and residual solids accumulation~~, capacity~~ for the twenty-five (25) year - twenty-four (24) hour storm event (precipitation and associated runoff) and at least one and one half (1 ½) feet of freeboard. New X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall be designed to provide storage capacity for all the above-mentioned items, including the fifty (50) year - twenty-four (24) hour storm event (precipitation and associated runoff) and at least ~~two (~~2~~)~~ feet of freeboard.

C. All lagoons and storage ponds constructed or expanded after the date of this regulation shall be provided with a geomembrane liner, designed with an initial specific discharge rate of less than 0.0156 feet/day in order to protect groundwater quality. ~~Lagoons and manure storage ponds at swine facilities shall be lined with either a natural liner or a geomembrane liner or a combination thereof.~~ Lagoons and manure storage ponds at X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight or at facilities~~ within delineated source water protection areas or vulnerable recharge areas, as determined by the Department, shall be lined with a geomembrane liner such that the vertical hydraulic conductivity does not exceed 5 x 10^{-7} cm/sec. Geomembrane liners, at a minimum, shall meet NRCS-CPS. ~~When~~For existing lagoons or manure storage ponds ~~are~~ lined using only soils with low permeability rates (e.g., clay), the Department shall require appropriate documentation to demonstrate that the computed soil permeability of the liner is sufficient to prevent seepage greater than the initial specific discharge rate. Appropriate certification shall be provided by the preparer of the Animal Facility Management Plan that the NRCS-CPS for lining lagoons and/or manure storage ponds with soils have been met.

D. Lagoons and manure storage ponds at swine facilities shall not exceed one million cubic feet of total volume, unless the lagoon or manure storage pond implements a design to control the discharge from a failed lagoon, treatment system, or manure storage pond so that it never enters Waters of the State.

E. Large swine facilities ~~with less than 1,000,000 pounds normal production live weight~~ are prohibited from utilizing open anaerobic lagoons or manure storage ponds. These facilities shall utilize best available technology that is economically achievable for the manure handling, treatment, storage, and utilization.

F. X-Large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ are prohibited from utilizing open lagoons or manure storage ponds. These facilities shall utilize best available technology for the manure handling, treatment, storage, and utilization. Lagoons and manure storage ponds utilized at X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall be designed with airtight covers. Air pollution control devices utilizing the Best Available Technology shall be installed on all lagoon cover vents and openings to remove ammonia, hydrogen sulfide, methane, formaldehyde, and any other organic and inorganic air pollutants, which may be required by the Department. Such air pollution control devices shall meet all the requirements of the Department and appropriate air quality permits shall be obtained. "Best Available Technology" means, for the air emissions purpose of this regulation, the rate of emissions which reflects the most stringent emissions limitations required by any State regulation or permit, existing at the time the application is made, for all pollutants emitted from this source category; or, the most stringent emissions limit achieved in actual practice, whichever is more stringent.

G. If seepage results in either an adverse impact to groundwater or a significant adverse trend in groundwater quality occurs, as determined by the Department, the lagoon or manure storage pond shall be repaired at the owner's or operator's expense. Assessment and/or additional monitoring (more wells,

additional constituents, and/or increased sampling frequency) may be required by the Department to determine the extent of the seepage. The repairs and/or assessment shall be completed in accordance with an implementation schedule approved by the Department. The Department may require groundwater corrective action.

H. Manure and other swine by-products shall not be placed directly in or allowed to come into contact with groundwater and/or surface water. The minimum separation distance between the lowest point of the lagoon and/or manure storage pond and the seasonal high water table beneath the lagoon and/or manure storage pond is 2 feet. If a geomembrane liner is installed, then the minimum separation distance is 1 foot from the seasonal high water table. Designs that include controlled drainage for water table adjustment shall be evaluated by the Department on a case-by-case basis, and may include additional monitoring and groundwater control requirements. If a design is proposed for water table adjustment, the design shall not impact wetlands. Groundwater monitoring wells may be required to be installed and monitored at a frequency as given in the permit for the facility in situations where a liner is used to allow the lowest point of a lagoon to be less than 2 feet to the seasonal high water table.

I. Owners of lagoons and manure storage ponds at large and X-large swine facilities ~~(greater than 500,000 pounds normal production live weight) are~~shall be required to install at least one (1) up-gradient and two (2) down-gradient monitoring wells at a depth which the Department considers appropriate around the lagoon or series of lagoons in order to monitor groundwater quality. For small swine facilities ~~(500,000 pounds or less of normal production live weight)~~, the Department may require monitoring wells upon Department review of the submittal package.

J. A groundwater monitoring plan shall be submitted with the permit application to the Department. All applicable State certification requirements regarding well installation, laboratory analyses, and report preparation shall be met. Groundwater monitoring wells shall be sampled at least once annually by qualified personnel, at the expense of the permittee. Monitoring wells at X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ must be sampled at least quarterly, unless more frequent sampling is specified in the permit. The results shall be submitted to the Department in accordance with the specified permit requirements. Groundwater monitoring results shall be maintained by the producer for eight (8) years. The Department may conduct routine and random visits to the swine facility to sample the monitoring wells.

K. The monitoring wells shall be properly installed and sampled prior to use of the lagoon or manure storage pond. All monitoring wells shall be sampled in accordance with the parameters identified in the permit such that a background concentration level can be established.

L. Before the construction of a lagoon and/or a manure storage pond, the owner or operator shall remove all under-drains that exist from previous agricultural operations that are under the lagoon or manure storage pond and/or within ~~twenty-five (~~25~~)~~ feet of the outside toe of the proposed lagoon or manure storage pond dike. This requirement does not include under-drains that are approved as a part of a design that includes controlled drainage for water table adjustment.

M. Lagoons and manure storage ponds at X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall install automated lagoon level monitoring devices.

N. Proper water levels in lagoons and manure storage ponds, as per plans and specifications, shall be maintained at all times by the permittee. The Department may require specific lagoon or manure storage pond volume requirements in permits. An approved marker shall be installed to measure waste levels.

O. If a lagoon, treatment system, or manure storage pond, or ~~both~~all of these, breaches or fails ~~in any way~~, the owner or operator of the swine facility shall immediately notify the Department, the appropriate local government officials, and the owners or operators of any potable surface water treatment plant located downstream from the swine facility that could reasonably be expected to be adversely impacted.

P. Lagoons, treatment systems, and manure storage ponds shall be completely enclosed with an acceptable fence, unless a fence waiver is obtained from the Department.

Q. Lagoons and manure storage ponds shall have at least four (4) warning signs posted in the four (4) cardinal directions around the perimeter of the structure. These signs ~~should~~must read, "Warning - Deep and Polluted Water"~~, and one should be posted on each side of the lagoon or manure storage pond~~.

R. Vegetation on the dikes and around the lagoon or manure storage pond should be kept below a maximum height of ~~eighteen~~18 inches. Trees or deeply rooted plants shall be prevented from growing on the dikes or within 25 feet of the outside toe of the dikes of the lagoon, treatment systems, or manure storage pond. Existing trees on the dikes shall be evaluated by NRCS staff or a dam engineer licensed in South Carolina to determine if they should be removed or remain.

S. Livestock or other animals that could cause erosion or damage to the dikes of the lagoon or manure storage pond shall not be allowed to enter the lagoon or manure storage pond, or graze on the dike or within 25 feet of the outside toe of the dike.

T. The Department shall require existing facilities, regardless of size, with a history of manure handling, treatment, and disposal problems related to a lagoon, to phase out the existing lagoon and incorporate new technology.

100.100. Manure Utilization Area Requirements.

A. Application Rates. The Department shall approve an Animal Facility Management Plan that establishes an application rate for each manure utilization area based on the agronomic application rate of the specific crop(s) being grown. Other factors considered are the manure and other swine by-products' impact on the environment, animals, and people living in the vicinity. The application rate shall also be based on the limiting constituent (either a nutrient or other constituent as given in item 100.100.B). In developing annual constituent loading rates and cumulative constituent loading rates, the Department shall consider:

1. Soil type;

2. Type of vegetation growing in land-applied area;

3. Proximity to 100-year floodplain;

4. Location in watershed;

5. Nutrient sensitivity of receiving land and waters;

6. Soil nutrient testing in conjunction with soil productivity information;

7. Nutrient, copper, zinc, and constituent content of the manure and other swine by-products being applied;

8. ~~Proximity to a State Designated Focus Area; Outstanding Resource Water; Heritage Corridor; Historic Preservation District;~~ State Approved Source Water Protection Area; ~~state or national park or forest; state or federal research area; and privately owned wildlife refuge, park, or trust property;~~

9. Proximity to other point and nonpoint sources;

10. Slope of land (anything over ten percent (10%) must use runoff best management practices, runoff controls, or conservation features as per NRCS);

11. Distance to water table or groundwater aquifer;

12. Timing of manure application to coincide with vegetative cover growth cycle;

13. Timing of harvest of vegetative cover;

14. Hydraulic loading limitations;

15. Soil assimilative capacity;

16. Type of vegetative cover and its nutrient uptake ability;

17. Method of land application; and

18. Aquifer vulnerability.

B. Constituent Limits for Land Application of Swine manure and other swine by-products.

1.~~Swine Manure and other swine by products.~~ The Department may establish constituent limits in permits on a case-by-case basis on swine manure and other swine by-products to be land applied. Swine manure and other swine by-products containing only the standard constituents at normal concentrations as given by commonly accepted reference sources, such as Clemson University, American Society of Agricultural Engineers, Midwest Planning Service Document, or NRCS, can be land applied at or below agronomic rates without any specific constituent limits in a permit. When the swine manure or other swine by-products analysis indicates there are levels of copper, or other constituents of concern, the Department shall establish constituent limits in permits for each constituent of concern to ensure the water quality standards of ~~Regulation~~ R.61-68 are maintained. For these cases, the producer shall comply with the following criteria:

a. Constituent Limits. If swine manure and other swine by-products subject to a constituent limit is applied to land, either:

i. the cumulative loading rate for each constituent shall not exceed the rates in Table 1 of Section 100.100; or

ii. the concentration of each constituent in the swine manure and other swine by-products shall not exceed the concentrations in Table 2 of Section 100.100.

b. Constituent concentrations and loading rates - swine manure.

i. Cumulative constituent loading rates.

TABLE 1 OF SECTION 100.100 - CUMULATIVE CONSTITUENT LOADING RATES			
Cumulative Constituent Loading Rate			
Constituent	(kilograms per hectare)	(pounds per acre)	
Copper	1500	1339	
Zinc	2800	2499	

ii. Constituent concentrations.

TABLE 2 OF SECTION 100.100 - CONSTITUENT CONCENTRATIONS	
Monthly Average Concentrations	
Constituent	Dry weight basis (milligrams per kilogram)
Copper	1500
Zinc	2800

iii. Annual constituent loading rates.

TABLE 3 OF SECTION 100.100 - ANNUAL CONSTITUENT LOADING RATES			
Annual Constituent Loading Rate			
	(kilograms per hectare per 365-day period)	(pounds per acre per 365-day period)	
Constituent			
Copper	75	67	
Zinc	140	125	

c. Additional constituents limits may be required, from the application information or subsequent monitoring in a permit thereafter, but such needs shall be assessed on an individual project basis.

d. No producer shall apply sSwine manure and other swine by-products shall not be applied subject to the cumulative constituent loading rates in Table 1 of Section 100.100.B.1 to land if any of the rates in Table 1 of Section 100.100.B.1 have been reached unless the constituent is removed from the manure and other swine by-products.

e. No producer shall apply sSwine manure and other swine by-products shall not be applied to land during a 365-day period after the annual application rate in Table 3 of Section 100.100.B.1 has been reached.

f. If swine manure and other swine by-products subject to the cumulative constituent loading rates in Table 1 of Section 100.100.B.1 have not been applied to the site, then the cumulative rates apply.

g. If swine manure and other swine by-products subject to the cumulative constituent loading rates in Table 1 of Section 100.100.B.1 have been applied to the site and the cumulative amount of each constituent is known, the cumulative amount of each constituent applied to the site shall be used to determine the additional amount of each constituent that can be applied to the site in accordance with Section 100.100.B.1.a.i (cumulative loading rate shall not exceed the cumulative constituent loading rate).

h. Manure application shall not exceed the agronomic rate of application for plant available nitrogen (PAN) for the intended crop(s) on an annual basis. For those years that fertilizer is land applied, manure in

combination with the fertilizer shall not ~~be used so as to~~ exceed the agronomic rate of nutrient utilization of the intended crop(s).

2. Any producer who confines swine shall ensure that the applicable requirements in this part are met when the swine manure and other swine by-products are applied to the land.

3. Swine manure and other swine by-products shall not be applied to land that is saturated from recent precipitation, flooded, frozen, or snow-covered. Swine manure and other swine by-products shall not be applied during inclement weather or when a significant rain event is forecasted to occur within forty-eight (48) hours, unless approved by the Department in an emergency situation.

4. Swine manure and other swine by-products shall not be placed directly in groundwater.

5.~~The~~All land application equipment, (e.g. Spreader, injection) when used once or more per year, shall be calibrated at least annually by the ~~producer~~person land applying. A permit may require more frequent calibrations to ensure proper application rates. The two (2) most recent calibration records should be retained by the producer and made available for Department review upon request. If the land application equipment has not been used in over a year, ~~then~~ the equipment shall be calibrated prior to use.

6. ~~No producer shall apply s~~Swine manure and other swine by-products shall not be applied to the land except in accordance with the requirements in this part.

7. A producer who supplies swine manure and other swine by-products to another person for land application shall provide the person who will land apply the manure and other swine by-products with the concentration of plant available nitrogen, phosphorus, potassium, and the concentration of all other constituents listed in the permit. The producer shall also supply the person who will land apply the manure with a copy of the crop management plan included in their Animal Facility Management Plan ~~or a copy of the Land Application brochure approved by the Department which outlines the land application requirements and responsibility for proper management of animal manure~~.

8. Swine manure and other swine by-products shall not be applied to or discharged onto a land surface when the vertical separation between the ground surface and the seasonal high water table is less than 1.5 feet at the time of application, unless approved by the Department on a case-by-case basis. For special cases, no land application can occur when the vertical separation from the ground surface to the water table is less than 1.5 feet at the time of application unless a situation is deemed an emergency with departmental concurrence.

9. Soil sampling (usually 6-8 inch depth) shall be conducted for each field prior to manure application to determine the appropriate application rate. Each field should be sampled at least once per year. If manure application frequency shall be less than once per year, then at least one (1) soil sample shall be taken prior to returning to that field for land application. All new manure utilization areas shall be evaluated using the NRCS-CPS to determine the suitability for application and the limiting nutrient (nitrogen or phosphorus). However, fields that are high in phosphorus may also be required to incorporate additional runoff control or soil conservation features as directed by the Department.

10. Soil sampling to a depth of ~~eighteen~~ 18 inches ~~shall~~may be ~~performed~~required by the Department within forty-five (45) calendar days after each application of swine manure, but no more than two (2) times per year if the application frequency is more than twice per year. This sampling shall be performed for at least three (3) years after the initial application on at least one (1) representative manure utilization area for each crop grown to verify the estimated calculated swine manure application rates for the utilization areas. The date of manure application and the date of sampling shall be carefully recorded. The sampling shall be

conducted at depths of ~~zero to six~~ 0 to 6 inches, ~~six to twelve~~ 6 to 12 inches, and ~~twelve to eighteen~~ 12 to 18 inches with nitrates and phosphorus being analyzed.

11. The results of the pre-application and post-application sampling shall be used by the ~~producer~~crop farmer to adjust as necessary, the amount of swine manure to be applied to a manure utilization area to meet the agronomic application rate for the crop(s) to be grown. These results shall be submitted to the Department at the time of application for permit renewal.

12. Additional soil sampling to greater depths may be required by the Department on a case-by-case basis to ensure there is no potential for groundwater contamination. ~~The permit shall give the appropriate depth and frequency for all soil sampling.~~

13. The permittee shall obtain the following information needed to comply with the requirements in this part~~.~~:

a. A manure transfer contract shall be developed for the producer to use with any person who is accepting manure in quantities greater than 12 tons per recipient per year. The contract should contain, at a minimum, the following information:

i. Name, address, county and telephone number of the person who is purchasing or accepting animal manure and other animal by-products;

ii. Manure nutrient composition (pounds per ton of plant available nitrogen, phosphorus, and potassium) to be filled in or provided by the producer. This information shall be obtained from the manure analysis results and the producer shall provide this information on the manure transfer contract.

iii. Land application field information;

iv. Physical description (acreage, crop, soil type);

v. Soil test results (phosphorus, zinc, and copper in pounds/acre); and

vi. Recommended application rates (nitrogen, phosphorus, and potassium in pounds/acre as reported on a soil test).

b. Attach a copy of a soils map, topographic map, county tax map, plat, FSA map, or a site plan sketch that includes the following information:

i. Manure application area with setbacks outlined;

ii. Known water supply wells within 100 feet of the property line;

iii. Adjacent surface waters, including ditches, streams, creeks, and ponds; and

iv. Identification of roads and highways to indicate location.

c. Description of application equipment and name of person to land apply manure;

d. Signed agreement that informs the landowner that he or she is responsible and liable for land applying the animal manure and other animal by-products in accordance with this regulation; and

e. A copy of the land application requirements shall be provided to the recipient of the manure.

14. ~~All persons who routinely accept manure from a producer, in quantities greater than twelve tons per recipient per year, shall be listed in the approved Animal Facility Management Plan. The Animal Facility Management Plan shall include the appropriate manure utilization area information for the sites routinely used by other persons. The producer shall inform the recipient of the responsibility to properly manage the land application of manure to prevent discharge of pollutants to Waters of the State (including ephemeral and intermittent streams). The person accepting the manure may be required by the Department to have an Animal Facility Management Plan and a permit for their manure utilization areas.~~All persons who routinely accept manure from a producer, in quantities greater than 12 tons per recipient per year, shall be listed in the approved Animal Facility Management Plan. The Animal Facility Management Plan shall include the appropriate manure utilization area information for the sites routinely used by other persons. The producer shall inform the applier of their responsibility and have a signed manure transfer contract to properly manage the land application of manure to prevent discharge of pollutants to Waters of the State (including ephemeral and intermittent streams). The person accepting the manure may be required by the Department to have an Animal Facility Management Plan and a permit for his or her manure utilization areas.

15. ~~All persons who accept manure from a producer, regardless of whether the land is included in the waste management plan, are responsible for land applying the manure in accordance with these requirements. The Department may require the person(s) land applying the manure to correct any problems that result from the application of manure.~~All persons who accept manure from a producer, in quantities less than 12 tons per recipient per year are responsible for land applying the manure in accordance with these requirements and must have a signed agreement with the producer explaining their responsibility to comply with this regulation. The Department may require the persons(s) land applying the manure to correct any problems that result from the application of manure.

16. Swine manure shall not be applied to cropland more than thirty (30) calendar days before planting or during dormant periods for perennial species, unless otherwise approved by the Department in an emergency situation.

17. When the Department receives nuisance complaints on a land application site, the Department may restrict land application of animal manure on this site completely or during certain time periods.

18. The Department may require manure~~, spread on cropland,~~ to be disked in immediately.

19. Manure (solid or liquid) shall only be applied when weather and soil conditions are favorable and when prevailing winds are blowing away from nearby dwellings. Animal manure should not be applied to land when the soil is saturated, flooded, during rain events, or when a significant rain event is forecasted to occur within forty-eight (48) hours, unless otherwise approved by the Department in an emergency situation.

20. Manure shall not be spread in the floodplain if there is danger of a major runoff event, unless the manure is incorporated during application or immediately after application.

21. If the manure is stockpiled ~~more than three (3) days~~outside, the manure shall be stored on a concrete pad or other approved pad (such as plastic or clay lined) and covered on a daily basis (unless otherwise specified in the permit) with an acceptable cover to prevent odors, vector attraction, and runoff. The cover should be vented properly with screen wire to let the gases escape. The edges of the cover should be properly anchored.

22. ~~Producers who contract to transfer the swine manure and other swine by-products produced at their facility to a manure broker shall modify their existing Animal Facility Management Plan if they discontinue using the designated broker or if the manure broker goes out of the manure brokering business.~~If a producer, who contracts to transfer the swine manure and other swine by-products produced at his or her facility, changes brokers, he or she must submit notification and a new broker contract for approval to the Department.

23. The body of vehicles transporting manure shall be wholly enclosed and, while in transit, be kept covered with a canvas cover provided with eyelets and rope tie-downs, or any other approved method that shall prevent blowing or spillage of loose material or liquids. Should any spillage occur during the transportation of the manure, the owner/operator shall take immediate steps to clean up the manure.

C. Setbacks for manure utilization areas (MUA) for small, large, and X-large swine facilities.

1. Siting Requirements applicable to all manure utilization areas associated with ~~small~~all swine facilities~~(500,000 pounds or less normal production live weight~~.

a. The minimum separation distance ~~in feet~~ required between a manure utilization area and a residence is 300 feet. If there are no residences within 300 feet of the manure utilization area, manure can be applied up to the property line. The 300-foot setback may be waived with the consent of the owner of the residence. If the application method is injection or immediate (same day) incorporation, manure may be applied up to the property line. The setbacks are imposed at the time of application. The Department may impose these setbacks on previously approved sites to address problems on a case-by-case basis.

b. The minimum separation distance ~~in feet~~ required between a manure utilization area and Waters of the State (not including ephemeral and intermittent streams), ditches, and swales that drain directly into Waters of the State (not including ephemeral and intermittent streams) is 100 feet.

c. The minimum separation distance ~~in feet~~ required between a manure utilization area and ephemeral and intermittent streams is 100 feet when spray application is the application method, 75 feet when incorporation is the application method, and 50 feet when injection is the application method. When incorporation is accomplished within twenty-four (24) hours of the initial application, the distance can be reduced to 50 feet.

d. The minimum separation distance ~~in feet~~ required between a manure utilization area and ditches and swales~~,~~ that drain directly into ephemeral and intermittent streams is 50 feet.

e. The minimum separation distance ~~in feet~~ required between a manure utilization area and a ~~public and private~~potable drinking water well is 200 feet.

~~2. Siting Requirements applicable to all manure utilization areas associated with large swine facilities with less than 1,000,000 pounds normal production live weight.~~

~~a. The minimum separation distance in feet required between a manure utilization area and a residence is 300 feet. If there are no residences within 300 feet of the manure utilization area, manure can be applied up to the property line. The 300-foot setback may be waived with the consent of the owner of the residence. If the application method is injection or immediate incorporation, manure may be applied up to the property line. The setbacks are imposed at the time of application. The Department may impose these setbacks on previously approved sites to address problems on a case-by-case basis.~~

~~b. The minimum separation distance in feet required between a manure utilization area and Waters of the State (not including ephemeral and intermittent streams), ditches, and swales that drain directly into Waters of the State (not including ephemeral and intermittent streams) is 100 feet.~~

~~c. The minimum separation distance in feet required between a manure utilization area and ephemeral and intermittent streams is 100 feet when spray application is the application method, 75 feet when incorporation is the application method, and 50 feet when injection is the application method. When incorporation is accomplished within 24 hours of the initial application, the distance can be reduced to 50 feet.~~

~~d. The minimum separation distance in feet required between a manure utilization area and ditches and swales that drain directly into ephemeral and intermittent streams is 50 feet.~~

~~e. The minimum separation distance in feet required between a manure utilization area and a public and private drinking water well is 200 feet.~~

~~3. Siting Requirements applicable to all manure utilization areas associated with large swine facilities with 1,000,000 pounds or more normal production live weight.~~

~~a. The minimum separation distance in feet required between a manure utilization area and real property owned by another person is 200 feet from the property lines.~~

~~b. The minimum separation distance in feet required between a manure utilization area and an occupied residence is 750 feet (excluding the applicant's residence).~~

~~c. The minimum separation distance in feet required between a manure utilization area and Waters of the State (not including ephemeral and intermittent streams), ditches, and swales is 150 feet.~~

~~d. The minimum separation distance in feet required between a manure utilization area and a public and private drinking water well is 200 feet.~~

~~e. The minimum separation distance in feet required between a manure utilization area and ephemeral and intermittent streams is 100 feet.~~

~~4~~2. Water (pond) that is completely surrounded by land owned by the applicant and has no connection to surface water is excluded from the setback requirements outlined in this part.

~~5~~3. The Department may establish in permits additional application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainage ways, and surface water (including ephemeral and intermittent streams) as deemed necessary to protect public health and the environment. Factors taken into consideration in the establishment of additional setbacks would be swine manure application method, adjacent land usage, public access, aerosols, runoff prevention, adjacent groundwater usage, aquifer vulnerability, and potential for vectors and odors.

D. The Department may establish additional permitting restrictions based upon soil and groundwater conditions to ensure protection of the groundwater and surface Waters of the State (including ephemeral and intermittent streams). Criteria may include, but is not limited to, soil permeability, clay content, depth to bedrock, rock outcroppings, aquifer vulnerability, proximity to State Approved Source Water Protection Area, and depth to the seasonal high groundwater table.

E. The Department may establish permit conditions to require that swine manure and other swine by-products application rates remain consistent with the lime and fertilizer requirements for the cover, feed, food, and fiber crops based on Southeastern land grant universities' ~~(in the southeast)~~ published lime and fertilizer recommendations (such as the Lime and Fertilizer Recommendations, Clemson Extension Services~~, Circular 476~~).

F. Groundwater Monitoring for Manure Utilization Areas.

1. For X-large swine facilities~~with 1,000,000 pounds or more normal production live weight~~, at least one (1) up-gradient and two (2) down-gradient groundwater monitoring wells shall be installed for each drainage basin intersected by the manure utilization areas. The location, design, and construction specifications for the monitoring wells shall be submitted in the application package. The information shall be reviewed and approved by the Department prior to permit issuance. The permit will contain specific requirements for sampling the groundwater monitoring wells, including the frequency and parameters for sampling.

2. For small and large swine facilities~~(500,000 pounds or less normal production live weight) and large swine facilities with less than 1,000,000 pounds normal production live weight~~, the Department may require groundwater monitoring at manure utilization areas as appropriate.

3. The Department may establish minimum requirements in permits for soil and/or groundwater monitoring for manure utilization areas. Factors taken into consideration in the establishment of soil and groundwater monitoring shall include ~~depth to the seasonal high groundwater~~groundwater depth, operation flexibility, application frequency, type of swine manure and other swine by-products, size of manure utilization area, aquifer vulnerability, proximity to a State Approved Source Water Protection Area, and loading rate.

a. The Department may establish pre-application and post-application site monitoring requirements in permits for limiting nutrients or limiting constituents as determined by the Department.

b. The Department may establish permit conditions, which require the permittee to reduce, modify, or eliminate the swine manure and other swine by-products applications based on the results of this monitoring data.

c. The Department may modify, revoke and reissue, or revoke a permit based on the monitoring data.

G. The Department may require periodic monitoring of any wet weather ditches or perennial streams which are in close proximity to any manure utilization areas.

100.110. Spray Application System Requirements.

A. Spray application of swine manure ~~utilizing~~using irrigation equipment. This includes all methods of surface spray application, including, but not limited to, fixed gun application, traveling or mobile gun application, or center pivot application.

B. New X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ are prohibited from utilizing spray application systems for manure application. Manure must be incorporated into the manure utilization fields ~~utilizing~~using subsurface injection at a depth of not less than ~~six~~6 inches.

C. Manure utilization area slopes shall not exceed ~~10~~ten percent (10%) unless approved by the Department. The Department may require that slopes be less than ten percent (10%) based on site conditions.

D. Swine manure distribution systems shall be designed so that the distribution pattern optimizes uniform application.

E. Hydraulic Application Rates.

1. Application rates shall normally be based on the agronomic rate for the crop to be grown at the manure utilization area. As determined by soil conditions, the hydraulic application rate may be reduced below the agronomic rate to ensure no surface ponding, runoff, or excessive nutrient migration to the groundwater occurs.

2. The hydraulic application rate may be limited based on constituent loading including any constituent required for monitoring under this regulation.

F. Swine manure and other swine by-products shall not be ~~land~~ applied ~~or discharged onto a land surface~~ when the vertical separation between the ground surface and the seasonal high water table is less than 1.5 feet at the time of application, unless approved by the Department on a case-by-case basis. For special cases, no land application can occur when the vertical separation from the ground surface to the water table is less than 1.5 feet at the time of application unless a situation is deemed an emergency with ~~d~~Departmental concurrence.

G. Conservation measures, such as terracing, strip cropping, etc., may be required in specific areas determined by the Department as necessary to prevent potential surface runoff from entering or leaving the manure utilization areas. The Department may consider alternate methods of runoff controls that may be proposed by the applicant, such as berms.

H. For swine facilities, a system for monitoring the quality of groundwater may also be required for the proposed manure utilization areas. The location of all the monitoring wells shall be approved by the Department. The number of wells, constituents to be monitored, and the frequency of monitoring shall be determined on a case-by-case basis based upon the site conditions such as type of soils, depth of water table, aquifer vulnerability, proximity to State Approved Source Water Protection Area, etc.

I. If an adverse trend in groundwater quality is identified, further assessment and/or corrective action may be required. This may include an alteration to the permitted application rate or a cessation of manure application in the impacted area.

J. Spray application systems shall be designed and operated in such a manner to prevent drift of liquid manure onto adjacent property.

100.120. Frequency of Monitoring for Swine Manure.

A. The producer and/or integrator shall be responsible for having representative samples based on Clemson University Extension Service recommendations of the swine manure collected and analyzed at least once per year and when the feed composition significantly changes. The constituents to be monitored shall be given in the permit. The analyses shall be used to determine the amount of swine manure to be land applied. In order to ensure that the permitted application rate (normally the agronomic rate) is met, the application amount shall be determined using a rolling average of the previous analyses. The Department shall establish minimum requirements for the proper method of sampling and analyzing of swine manure.

Facilities with permits that do not specify which constituents to monitor shall monitor for ~~A~~ammonium-~~N~~nitrogen, Total Kjeldahl Nitrogen (TKN), ~~O~~organic ~~N~~nitrogen (~~O~~organic ~~N~~nitrogen = TKN - ~~A~~ammonium ~~N~~nitrogen), P_2O_5, and K_2O.

B. The Department may require nitrogen, potassium, phosphorus, the constituents listed in Table 1 and Table 2 of Section 100.100 (Manure Utilization Area Requirements), and any other constituent contained in a permit to be monitored prior to each application.

C. Permittees do not have to analyze for any constituent they can demonstrate, to the satisfaction of the Department, is not present in their swine manure.

D. All monitoring shall be done in accordance with collection procedures in Standard Methods for Analysis of Water and Wastewater or other Department guidelines. Analysis shall be conducted by Clemson University Extension Service or a laboratory certified by the Department. This laboratory shall have and maintain certification for the constituents to be analyzed.

100.130. Dead Swine Disposal Requirements.

A. Dead swine disposal shall be done as specified in the approved Animal Facility Management Plan. The Dead Swine Disposal Plan shall include the following:

1. Primary Method ~~of disposal~~ for the handling and disposal of ~~dead swine~~ ~~that result from~~ normal mortality on the farm.

2. Alternate Method for the handling and disposal of ~~dead swine that result from~~ excessive mortality ~~on the farm~~at the facility. The normal method of disposal may not be sufficient to handle an excessive mortality situation. Each producer ~~should~~shall have ~~an~~a Department-approved emergency or alternate method to dispose of excessive mortality. Excessive mortality burial sites shall be preapproved by the Department prior to utilization.

B. Burial. (For existing facilities permitted prior to January 2023 with a burial site approved by the Department) Facility permits issued after January 2023 or facilities permitted prior to January 2023 without an approved burial site from the Department must find an alternate method for daily and emergency dead animal disposal. After January 2023 burial sites will be approved by the Department for an emergency that is declared by the South Carolina State Veterinarian, Clemson Livestock Poultry Health charged with protecting animal health through control of endemic, foreign, and emerging diseases in livestock and poultry and protecting the health of S.C. consumers.

1. Burial pits may be utilized for emergency conditions, as determined by the Department, when the primary method of disposal is not sufficient to handle excessive mortality.

2. Burial pits shall not be located in the 100-year floodplain.

3. Soil type shall be evaluated for leaching potential.

4. Burial pits shall not be located or utilized on sites that are in areas that may adversely ~~affect~~impact surface or groundwater quality or further impact impaired water bodies.

5. The bottom of the burial pit may not be within 2 feet of the seasonal high groundwater ~~level~~table.

6. No burial site shall be allowed to flood with surface water.

7. Swine placed in a burial site shall be covered daily with sufficient cover (6 inches per day minimum) to prohibit exhumation by feral animals.

8. When full, the burial site shall be properly capped (minimum 2 feet) and grassed to prohibit erosion.

9. Proposed burial pit sites shall be approved by the Department. The Department may conduct a geologic review of the proposed site prior to approval.

10. The Department may require any new or existing producers to utilize another method of dead swine disposal if burial is not managed according to the Dead Swine Disposal Plan or repeated violations of these burial requirements occur or adverse impact to surface or groundwater is determined to exist.

11. The Department may require groundwater monitoring for dead animal burial pits on a case-by-case basis. The Department shall consider all of the facts including, but not limited to, the following: depth to the seasonal high water table; aquifer vulnerability; proximity to a State Approved Source Water Protection Area; groundwater use in the area; distance to adjacent surface waters; number of dead animals buried; and frequency of burial in the area.

C. Incinerators.

1. For facilities proposing an incinerator for dead swine disposal, either a permit for the air emissions shall be obtained from the Department's Bureau of Air Quality before the incinerator can be built or the following criteria shall be met in order to qualify for an exemption from an air permit:

a. The emission of particulate matter shall be less than ~~one~~ 1 pound per hour at the maximum rated capacity.

b. The incinerator shall be a package incinerator ~~and have a rated capacity of 500 pounds per hour or smaller which burns virgin fuel only.~~that meets the requirements from the Department's Bureau of Air Quality; and

c. The incinerator shall not exceed an opacity limit of ten percent (10%).

2. Incinerators used for dead swine disposal shall be properly operated and maintained. Operation shall be as specified in the owner's manual provided with the incinerator. The owner's manual shall be kept on site and made available to Department personnel upon request.

3. The use of the incinerator to dispose of waste oil, hazardous waste, or any other waste chemical is prohibited. The use of the incinerator shall be limited to dead swine disposal only unless otherwise approved by the Department's Bureau of Air Quality.

D.~~Composters.~~ Composters used for dead swine disposal shall be designed by a professional engineer or an NRCS representative and operated in accordance with the approved Animal Facility Management Plan. Packaged composters shall be approved on a case-by-case basis.

E. Disposal of dead swine in a municipal solid waste landfill shall be in accordance with ~~Regulation~~ R.61- 107.~~258~~19.

F. Disposal of swine carcasses or body parts into manure lagoons, treatment systems, storage ponds, Waters of the State, ephemeral and intermittent streams, ditches, and swales is prohibited.

G. ~~Other methods of dead swine disposal that are not addressed in this regulation may be proposed in the Dead Swine Disposal Plan.~~ Disposal of animal carcasses or body parts by rendering shall be approved by the Department and include a signed contract with the rendering company.

H. Other methods of dead animal disposal that are not addressed in this regulation may be proposed in the Dead Animal Disposal Plan.

100.140. Other Requirements.

A. There shall be no discharge of pollutants from the operation into surface Waters of the State (including ephemeral and intermittent streams). There shall be no discharge of pollutants into groundwater, which could cause groundwater quality not to comply with the groundwater standards established in ~~South Carolina Regulation~~R.61-68.

B. On a case-by-case basis, the Department may impose additional or more stringent requirements for the management, handling, treatment, storage, or utilization of swine manure and other swine by-products.

C. The following cases shall be evaluated for additional or more stringent requirements:

1. Source water protection. Facilities and manure utilization areas located within a ~~s~~State-approved source water protection area.

2. 303(d) Impaired ~~Water bodies~~Water Bodies List. Facilities and manure utilization areas located upstream of an impaired waterbody.

3. Proximity to Outstanding Resource Waters, trout waters, shellfish waters, or potential to adversely affect a federally listed endangered or threatened species, its habitat, or a proposed or designated critical habitat.

4. Aquifer Vulnerability Area ~~which~~ is an area where groundwater recharge may affect an aquifer.

D. If an adverse impact to the Waters of the State, including ephemeral and intermittent streams, or groundwater from swine manure and other swine by-products handling, storage, treatment, or utilization practices are documented, through monitoring levels exceeding the standards set forth in ~~Regulation~~ R.61-68 or a significant adverse trend occurs, the Department may require the producer responsible for the swine manure and other swine by-products to conduct an investigation to determine the extent of impact. The Department may require the producer to remediate the water to within acceptable levels as set forth in ~~Regulation~~ R.61-68.

E. No manure may be released from a swine manure lagoon, treatment system, or storage pond or the premises of a swine facility to Waters of the State, ~~(~~including ephemeral and intermittent streams.~~) unless the manure is treated to water quality standards and a permit pursuant to Section 402 or 404 of the CWA has been issued by the Department.~~

F. Swine medical waste cannot be disposed into swine lagoons, treatment systems, or manure storage ponds, or land applied with swine manure and other swine by-products.

G. In the event of a discharge from a swine lagoon, treatment system, or manure storage pond, the permittee is required to notify the Department immediately, within twenty-four (24) hours of the discharge.

H. When the Department determines that a nuisance exists at a swine facility, the permittee shall take action to correct the nuisance to the degree and within the time frame designated by the Department.

I. Permittees shall maintain all-weather access roads to their facilities at all times.

~~J. The body of vehicles transporting manure shall be wholly enclosed and while in transit, be kept covered with a canvas cover provided with eyelets and rope tie-downs, or any other approved method which shall prevent blowing or spillage of loose material or liquids. Should any spillage occur during the transportation of the manure, the owner/operator shall take immediate steps to clean up the manure.~~

100.150. Odor Control Requirements.

A. The Animal Facility Management Plan shall contain an odor abatement plan for the swine facility, lagoon, treatment system, manure storage pond, and manure utilization areas. The plan shall consist of the following:

1. Operation and maintenance practices which are used to eliminate or minimize undesirable odor levels in the form of a Best Management Plan for Odor Control;

2. Use of treatment processes for the reduction of undesirable odor levels;

3. Additional setbacks from property lines beyond the minimum setbacks given in this part;

4. Other methods as may be appropriate; or

5. Any combination of these methods.

B. Producers shall utilize Best Management Practices normally associated with the proper operation and maintenance of a swine facility, lagoon, treatment system, manure storage pond, and any manure utilization area to ensure an undesirable level of odor does not exist.

C. No producer may cause, allow, or permit emission into the ambient air of any substance or combination of substances in quantities that an undesirable level of odor is determined to result unless preventive measures of the type set out below are taken to abate or control the emission to the satisfaction of the Department. When an odor problem comes to the attention of the Department through field surveillance or specific complaints, the Department shall determine if the odor is ~~at an~~ undesirable ~~level by considering the character and degree of injury or interference to:~~.

~~1. The health or welfare of the people;~~

~~2. Plant, animal, freshwater aquatic, or marine life;~~

~~3. Property; or~~

~~4.Enjoyment of life or use of affected property.~~

D.~~After determining an undesirable level of odor exists, the Department shall require remediation of the undesirable level of odor.~~ If the Department determines an undesirable level of odor exists, the Department may require these abatement or control practices, including, but not limited to, the following:

~~E. The Department may require abatement or control practices, including, but not limited to the following:~~

1. Remov~~al~~e or dispos~~al~~e of odorous materials;

2. Methods in handling and storage of odorous materials that minimize emissions;

a. Dry~~ing~~ to a moisture content of fifty percent (50%) or less;

b. Solids ~~S~~separation from liquid manure, and composting of solids;

c. Use ~~D~~disinfection to kill microorganisms present in manure;

d. Aerat~~ion~~e ~~of~~ manure;

e. Anaerobic digestion in a sealed vessel;

f. Compost~~ing of~~ solid manure and other swine by-products;

g. Utilize ~~O~~odor ~~C~~control ~~A~~additives.

3. Prescribed standards in the maintenance of premises to reduce odorous emissions;

a. Filtration (biofilters or other filter used to remove dust and odor) of ventilation air;

b. Keep~~ing~~ animals clean ~~or~~and separate~~d~~ from manure;

c. Adjust number of animals confined in the pens or paddocks in accordance with Clemson University Animal Space Guidelines~~.~~;

d. Frequent removal of manure from animal houses;

e. Add~~ing~~ a layer of water in the shallow pits after the manure is removed;

f. Feeding areas should be kept dry, and waste feed accumulation should be minimized;

g. Maintain~~ing~~ feedlot surfaces in a dry condition (twenty-five to forty percent (25~~%~~ to 40% moisture content), with effective dust control;

h. Proper maintenance of the dead swine disposal system;

i. Cover~~ing~~ or reduc~~ing~~e the surface area of manure and other swine by-products storage. (Vents shall be provided for release of pressure created by manure gases if completely sealed covers are used);

j. Plant~~ing~~ trees around or downwind of the manure and other swine by-products storage and treatment facilities (trees shall not be planted within 25 feet of the toe of the dike);

k. Incorporat~~ion~~e ~~of~~ manure and other swine by-products immediately after land application; and

l. Select~~ion of~~ appropriate times for land application.

4. Best Available Technology to reduce odorous emissions.

~~F.~~ E. Nothing in this section prohibits an individual or group of persons from bringing a complaint against a swine facility, including problems at lagoons, treatment systems, manure storage ponds, and manure utilization areas.

~~G.~~F. ~~If the permittee fails to control or abate the odor problems at a land application site to the satisfaction and within a time frame determined by the Department, approval for land application of manure on the manure utilization area in question may be revoked. Additional land may be required to be added to the Animal Facility Management Plan, if necessary to provide a sufficient amount of land for manure utilization.~~ If the permittee fails to control or abate the odor problems at a swine facility, lagoon, treatment system, manure storage pond, and any manure utilization area to the satisfaction and within a time frame determined by the Department, the permit may be revoked. If the permittee fails to control or abate the odor problems at land application sites, approval for land application of manure on the manure utilization area in question may be revoked. Additional land may be required to be added to the Animal Facility Management Plan, if necessary, to provide a sufficient amount of land for manure utilization.

100.160. Vector Control Requirements.

A. ~~Vector Abatement Plan.~~ The Vector Abatement Plan shall, at a minimum, consist of the following:

1.~~Normal~~ Best management practices used at the swine facility, lagoon, treatment system, manure storage pond, and manure utilization areas to ensure there is no accumulation of organic or inorganic materials to the extent and in such a manner as to create a harborage for rodents or other vectors that may be dangerous to public health.

2. A list of specific actions to be taken by the producer if vectors are identified as a problem at the swine facility, lagoon, treatment system, manure storage pond, or any manure utilization area. These actions should be listed for each vector problem, e.g., actions to be taken for fly problems, actions to be taken for rodent problems, etc.

B. No producer may cause, allow, or permit vectors to breed or accumulate in quantities that result in a nuisance level, as determined by the Department.

C. ~~The Department shall require remediation of the problem to the satisfaction of the Department, after determining a vector problem exists.~~ For an existing facility, if the Department determines a vector problem exists, the Department may require these abatement or control practices, including, but not limited to, the following:

~~D.The Department may require abatement or control practices, including, but not limited to the following:~~

1. Remove and properly dispose of vector infested materials;

2. Methods in handling and storage of materials that minimize vector attraction;

a. Remove spilled or spoiled feed from the house as soon as practicably possible, not to exceed forty-eight (48) hours, unless otherwise approved by the Department;

b. Remove and properly dispose of dead animals as soon as practicably possible, not to exceed twenty-four (24) hours, unless otherwise approved by the Department;

c. Increase the frequency of manure removal from animal houses;

d. Prevent solids buildup in the pit storage or on the floors or walkways;

e. Remove excess manure packs along walls and curtains;

f. Compost solid manure and other swine by-products;

g. Appropriate use of vector control chemicals, poisons, or insecticides (take caution to prevent insecticide resistance problems);

h. Utilize traps, or electrically charged devices;

i. Utilize biological agents;

j. Utilize Integrated Pest Management; and

k. Incorporate manure and other swine by-products immediately (within twenty-four (24) hours) after land application.

3. Prescribed standards in the maintenance of premises to reduce vector attraction;

a. Remove standing water that may be a breeding area for vectors;

b. Keep animals clean or separated from manure;

c. Keep facility clean and free from trash or debris;

d. Properly utilize and service bait stations;

e. Keep feeding areas dry, and minimize waste feed accumulation;

f. Keep grass and weeds mowed around the facility and manure storage or treatment areas;

g. Maintain the dead swine disposal system;

h. Cover or reduce the surface area of manure and other swine by-products storage. (Vents shall be provided for release of pressure created by manure gases if completely sealed covers are used);

i. ~~Store feed and feed supplements properly~~Properly store feed and feed supplements;

j. Conduct a weekly vector monitoring program;

k. Be aware of insecticide resistance problems, and rotate use of different insecticides;

l. Prevent and repair leaks in waterers, water troughs or cups; and

m. Ensure proper grading and drainage around the buildings to prevent rain water from entering the buildings or ponding around the buildings.

4. Utilize the ~~B~~best available control technology to reduce vector attraction and breeding.

100.170. Record Keeping.

A. A copy of the approved Animal Facility Management Plan, including approved updates, and a copy of the permit(s) issued to the producer shall be retained by the permittee for as long as the swine facility is in operation.

B. All application information submitted to the Department shall be retained by the permittee for eight (8) years. However, if the facility was permitted prior to June 26, 1998, and the permittee has previously discarded these documents since there was no requirement to maintain records at that time, this requirement shall not apply.

C. Records shall be developed for each manure utilization area. These records shall be kept for eight (8) years. The records shall include the following:

1. For each time swine manure and other swine by-products are applied to the site, the amount of swine manure and other swine by-products applied (in gallons per acre or pounds per acre, as appropriate), the ~~location of the site, and the date and time of manure and other swine by-products application~~date and time of the application, and the location of the application;

2. All sampling results for swine manure that is land applied~~, if applicable~~;

3. All soil monitoring results~~, if applicable~~;

4. All groundwater monitoring results, if applicable; and

5. Crops grown.

D. Records for the facility to include the following on a monthly basis:

1. ~~Monthly a~~Animal count and the normal production animal live weight; and

2. Mortality count and method of disposal.

E. Records for lagoon, treatment system, or manure storage pond operations to include the following:

1. Monthly water levels of the lagoon, treatment system, and manure storage pond; and

2. Groundwater monitoring results, if applicable.

F. All records retained by the producer shall be kept at either the facility, an appropriate business office, or other location as approved by the Department.

G. All records retained by the producer shall be made available to the Department during normal business hours for review and copying, upon request by the Department.

100.180. Reporting.

A. All large and X-large swine operations ~~(greater than 500,000 pounds of normal production live weight)~~ shall submit, on a form approved by the Department, the following on an annual basis or more frequently if required by a permit or regulation:

1. All manure sampling results for the last year, if applicable, and the latest rolling average concentration for the land limiting constituent;

2. All soil monitoring results, if applicable;

3. All groundwater monitoring results, if applicable;

4. Calculated application rates for all manure utilization areas; and

5. The adjusted application rates, if applicable, based on the most recent swine manure sampling, soil samples, and crop yields. The application rate change could also be due to a change in field use, crop grown, or other factors.

B. The Department may require small swine facilities ~~(500,000 pounds or less of normal production live weight)~~ to submit annual reports on a case-by-case basis.

C. The Department may establish permit conditions to require a swine facility to complete and submit a comprehensive report every five (5) years. The Department shall review this report to confirm that the permitted nutrient application rates have not been exceeded. Based on the results of the review, additional soil and/or groundwater monitoring requirements, permit modification, and/or corrective action may be required.

100.190. Training Requirements.

A. An owner/operator of a new or existing swine facility, lagoon, manure storage pond, or manure utilization area shall complete a training program on the operation of swine manure management created by Clemson University, i.e. (CAMM).

B. Owners/Operators of new and existing ~~large~~ swine facilities ~~(greater than 500,000 pounds of normal production live weight)~~ shall be required to pass a test and become certified as a part of the training program created by Clemson University. ~~The Department may require operators with documented violations to pass a test through Clemson's program.~~

C. The ~~training and/or~~ certification shall be completed by owners/operators of new facilities prior to start-up of operations.

D. The ~~training and/or~~ certification shall be completed by owners/operators of existing facilities within two (2) years of the effective date of this regulation. The certification program shall be completed by owners/operators involved in a transfer of ownership within one (1) year of the transfer of ownership approval.

E. ~~Training and/or~~The certification shall be maintained as long as the facility remains in operation.

F. Failure to obtain the ~~training and~~ certification as provided in this Section shall be deemed a violation of this ~~R~~regulation.

G. Additional Training and Certification Requirements for X-Large Swine Facilities~~with 1,000,000 pounds or greater normal production live weight.~~:

1. The Department shall classify all manure treatment systems serving X-large swine facilities, giving due regard to size, types of work, character, and volume of manure to be treated, and the use and nature of the land resources receiving the manure.

2. Manure treatment systems may be classified in a group higher than indicated at the discretion of the Department by reason of the following:

a. Incorporation in the treatment system of complex features which cause the treatment system to be more difficult to operate than usual; or

b. A waste stream that is unusually difficult to treat; or

c. Conditions of flow; or

d. Use of the receiving lands requiring an unusually high degree of system operation control; or

e. Combinations of such conditions or circumstances.

3. The classifications for biological treatment systems are based on the following groups:

a. Group I - B. All agricultural manure treatment systems which include one (1) or more of the following units: primary settling, chlorination, sludge removal, ~~i~~Imhoff tanks, sand filters, sludge drying beds, land spraying, grinding, screening, oxidation, and stabilization ponds.

b. Group II - B. All agricultural manure treatment systems which include one (1) or more of the units listed in Group I-B and, in addition, one (1) or more of the following units: sludge digestion, aerated lagoon, and sludge thickeners.

c. Group III - B. All agricultural manure treatment systems which include one (1) or more of the units listed in Groups I-B and II-B and, in addition, one (1) or more of the following: trickling filters, secondary settling, chemical treatment, vacuum filters, sludge elutriation, sludge incinerator, wet oxidation process, contact aeration, and activated sludge (either conventional, modified, or high rate processes).

d. Group IV - B. All agricultural manure treatment systems which include one (1) or more of the units listed in Groups I-B, II-B, and III-B and, in addition, treat manure having a raw five (5)-day biochemical oxygen demand of ~~five thousand~~5,000 pounds ~~a~~per day or more.

4. The classifications for physical chemical manure treatment systems are based on the following groups:

a. Group I-P/C. All agricultural manure treatment systems which include one (1) or more of the following units: primary settling, equalization, pH control, and oil skimming.

b. Group II-P/C. All agricultural manure treatment systems which include one (1) or more of the units listed in Group I-P/C and, in addition, one (1) or more of the following units: sludge storage, dissolved air flotation, and clarification.

c. Group III-P/C. All agricultural manure treatment systems which include one (1) or more of the units listed in Groups I-P/C and II-P/C and, in addition, one (1) or more of the following: oxidation/reduction reactions, cyanide destruction, metals precipitation, sludge dewatering, and air stripping.

d. Group IV-P/C. All agricultural manure treatment systems which include one (1) or more of the units listed in Groups I-P/C, II-P/C, and III-P/C and, in addition, one (1) or more of the following: membrane technology, ion exchange, tertiary chemicals, and electrochemistry.

5. It shall be unlawful for any person or corporation to operate an agricultural manure treatment system at ~~a~~an X-large swine facility ~~with 1,000,000 pounds or more normal production live weight~~ unless the operator-in-charge holds a valid certificate of registration issued by the Board of Certification of Environmental Systems Operators in a grade corresponding to the classification of the agricultural manure treatment system supervised by him or her.

100.200. Violations.

A. Persons who violate this regulation or any permit issued under this regulation are subject to the penalties in Sections 48-1-320 (Criminal Penalties) and 48-1-330 (Civil Penalties) of the South Carolina Pollution Control Act.

B. X-Large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall be assessed automatic penalties (up to $10,000 per day per violation) for the following violations:

1. Lagoon, treatment system, or manure storage pond breach, or loss of containment that is not the direct result of an Act of God.

2. Manure Utilization Area runoff due to improper manure application methods.

3. Discharge to groundwater on site causing groundwater to exceed any water quality standard established in ~~Regulation~~R.61-68.

C. Second occurrence of any of the violations outlined in 100.2~~10~~00.B. at ~~a~~an X-large swine facility ~~with 1,000,000 pounds or more normal production live weight~~ shall result in immediate revocation of the permit and the automatic assessment of appropriate penalties.

D. Immediate cessation of manure application will also be enforced on sites where groundwater quality is adversely affected.

E. Any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required by the Department to be maintained as a condition in a permit, or who alters or falsifies the results obtained by such devices or methods, shall be deemed to have violated a permit condition and shall be subject to the penalties provided for pursuant to Sections 48-1-320 and 48-1-330 of the S.C. Code of Regulations.

PART 200
ANIMAL FACILITIES (OTHER THAN SWINE)

~~200.10. Purpose, Applicability, Inactive Facilities and Facilities Permitted Prior to the Effective Date of Regulation.~~
~~200.20. Permits and Compliance Period.~~

~~200.30. Exclusions.~~
~~200.40. Relationship to Other Regulations.~~
~~200.50. Permit Application Requirements (Animal Facility Management Plan Submission Requirements).~~
~~200.60. Public Notice Requirements.~~
~~200.70. Permit Decision Making Process.~~
~~200.80. Facility, Lagoon, Treatment Systems, and Manure Storage Pond Siting Requirements.~~
~~200.90. General Requirements for Animal Manure Lagoons, Treatment Systems, and Animal Manure Storage Ponds.~~
~~200.100. Manure Utilization Area Requirements.~~
~~200.110. Spray Application System Requirements.~~
~~200.120. Frequency of Monitoring for Animal Manure.~~
~~200.130. Dead Animal Disposal Requirements.~~
~~200.140. Other Requirements.~~
~~200.150. Odor Control Requirements.~~
~~200.160. Vector Control Requirements.~~
~~200.170. Record Keeping.~~
~~200.180. Reporting.~~
~~200.190. Training Requirements.~~
~~200.200. Violations.~~

200.10. Purpose, Applicability, Inactive Facilities, and Facilities Permitted Prior to Effective Date of the Regulation.

A. Purpose.

1. To establish standards for the growing or confining of animals, processing of animal manure and other animal by-products, and land application of animal manure and other animal by-products in such a manner as to protect the environment, and the health and welfare of citizens of ~~T~~the State from pollutants generated by this process.

2. To establish standards, which consist of general requirements, constituent limits, management practices, and operational standards, for the utilization of animal manure and other animal by-products generated at animal facilities. Standards included in this part are for animal manure and other animal by-products applied to the land.

3. To establish standards for the frequency of monitoring and record keeping requirements for producers who operate animal facilities.

4. To establish standards for the proper operation and maintenance of animal facilities.

5. To establish criteria for animal facilities' and manure utilization areas' location as they relate to protection of the environment and public health. The location of animal facilities and manure utilization areas as they relate to zoning in an area is not covered in this regulation. Local county or municipal governments may have zoning requirements and ~~these~~this regulation~~s~~ neither interferes with nor restricts such zoning requirements. Permit applicants should contact local municipal and county authorities to determine any local requirements that may be applicable.

B. Applicability.

1. This part applies to:

a. All new animal facilities;

b. All expansions of existing animal facilities;~~and~~

c. New manure utilization areas for existing animal facilities~~.~~;

d. All inactive facilities; and

e. All facilities and lagoon closures.

2. This part applies to all animal manure and other animal by-products applied to the land.

3. This part applies to all land where animal manure and other animal by-products are applied.

C. Inactive Facilities.

1. If an animal facility is ~~closed~~inactive for two (2) years or less, a producer may ~~renew~~resume operations of the facility under the same conditions by which it was previously permitted by notifying the Department in writing that the facility is being operated again.

2. For animal facilities that have been ~~closed~~inactive for more than two (2) years but less than five (5) years, the Department shall review the existing permit and modify its operating conditions as necessary prior to the facility being placed back into operation.

3. For all other than swine animal facilities that have been ~~closed~~inactive for five (5) or more years, the producer shall properly close out any lagoon, treatment system, or manure storage pond associated with the facility. The closeout shall be accomplished in accordance with ~~Regulation~~R.61-82. The permittee shall submit a closeout plan that meets, at a minimum, NRCS-CPS within a time frame prescribed by the Department. Additional time may be granted by the Department to comply with the closeout requirement or to allow the producer to apply for a new permit under this regulation, as appropriate.

~~4.If an animal facility closes for more than five years, the requirements under this part shall be met before the facility can renew operations.~~ If an animal facility is inactive for more than five (5) years, the permit is considered expired and the producer shall apply for a new permit and all requirements of this regulation shall be met before the facility can resume operations.

5. During the closeout of the facilities and/or lagoons/waste storage ponds, annual fees are required until proper closeout is certified and approved.

D. Facilities Permitted Prior to the Effective Date of the Regulation.

1. All existing animal facilities with permits issued by the Department before June 2~~8~~6, 1998, do not need to apply for a new permit as they are deemed permitted (deemed permitted animal facilities) unless they have been ~~closed~~inactive for more than two (2) years or expand operations. These facilities shall meet the following sections of Part 200: Section 200.20 (Permits and Compliance Period)~~.~~; Section 200.90.A~~.~~, D~~.~~, and J~~.~~ ~~—~~O~~.~~ (General Requirements for Animal Manure Lagoons, Treatment Systems, and Animal Manure Storage Ponds)~~.~~; Section 200.100~~.B.1.-22~~. (Manure Utilization Area Requirements)~~.~~; Section 200.110.H~~.~~-I~~.~~ (Spray Application System Requirements)~~.~~; Section 200.120.A~~.~~, C~~.~~-D~~.~~ (Frequency of Monitoring for Animal Manure)~~.~~; Section 200.130.A~~.~~, B~~.~~, and C.2.-3. (Dead Animal Disposal Requirements)~~.~~; Section 200.140.A~~.~~, C~~.~~-I~~.~~ (Other Requirements)~~.~~; Section 200.150.B~~.~~-F~~.~~ (Odor Control

Requirements)~~,~~; Section 200.160.B~~.~~-D~~.~~ (Vector Control Requirements)~~,~~; Section 200.170 (Record Keeping)~~,~~; Section 200.180 (Reporting)~~,~~; Section 200.190 (Training Requirements)~~,~~; and Section 200.200 (Violations). The capacity of a deemed permitted facility that does not have a lagoon is the number of animals and normal production animal live weight permitted by the Department prior to the effective date of ~~these~~this regulation~~s~~. For deemed permitted facilities with lagoons, the capacity is the maximum capacity of the existing animal manure lagoon, treatment system, and animal manure storage pond as determined using the appropriate animal manure lagoon, treatment system, and animal manure storage pond capacity design criteria of the United States Department of Agriculture's Natural Resource Conservation Service.

2. All existing animal facilities with permits issued by the Department between June 26, 1998, and the effective date of ~~these~~this regulation~~s~~ do not need to apply for a new permit if they hold a valid permit from the Department, unless they have been ~~closed~~inactive for more than two (2) years. These facilities shall meet all the requirements of ~~these~~this regulation~~s~~.

3. All existing animal facilities that were constructed and placed into operation prior to June 26, 1998, but have never received an agricultural permit from the Department, shall apply for a permit from the Department. This facility shall meet all the requirements of this regulation as the Department determines appropriate. The Department shall review the site and make a determination on a case-by-case basis on which requirements are applicable.

4. An existing animal facility may be required to ~~obtain~~submit an updated Animal Facility Management Plan on a case-by-case basis by the Department. The Department shall notify the permittee in writing of this requirement. The permittee has six (6) months or an agreed upon time frame from the date of notification to submit an updated Animal Facility Management Plan. Failure to submit the updated plan within this time frame is a violation of the South Carolina Pollution Control Act and ~~these~~this regulation~~s~~, and may result in permit revocation.

5. Both the setbacks and other requirements for manure utilization areas shall be met when a new manure utilization (MUA) area is added by the owner of any animal facility regardless of when the facility was permitted.

6. If an existing animal facility regulated under this part proposes to convert to a swine facility, it shall be considered a new swine facility under ~~these~~this regulation~~s~~. Converted facilities shall be permitted as new swine facilities and meet all criteria for new swine facilities before they begin operation as a swine facility.

200.20. Permits and Compliance Period.

A. Permit Requirement. Animal manure and other animal by-products from a new or expanded animal facility can only be generated, handled, stored, treated, processed, or land applied in the State in accordance with a permit issued by the Department under the provisions of this part. Existing producers that are required by the Department to update their Animal Facility Management Plan shall meet the requirements of this part to the extent practical as determined by the Department.

B. Permits issued under this regulation are no-discharge permits.

C. The requirements in this part shall be implemented through a permit issued to any producer who operates an animal facility where animal manure and other animal by-products are ~~produced, processed, or disposed~~generated, handled, treated, stored, processed, or land applied.

D. The requirements under this part may be addressed in permits issued to producers who only land apply animal manure and other animal by-products.

E. Notification Requirements. The permittee shall notify the Department in writing and receive written Departmental approval, except ~~where noted~~as otherwise noted, prior to any change in operation~~als procedures~~ at a permitted facility, including, but not limited to, the following:

1. Change in ownership and control of the facility. The Department has thirty (30) calendar days from the receipt of a complete and accurate notification of transfer of ownership to either: request additional information regarding the transfer or the new owner; deny the transfer; or approve the transfer of ownership. If the Department does not act within thirty (30) calendar days, the transfer is automatically approved. If additional information is requested by the Department in a timely manner, the Department shall act on this additional information, when it is received, within the same time period as the initial notification.

2. Increase in the permitted number of animals.

3. Addition of manure utilization areas.

4. Change in animal manure and other animal by-products treatment, handling, storage, processing, or utilization.

5. Change in method of dead animal disposal.

F. ~~Permit Modification.~~ Permit modifications for items 200.20.E.2 and 200.20.E.4 for facilities regulated under this part, which will result in expansions, shall adhere to the requirements of this part and other applicable statutes, regulations, or guidelines.

G. Permit modification for item~~s~~ 200.20.E.2 which result in an expansion may be required to obtain new written waivers or agreement for reduction of setbacks from adjoining property owners (if applicable).

200.30. Exclusions.

The following do not require permits from this part unless specifically required by the Department under item 200.30.G.

A. Existing animal facilities that are deemed permitted under Section 200.10.D.1 are excluded from applying for a new permit unless an expansion is proposed, new manure utilization areas are added, or as required by the Department. However, deemed permitted facilities shall meet the requirements of this regulation as outlined in Section 200.10.D (Purpose, Applicability, Inactive Facilities, and Facilities Permitted Prior to the Effective Date of the Regulation).

B. Except as given in Section 200.30.G, animal facilities with only ranged animals, and no lagoon, treatment system, or manure storage pond is associated with the facility, are excluded from obtaining a permit from the Department. The range area shall be of sufficient size to allow for natural degradation or utilization of the animal manure with no adverse impact to the environment. Ranged facilities shall also maintain adequate vegetative buffers between the animal range and Waters of the State.

C. Except as given in Section 200.30.G, animal facilities, ~~that~~which do not have a lagoon, manure storage pond, or liquid manure treatment system, having 10,000 pounds or less of normal production animal live weight at any one time are excluded from obtaining a permit from the Department~~, but~~ . However, these

facilities shall have and implement an Animal Facility Management Plan for their facility that meets the requirements of this regulation.

D. Except as given in Section 200.30.G, animal facilities, ~~that~~which do not have a lagoon, manure storage pond, or liquid manure treatment system, having more than 10,000 pounds of normal production animal live weight at any one time and having less than 30,000 pounds of normal production animal live weight at any one time are excluded from obtaining a permit from the Department. However, these facilities shall submit an Animal Facility Management Plan to the Department and implement an Animal Facility Management Plan for their facility that meets the requirements of this regulation.

E. Except as given in Section 200.30.G, animal facilities that are not classified as commercial facilities are excluded from obtaining a permit from the Department.

F. Except as given in Section 200.30.G, animal facilities that hold valid permits issued by the Department are not required to obtain a new permit if they decide to replace in kind any of the animal growing houses. ~~If the permittee chooses to leave the old houses in place to utilize for another purpose other than housing animals, the Department shall perform a preliminary site inspection for the proposed location of the replacement houses and approve the site prior to construction.~~

G. Animal facilities exempted under Sections 200.30.A, B, C, D, E, and F may be required by the Department to obtain a permit. The Department shall visit the site before requiring any of these facilities to obtain a permit.

200.40. Relationship to Other Regulations.

The following regulations are referenced throughout this part and may apply to facilities covered under this regulation.

~~A.Nuisances are addressed in Regulation 61-46.~~

~~B~~A. Application and annual operating fees are addressed in ~~Regulation~~R.61-30, Environmental Protection Fees.

~~C~~B. The proper closeouts of wastewater treatment facilities are addressed in ~~Regulation~~R.61-82, Proper Closeout of Wastewater Treatment Facilities. This includes animal lagoons and manure storage ponds.

~~D.Permitting requirements for concentrated animal feeding operations as defined by Regulation 61-9 are contained in Regulation 61-9.~~

~~E~~C. Setbacks and construction specifications for potable water wells and monitoring wells shall be in accordance with ~~Regulation~~R.61-71, Well Standards.

~~F~~D. Permits for air emissions from incinerators are ~~contained~~addressed in ~~Regulation~~R.61-62, Air Pollution Control Regulations and Standards.

~~G~~E. Disposal of animal manure in a municipal solid waste landfill unit is addressed in ~~Regulation~~R.61-107.~~258~~19, Solid Waste Management: Solid Waste Landfills and Structural Fill.

~~H~~F. Disposal of animal manure with domestic or industrial sludge is addressed in ~~Regulation~~R.61-9, Water Pollution Control Permits, and permitted under R.61-9.

~~I. Procedures for contested cased are addressed in Regulation61-72 and the Rules of the State's Administrative Law Judge Division.~~

~~J~~G. Laboratory ~~C~~certification is addressed in ~~Regulation~~R.61-81, State Environmental Laboratory Certification Program.

~~K~~H. Water Classifications and Standards are addressed in ~~Regulation~~R.61-68.

200.50. Permit Application Procedures (Animal Facility Management Plan Submission Requirements).

A. Preliminary Site Evaluations. The Department shall perform a preliminary evaluation of the proposed site at the request of the applicant. Written requests for a preliminary site inspection shall be made using a form~~, as designated~~ provided by the Department. The Department shall not schedule a preliminary site inspection until all required information specified in the form has been submitted to the Department. This evaluation should be performed prior to preparation of the Animal Facility Management Plan. Once the preliminary site inspection is performed, the Department shall issue an approval or disapproval letter for the proposed site.

B. A producer who proposes to build a new animal facility or expand an existing animal facility shall make application for a permit under this part using an application form ~~as designated~~provided by the Department. The following information shall be included in the application package.

1. A completed and accurate application form.

2. An Animal Facility Management Plan prepared by qualified Natural Resources Conservation Service (NRCS) personnel or a S.C. registered professional engineer (PE). Other qualified individuals, such as certified soil scientists~~, etc.,~~ or S.C. registered professional geologists (PG), may prepare the land application component of an Animal Facility Management Plan. The Animal Facility Management Plan shall, at a minimum, contain:

a. Facility name, address, telephone numbers, email address (if applicable), county, and National Pollutant Discharge Elimination System Permit or other permit number (if applicable);

b. Facility location description and the zoning or land use restrictions in this area (this information is available from the county);

c. Applicant's name, address, email, and telephone number (if different from above);

d. Operator's name and CAMM number (if available)

e. Facility capacity;

i. Number and type of animals;

ii. Pounds of normal production animal live weight at any one time;

iii. Amount of animal manure and other animal by-products generated per year (gallons for liquid animal manure and pounds for dry animal manure);

iv. Amount in tons of any scraped or separated solid animal manure and other animal by-products generated per year (if applicable);

v. Description of animal manure and other animal by-products storage and storage capacity of lagoon, treatment system, or manure storage pond (if applicable); and

vi. Description of animal manure and other animal by-products treatment (if any).

f. Concentration of constituents in liquid animal manure including, but not limited to, the constituents given below:

i. Nutrients.

(a) Nitrate (only needed for aerobic systems).

(b) Ammonium-Nitrogen.

(c) Total Kjeldahl Nitrogen (TKN).

(d) Organic-Nitrogen (TKN - Ammonium-Nitrogen).

(e) P_2O_5.

(f) K_2O (potash).

ii. Constituents.

(a) Arsenic.

(b) Copper.

(c) Zinc.

iii. Name, address, S.C. lab certification number, and telephone number of the laboratory conducting the analyses.

iv. For new animal facilities, liquid animal manure analysis information does not have to be submitted as the Department shall use manure analyses from similar sites or published data (such as: Clemson University, American Society of Agricultural Engineers, Midwest Planning Service Document, NRCS Technical Guide or equivalent) in review of the application. Analysis of the actual animal manure generated shall be submitted to the Department twelve (12) months after a new animal facility starts operation or prior to the first application of animal manure to a manure utilization area, whichever occurs first. If this analysis is significantly different from the estimated analysis used in the permitting decision, the Department may require a permit modification as necessary to address the situation. Analysis shall be conducted by a laboratory certified by the Department. This laboratory shall have and maintain certification for the constituents to be analyzed.

g. Concentration of constituents in dry animal manure including, but not limited to, the following:

i. Nutrients (on a dry weight basis).

(a) Total Kjeldahl Nitrogen (mg/kg).

(b) Total inorganic nitrogen (mg/kg).

(c) Total ammonia nitrogen (mg/kg) and Total nitrate, nitrogen (mg/kg).

(d) P_2O_5 (mg/kg).

(e) K_2O (mg/kg).

(f) Calcium Carbonate equivalency (if animal manure is alkaline stabilized).

ii. Constituents (on a dry weight basis).

(a) Arsenic (mg/kg).

(b) Copper (mg/kg).

(c) Zinc (mg/kg).

iii. Name, address, S.C. lab certification number, and telephone number of the laboratory conducting the analyses.

iv. For new animal facilities, dry animal manure analysis information does not have to be submitted as the Department shall use manure analyses from similar sites or published data (such as: Clemson University, American Society of Agricultural Engineers, Midwest Planning Service Document, NRCS Technical Guide or equivalent) in review of the application. Analysis of the actual dry animal manure generated shall be submitted to the Department twelve (12) months after a new animal facility starts operation or prior to the first application of animal manure to a manure utilization area, ~~which ever~~ whichever occurs first. If this analysis is significantly different from the estimated analysis used in the permitting decision, the Department may require a permit modification as necessary to address the situation. Analysis shall be conducted by a laboratory certified by the Department. This laboratory shall have and maintain certification for the constituents to be analyzed.

h. Animal manure and other animal by-products handling and application information shall be included as follows:

i. A crop management plan which includes the time of year of the animal manure application and how it relates to crop type, crop planting, and harvesting schedule (if applicable) for all manure utilization areas;

ii. Name, address, and telephone number of the producer(s) that will land apply the animal manure and other animal by-products if different from the permittee;

iii. Type of equipment used to transport and/or spread the animal manure and other animal by-products (if applicable); and

iv. For spray application systems, plans and specifications with supporting details and design calculations for the spray application system.

i. Facility and manure utilization area information shall be included (as appropriate):

i. Name ~~and~~, address, and tax map number of landowner and location of manure utilization area(s);

ii. List previous calendar years that animal manure and other animal by-products ~~was~~were applied and application amounts, where available;

iii. Facility and manure utilization area location(s) on maps drawn to approximate scale including:

(a) Topography (7.5' or equivalent) and drainage characteristics (including ditches);

(b) Adjacent land usage (within 1/4 mile of property line minimum) and location of inhabited dwellings and public places showing property lines and tax map number;

(c) All known water supply wells on the applicant's property and within 200 feet of the facility's property line or within 200 feet of any manure utilization areas;

(d) Adjacent surface water bodies (including ephemeral and intermittent streams);

(e) Animal manure utilization area boundaries and buffer zones;

(f) ~~R~~right-of-~~W~~ways (Utilities, roads, etc.);

(g) Soil types as given by soil tests or soils maps, a description of soil types, and boring locations (if applicable);

(h) Recorded ~~P~~plats, ~~S~~surveys, or other acceptable maps that include property boundaries; and

(i) Information showing the 100-year and 500-year floodplain (as determined by FEMA).

vi. For manure utilization areas not owned by the permit applicant, a signed agreement between the permit applicant and the landowner acceptable to the Department detailing the liability for the land application. The agreement shall include, at a minimum, the following:

(a) Producer's name, farm name, farm address, CAMM number, and county in which the farm is located;

(b) Landowner's name, address, phone number;

(c) Location (map with road names, tax map numbers, and county identified) of the land to receive manure application;

(d) Field acreage, acreage less setbacks, and crops grown;

(e) Name of manure hauler;

(f) Name of manure applier;

(g) A statement that land is not included in any other management plans and manure or compost from another farm is not being applied on this land; and any manure utilization areas that are included in

multiple Animal Facility Management Plans, identify the names of all facilities that include this manure utilization area in their plan; and

(h) A signed statement which informs the landowner that he or she is responsible for spreading and utilizing this manure in accordance with the requirements of the Department and ~~Regulation61-43~~this regulation.

~~v. For other manure utilization areas that are included in multiple Animal Facility Management Plans, identify the names of all facilities that include this manure utilization area in their plan.~~

3. Groundwater monitoring well details and proposed groundwater monitoring program (if applicable).

4. The Animal Facility Management Plan shall contain an odor abatement plan for the animal facility, lagoon, treatment system, manure storage pond, and manure utilization areas. For more specific details, see Section 200.150 (Odor Control Requirements).

5. A Vector Abatement Plan shall be included for the animal facility, lagoon, treatment system, ~~or~~ manure storage pond, and manure utilization areas. For more specific details see Section 200.160 (Vector Control Requirements).

6. The Dead Animal Disposal Plan~~. The plan~~ shall include written details for the handling and disposal of dead animals. Plans should detail method of disposal, any construction specifications necessary, and management practices. See Section 200.130 (Dead Animal Disposal Requirements) for specific requirements on dead animal disposal.

7. A Soil Monitoring Plan~~. A soil monitoring plan~~ shall be developed for all manure utilization areas. See Section 200.100 (Manure Utilization Area Requirements) for more detailed information.

8. Plans and specifications for all other manure treatment or storage structures, such as holding tanks or manure storage sheds.

9. All "Notice of Intent to Build or Expand an Animal Facility" forms ~~as~~ provided by the Department and a tax map (or equivalent) to scale showing all neighboring property owners and identifying which property has inhabited dwellings. See Section 200.60 (Public Notice Requirements) for more detailed information.

10. An Emergency Plan. The emergency plan should, at a minimum, contain a list of entities or agencies the producer ~~should~~shall contact in the event of lagoon, treatment system, or manure storage pond breach, ~~major~~mass animal mortality, fire, flood, or other similar type problem. For facilities in the coastal areas of the state, the emergency plan should address actions to be taken by a producer during hurricane season (such as providing additional freeboard during that time) and when advance warning is given on any extreme weather condition.

11. ~~Adjoining property owners written agreement for reduction of setbacks (if applicable)~~All waivers as specified in Section 200.80 (Facility, Lagoon, Treatment System, and Manure Storage Pond Siting Requirements), if applicable.

12. Application fee and first year's operating fee as established by ~~Regulation~~R.61-30.

C. The Department may request an applicant to provide any additional information deemed necessary to complete or correct deficiencies in the animal facility permit application prior to processing the application or issuing, modifying, or denying a permit.

D. Applicants shall submit all required information in a format acceptable to the Department.

E. An application package for a permit is complete when the Department receives all of the required information which has been completed to its satisfaction. Incomplete submittal packages may be returned to the applicant by the Department.

F. Application packages for permit modifications only need to contain the information applicable to the requested modification or any additional information the Department deems necessary.

200.60. Public Notice Requirements.

A. For new animal facilities, the applicant shall notify all property owners within 1,320 feet of the proposed location of the facility (footprint of construction) of the applicant's intent to build an animal facility. The applicant shall use a notice of intent form provided by the Department. The Department shall post the Public Notice of application received on the Department's website for fifteen (15) business days. The Department ~~shall~~may also post up to four (4) notices, in the four (4) cardinal directions ~~on~~around the perimeter of the property or in close proximity to the property, in locations visible ~~locations~~to the public within the public right-of-ways determined by the Department. The notice of intent on the Department's website shall advise adjoining property owners that they can send comments on the proposed animal facility directly to the Department.

B. For properties that have multiple owners or properties that are in an estate with multiple heirs, the Department, ~~at the expense of the applicant,~~ shall publish a notice of intent to construct an animal facility ~~in a local paper of general circulation in the area of the facility~~on the Department's website. This notice ~~in the newspaper~~on the Department's website shall serve as notice to these multiple property owners of the producer's intent to build an animal facility. ~~The cost to run this notice is not included in the application fee, and therefore shall be billed directly to the permit applicant for payment. This notice fee shall be paid prior to the issuance of the permit.~~

C. For existing animal facilities seeking to expand their current operations, the Department shall post the Public Notice of application received on the Department's website for fifteen (15) business days. The Department may also post up to four (4) notices in the four (4) cardinal directions ~~on~~around the perimeter of the property or in close proximity to the property, in locations visible ~~locations~~ to the public right-of-way or as determined by the Department.

D. The Department shall review all comments received. If the Department receives twenty (20) or more letters from different ~~people~~"Affected Persons" requesting a meeting or the Department determines significant comment exists, a meeting shall be held to discuss and seek resolution to the concerns prior to a permit decision being made. All persons who have submitted written comments shall be invited in writing to the meeting. First Class US mail service, email, or hand delivery to the address of a person to be notified shall be used by the Department for the meeting invitation. However, if the Department determines that the number of persons who submitted written comments is significant, the Department shall publish a notice of the public meeting ~~in a local newspaper of general circulation~~on the Department's website instead of notifying each individual by ~~f~~First ~~c~~Class mail or email. In addition, the Department shall notify all group leaders and petition organizers in writing. Agreement of the parties is not required for the Department to make a permit decision.

E. When comments are received by ~~electronic mail~~email, the Department shall acknowledge receipt of the comment by ~~electronic mail~~email. These comments shall be handled in the same manner as written comments received by postal mail.

F. The Department shall consider all relevant comments received in determining a permit decision.

G. The Department shall give notice of the permit decision to issue or deny the permit to the applicant, all persons who commented in writing to the Department, and all persons who attended the meeting, if held. First Class US mail service or email shall be used by the Department for the notice of decision. However, if the Department determines that members of the same group or organization have submitted comments or a petition, the Department shall only notify all group leaders and petition organizers in writing. The Department shall ask these leaders and organizers to notify their groups or any concerned citizens who signed the petitions.

H. For permit issuances, the Department shall publish a notice of issuance of a permit to construct or expand an animal facility ~~in a local newspaper of general circulation in the area of the facility~~on the Department's website.

I. For permit denials, the Department shall give the permit applicant a written explanation, which outlines the specific reasons for the permit denial.

J. For permit denials, the Department shall publish a notice of decision ~~in a local newspaper of general circulation in the area of the facility or send each concerned citizen who submitted written comments a letter by first class mail.~~on the Department's website.

K. The Department shall include, at a minimum, the following information in the public notices on permit decisions: the name and location of the facility; a description of the operation and the method of manure handling; instructions on how to appeal the Department's decision; the time frame for filing an appeal; the date of the decision; and the date upon which the permit becomes effective.

200.70. Permit Decision Making Process.

A. No permit shall be issued before the Department receives a complete application ~~for a permit~~package.

B. The agricultural program of the Department is not involved in local zoning and land use planning. Local government(s) may have more stringent requirements for agricultural animal facilities. The permittee is responsible for contacting the appropriate local government(s) to ensure that the proposed facility meets all the local requirements.

C. After the Department has received a complete application package, a technical review shall be conducted by the Department. The Department may request any additional information or clarification from the applicant or the preparer of the Animal Facility Management Plan to help with the determination on whether a permit should be issued or denied. If a permit application package meets all applicable requirements of this part, a permit may be issued.

D. A preliminary site inspection shall be made by the Department before a ~~permit decision is made~~complete application package is received by the Department.

E. The Department shall act on all permits to prevent, so far as reasonably possible considering relevant standards under state and federal laws, an increase in pollution of the waters and air of the State from any new or enlarged sources.

F. The setback limits given in ~~this part~~Part 200 are ~~minimum~~ siting requirements~~(with exception to those that are not labeled as minimum requirements, which are absolutes). On a case-by-case basis the Department may require additional separation distances applicable to animal facilities, lagoons, treatment systems, manure storage ponds, and manure utilization areas~~. The Department shall evaluate the ~~proposed~~ site including, but not limited to, the~~ following factors ~~when determining~~ to determine if ~~additional distances~~ any special conditions are necessary:

1. ~~Proximity to 100-year floodplain~~ Latitude and Longitude;

2. ~~Geography and soil types on the site;~~ Down-wind receptors; and

3. ~~Location in a watershed;~~ Nutrient Management Plan.

~~4. Classification or impairment of adjacent waters;~~

~~5. Proximity to a State Designated Focus Area; Outstanding Resource Water; Heritage Corridor; Historic Preservation District; State Approved Source Water Protection Area; state or national park or forest; state or federal research area; and privately-owned wildlife refuge, park, or trust property;~~

~~6. Proximity to other known point source discharges and potential nonpoint sources;~~

~~7. Slope of the land;~~

~~8. Animal manure application method and aerosols;~~

~~9. Runoff prevention;~~

~~10. Adjacent groundwater usage;~~

~~11. Down-wind receptors; and~~

~~12. Aquifer vulnerability.~~

~~G. The appeal of a permit decision is governed by the SC Administrative Procedures Act, Regulation61-72, and the Rules of the State's Administrative Law Division.~~

~~H~~G. When a permit is issued, it shall contain an issue date, an effective date, and, when applicable, a construction expiration date. The effective date shall be at least ~~twenty (20)~~fifteen (15) calendar days after the issue date to allow for any appeals. If a timely appeal is not received, the permit shall be effective on the effective date.

~~I. The permit may contain a permit expiration date. If a facility is classified as a CAFO under the NPDES Regulation 61-9, the expiration date shall be no more than five years after the issue date.~~

~~J~~H. An expired permit (final expiration date for renewal) issued under this part continues in effect until a new permit is effective if the permittee submits a complete application, to the satisfaction of the Department, at least one hundred eighty (180) calendar days before the existing permit expires. The Department may grant permission to submit an application later than the deadline for submission stated above, but no later than the permit expiration date. If the facility has been closed for any two (2) consecutive years since the last permit was issued, the provision for the expiring permit remaining in effect does not

apply since the permit is no longer valid. Permittees shall notify the Department in writing within thirty (30) calendar days of when they go out of business.

~~K~~I. The animal facility, lagoon, treatment system, or manure storage pond can be built only when the permit is effective ~~with no appeals pending~~. The facility cannot be placed into operation until the Department ~~grants written authorization to begin operations~~has issued a written Approval to Operate (ATO).

~~L~~J. To receive ~~authorization to begin operations~~an ATO, the producer shall have the preparer of the Animal Facility Management Plan submit to the Department~~,~~ written certification that the construction has been completed in accordance with the approved Animal Facility Management Plan and the requirements of this regulation.

~~M~~K. The Department ~~may~~ shall conduct a final inspection before granting ~~authorization~~an ATO to a producer to begin operations.

~~N~~L. The Department shall grant written ~~authorization~~approval for the producer to begin operations after it has received the certification statement in 200.70.~~L~~J and the results of the final inspection~~, if conducted,~~ are satisfactory.

~~O~~M. Animal Facility Construction Permit Expiration and Extensions.

1. Construction permits issued by the Department for agricultural animal facilities shall be given two (2) years from the effective date of the permit to start construction and three (3) years from the effective date of the permit to complete construction.

2. If the proposed construction ~~proposed under~~as outlined in the permit is not started prior to the construction start expiration date, the construction permit is invalid unless an extension in accordance with this regulation is granted.

3. If construction is not completed and the facility is not placed into operation prior to the construction completion expiration date, the construction permit is invalid unless an extension in accordance with this regulation is granted.

4. If a portion of the permitted facility (some of the animal growing houses are completely constructed, but not all houses originally permitted were constructed) is completed prior to the construction completion expiration date, the construction for the remainder of the permit may be utilized within the permit life. The permittee shall obtain Departmental approval prior to utilizing the permit in this manner. The Department may require that the permittee submit additional information or update the Animal Facility Management Plan prior to approval.

5. Extensions of the permit construction start and completion expiration dates may be granted by the Department. The permittee shall submit a written request explaining the delay and detailing any changes to the proposed construction. This request shall be received no~~t~~ later than ~~10 days prior to~~ the expiration date that the permittee proposes to extend. The maximum extension period shall not exceed one (1) year. There shall be no more than two (2), one (1)-year extension periods per permit to construct, granted.

200.80. Animal Facility, Lagoon, Treatment Systems, and Manure Storage Pond Siting Requirements.

A. Siting requirements applicable to all animal facilities.

1. The minimum separation distance between an animal facility (animal growing areas, houses, pens or barns, not including range areas or manure utilization areas) and a public or private drinking water well (excluding the applicant's well) is 200 feet. The minimum separation distance between an animal facility and a potable water well owned by the applicant is 50 feet (as required by R.61-71).

2. The minimum separation distance between an animal facility and Waters of the State (including ephemeral and intermittent streams) located down slope from the facility is 100 feet. ~~The setbacks required from ephemeral and intermittent streams may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

3. Except for site drainage, the minimum separation distance required between an animal facility and a ditch or swale located down slope from the facility is 50 feet. ~~The setbacks required from ditches may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

4. A new animal facility or an expansion of an established animal facility shall not be located in the 100-year floodplain.

5. The separation distance required between ~~the~~a small animal facility or growing areas (pens or barns not including range areas) and the lot line of real property owned by another person is 200 feet ~~or~~and 1,000 feet from the nearest residence~~, whichever is greater, when the normal production animal live weight at any time is 500,000 pounds or less~~.

6. The separation distance required between ~~the~~large or X-large animal facilit~~y~~ies or growing areas (pens or barns not including range areas) and the lot line of real property owned by another person is 400 feet ~~or~~and 1,000 feet from the nearest residence~~, whichever is greater, when the normal production animal live weight at any time is greater than 500,000 pounds~~.

B. Siting requirements applicable to all animal lagoons, treatment systems, and manure storage ponds.

1. The minimum separation distance between a lagoon, treatment system, or manure storage pond and a public or private drinking water well (excluding the applicant's well) is 200 feet. The minimum separation distance between an animal lagoon, treatment system, or manure storage pond and a potable water well owned by the applicant is 100 feet.

~~2. The minimum separation distance between an animal lagoon, treatment system, or manure storage pond and ephemeral and intermittent streams located down slope from the facility is 100 feet. The setback from ephemeral and intermittent streams may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

~~3~~2. Except for site drainage, the minimum separation distance required between an animal lagoon, treatment system, or manure storage pond and a ditch or swale located down slope from the facility is 50 feet. ~~The setback from ditches may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

~~4~~3. The minimum separation distance required between an animal lagoon, treatment system, or manure storage pond and Waters of the State (~~not~~ including ephemeral and intermittent streams) located down slope from the facility is 100 feet. If the Waters of the State are designated Outstanding Resource Waters, Critical Habitat Waters of federally endangered species, or Shellfish Harvesting Waters, the minimum separation

distance required between a lagoon, treatment system, or manure storage pond and Waters of the State is 500 feet.

~~5~~4. A new animal lagoon, treatment system, or manure storage pond or an expansion of an established animal lagoon, treatment system, or manure storage pond shall not be located in the 100-year floodplain.

~~6~~5.The separation distance required between a small animal facility lagoon, treatment system, or manure storage pond and real property owned by another person is 300 feet or 1,000 feet from the nearest residence~~, whichever is greater, when the normal production animal live weight at any time is 500,000 pounds or less~~.

~~7~~6. The separation distance required between a large animal facility lagoon, treatment system, or manure storage pond and real property owned by another person is 500 feet ~~or~~and 1,000 feet from the nearest residence~~, whichever is greater, when the normal production animal live weight at any time is greater than 500,000 pounds~~.

7. The separation distance required between an X-large animal facility lagoon, treatment system, or manure storage pond and real property owned by another person is 600 feet and 1,320 feet from the nearest residence.

C. Siting requirements applicable to all dry animal manure and other animal by-products treatment or storage facilities (including, but not limited to, stacking sheds, burial sites, incinerators, ~~and~~ manure ~~or~~, and dead animal composters).

1. The minimum separation distance between a dry animal manure and other animal by-products treatment or storage facility and a public or private drinking water well (excluding the applicant's well) is 100 feet. The minimum separation distance between a dry animal manure and other animal by-products treatment or storage facility and a potable water well owned by the applicant is 50 feet.

2. Except for site drainage, the minimum separation distance required between a dry animal manure and other animal by-products treatment or storage facility and a ditch or swale located down slope from the facility is 50 feet. ~~The setback from ditches may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

3. The minimum separation distance between a dry animal manure and other animal by-products treatment or storage facility and Waters of the State including ephemeral and intermittent streams located down slope from the facility is 100 feet. ~~The setback from ephemeral and intermittent streams may be reduced by the Department, if a permanent vegetative water quality buffer, that meets NRCS standards at a minimum, is installed and maintained.~~

4. A new dry animal manure and other animal by-products treatment or storage facility or an expansion of an established dry animal manure and other animal by-products treatment or storage facility shall not be located in the 100-year floodplain.

5. The separation distance required between a dry animal manure and other animal by-products treatment or storage facility operated at an animal growing facility and the lot line of real property and a residence owned by another person shall be equivalent to the setback required for the animal growing areas or houses.

6. The minimum separation distance required between a dry animal manure and other animal by-products treatment or storage facility operated by a manure broker and the lot line of real property owned

by another person is 200 feet and 1,000 feet to the nearest residence. ~~However, the Department shall evaluate each proposed site to consider increasing this minimum amount distances, when the amount of manure stored, treated or processed at this facility is significant.~~

D. Water (a pond) that is completely surrounded by land owned by the permit applicant and has no connection to surface water is excluded from the setback requirements outlined in this part.

E. All lagoon and manure storage pond setbacks contained in this part shall be measured from the outside toe of the dike.

~~F. The setback limits given in this part are minimum siting requirements, except those not labeled as minimum requirements, which are absolutes. On a case-by-case basis the Department may require additional separation distances for the minimum setbacks applicable to animal facilities. See Section 200.70.F. (Permit Decision Making Process), which outlines some of the factors considered to determine if additional setbacks should be required.~~

~~G~~F. The separation distances for property lines given in Section 200.80.A, B, and C above can be waived or reduced by written consent of the adjoining property owner. Written consent is not needed when the Department reduces the distances under the requirements of Part 300.

~~H.The separation distances to the property lines of adjacent land as provided in Section 200.80.A, B and C above do not apply to an animal facility, lagoon, treatment system, or manure storage pond which is constructed or expanded, if the adjoining land is owned and managed by a professional silvicultural corporation, is currently in agricultural crop production, or is zoned for agricultural land use. However, the separation distances for residences shall be met by the animal facility, lagoon, treatment system, or manure storage pond, unless a written waiver from the property owner has been obtained.~~

200.90. General Requirements for Animal Manure Lagoons, Treatment Systems, and Animal Manure Storage Ponds.

A. The lagoon, treatment system, or manure storage pond shall be designed by a professional engineer or an NRCS engineer and the construction shall be certified by the design engineer or professional engineer licensed in S.C. It is a violation of these regulations and the South Carolina Pollution Control Act for the owner or operator of the facility to make modifications or physical changes to the lagoon, treatment system, or manure storage pond without the prior approval of the Department and supervision of NRCS or a professional engineer. Plans and specifications for lagoon, treatment system, or manure storage pond modifications shall be designed and certified by NRCS or a professional engineer and submitted to the Department for approval prior to the modification.

B. Animal manure lagoons and manure storage ponds shall be designed, at a minimum, to NRCS-CPS. The lagoon or manure storage pond shall be designed to provide a minimum storage for manure, wastewater, normal precipitation less evaporation, normal runoff, residual solids accumulation, capacity for the ~~25~~fifty (50) year-twenty-four (24) hour storm event (precipitation and associated runoff) and at least ~~one and one half (1 ½)~~2 feet of freeboard.

C. All lagoons and storage ponds shall be provided with a liner, designed with an initial specific discharge rate of less than 0.0156 feet/day, in order to protect groundwater quality. When lagoons or manure storage ponds are lined only using soils with low permeability rates (e.g., clay), the Department shall require appropriate documentation to demonstrate that the computed soil permeability rates of the liner are sufficiently low or certification from the preparer of the Animal Facility Management Plan that the NRCS

design standards for lining lagoons and/or manure storage ponds with soils have been met. When geomembrane liners are utilized, they shall be designed, at a minimum, to meet NRCS-CPS.

D. If seepage results in either an adverse impact to groundwater or a significant adverse trend in groundwater quality occurs as determined by the Department, the lagoon or manure storage pond shall be repaired at the owner's or operator's expense. Assessment and/or additional monitoring (more wells, additional constituents, and/or increased sampling frequency) may be required by the Department to further assess the extent of the seepage. The repairs and/or assessment shall be completed in accordance with an implementation schedule approved by the Department. The Department may require groundwater corrective action.

E. Manure shall not be placed directly in or allowed to come into contact with groundwater and/or surface water. The minimum separation distance between the lowest point of the lagoon or manure storage pond and the seasonal high water table beneath the lagoon or manure storage pond is 2 feet. If a geomembrane liner is installed, the minimum separation distance is ~~one~~1 foot from the seasonal high water table. Designs that include controlled drainage for water table adjustment shall be evaluated by the Department on a case-by-case basis, and may include additional monitoring and groundwater control requirements. If a design is proposed for water table adjustment, the design shall not impact wetlands.

F. Monitoring wells may be required by the Department on a case-by-case basis upon Department review of the submittal package.

G. A groundwater monitoring plan shall be submitted with the permit application to the Department. All applicable State certification requirements regarding well installation, laboratory analyses, and report preparation shall be met. Each groundwater monitoring well installed shall be permitted and shall be sampled at least once annually by qualified personnel at the expense of the permittee. The results shall be submitted to the Department in accordance with the specified permit requirements. Groundwater Sampling results shall be maintained by the producer for eight (8) years. The Department may conduct routine and random visits to the animal facility to sample the monitoring wells.

H. Prior to operation of the lagoon or manure storage pond, all monitoring wells shall be sampled in accordance with the parameters identified in the permit such that a background concentration level can be established.

I. Before the construction of a lagoon and/or a manure storage pond, the owner or operator shall remove all under-drains that exist from previous agricultural operations that are under the lagoon or manure storage pond and/or within ~~twenty-five (~~25~~)~~ feet of the outside toe of the proposed lagoon or manure storage pond dike. This requirement does not include under-drains that are approved as a part of designs that include controlled drainage for water table adjustment.

J. Proper water levels in lagoons and manure storage ponds, as per plans and specifications, shall be maintained at all times by the permittee. The Department may require specific lagoon or manure storage pond volume requirements in permits. An approved marker shall be installed to measure water levels.

K. If a lagoon, treatment system, or manure storage pond, ~~or both~~all of these, breaches or fails ~~in any way~~, the owner or operator of the animal facility shall immediately notify the Department, the appropriate local government officials, and the owners or operators of any potable surface water treatment plant located downstream from the animal facility that could reasonably be expected to be adversely impacted.

L. Lagoons, treatment systems, and manure storage ponds shall be completely enclosed with an acceptable fence, unless a fence waiver is obtained from the Department.

M. Lagoons and manure storage ponds shall have at least four (4) warning signs posted in the four (4) cardinal directions around the perimeter of the structure. These signs ~~should~~must read, "Warning - Deep and Polluted Water"~~, and one should be posted on each side of the lagoon or manure storage pond~~.

N. Vegetation on the dikes and around the lagoon, treatment system, or manure storage pond should be kept below a maximum height of ~~eighteen~~ 18 inches. Trees or deeply rooted plants shall be prevented from growing on the dikes or within 25 feet of the outside toe of the dikes of the lagoon, treatment system, or manure storage pond. Existing trees on the dikes shall be evaluated by NRCS staff or a dam engineer licensed in South Carolina to determine if they should be removed or remain.

O. Livestock or other animals that could cause erosion or damage to the dikes of the lagoon, treatment system, or manure storage pond shall not be allowed to enter the lagoon, treatment system, or manure storage pond, or graze on the dike or within 25 feet of the outside toe of the dike.

P. The Department shall require existing facilities, regardless of size, with a history of manure handling, treatment, and disposal problems related to a lagoon, to phase out the existing lagoon and incorporate new technology.

200.100. Manure Utilization Area Requirements.

A. Application Rates. The Department shall approve an Animal Facility Management Plan that establishes an application rate for each manure utilization area based on the agronomic application rate of the specific crop(s) being grown, and the manure and other animal by-products' impact on the environment. The application rate shall be based on the limiting constituent (a nutrient or other constituent as given in item 200.100.B). In developing annual constituent loading rates and cumulative constituent loading rates, the Department shall consider:

1. Soil type;

2. Type of vegetation growing in land-applied area;

3. Proximity to 100-year floodplain;

4. Location in watershed;

5. Nutrient sensitivity of receiving land and waters;

6. Soil nutrient testing in conjunction with soil productivity information;

7. Nutrient, copper, zinc, and constituent content of the manure and other swine by-products being applied;

8. Proximity to a State Approved Source Water Protection Area;

9. Proximity to other point and nonpoint sources;

10. Slope of land (anything over ten percent (10%) must use runoff best management practices, runoff controls, or conservation features as per NRCS);

11. Distance to water table or groundwater aquifer;

12. Timing of manure application to coincide with vegetative cover growth cycle;

13. Timing of harvest of vegetative cover;

14. Hydraulic loading limitations;

15. Soil assimilative capacity;

16. Type of vegetative cover and its nutrient uptake ability;

17. Method of land application; and

18. Aquifer vulnerability.

B. Constituent Limits for Land Application of Liquid and Dry Animal manure and other animal by-products and Operational Practices for Land Application.

1. ~~Liquid and dry animal manure and other animal by-products.~~ Animal manure and other animal by-products containing only the standard constituents at normal concentrations as given by commonly accepted reference sources, such as Clemson University, American Society of Agricultural Engineers, Midwest Planning Service Document, or NRCS, can be land applied at or below agronomic rates without any specific constituent limits in a permit. When the animal manure analysis indicates there are levels of arsenic, copper, zinc, or other constituents of concern, the Department shall establish constituent limits in permits for each constituent of concern to ensure the water quality standards of ~~Regulation~~R.61-68 are maintained. For these cases the producer shall comply with the following criteria:

a. Constituent Limits. If animal manure and other animal by-products subject to a constituent limit is applied to land, either:

i. The cumulative loading rate for each constituent shall not exceed the cumulative constituent loading rate for the constituent in Table 1 of Section 200.100; or

ii. The concentration of each constituent in the animal manure and other animal by-products shall not exceed the concentration for the constituent in Table 2 of Section 200.100.

b. Constituent concentrations and loading rates - animal manure and other animal by-products.

i. Cumulative constituent loading rates.

TABLE 1 OF SECTION 200.100 - CUMULATIVE CONSTITUENT LOADING RATES			
Cumulative Constituent Loading Rate			
Constituent	(kilograms per hectare)	(pounds per acre)	
Arsenic	41	37	
Copper	1500	1339	
Zinc	2800	2499	

ii. Constituent concentrations.

TABLE 2 OF SECTION 200.100 - CONSTITUENT CONCENTRATIONS

Monthly Average Concentrations	
Constituent	Dry weight basis (milligrams per kilogram)
Arsenic	41
Copper	1500
Zinc	2800

iii. Annual constituent loading rates.

TABLE 3 OF SECTION 200.100 - ANNUAL CONSTITUENT LOADING RATES			
Annual Constituent Loading Rate			
	(kilograms per hectare	(pounds per acre per	
Constituent	per 365-day period)	365-day period)	
Arsenic	2.0	1.8	
Copper	75	67	
Zinc	140	125	

c. Additional constituents limits may be required, from the application information or subsequent monitoring in a permit thereafter, but such needs shall be assessed on an individual project basis.

d. ~~No producer shall apply a~~Animal manure and other animal by-products shall not be applied subject to the cumulative constituent loading rates in Table 1 of Section 200.100.B.1 to land if any of the rates in Table 1 of Section 200.100.B.1 have been reached.

e. ~~No producer shall apply a~~Animal manure and other animal by-products or animal lagoon sludge shall not be applied to land during a 365-day period after the annual application rate in Table 3 of Section 200.100.B.1 has been reached.

f. If animal manure and the animal by-products subject to the cumulative constituent loading rates in Table 1 of Section 200.100.B.1 ~~has~~have not been applied to the site, ~~those~~then cumulative rates apply.

g. If animal manure and other animal by-products subject to the cumulative constituent loading rates in Table 1 of Section 200.100.B.1 ~~has~~have been applied to the site and the cumulative amount of each constituent applied to the site in the animal manure and other animal by-products is known, the cumulative amount of each constituent applied to the site shall be used to determine the additional amount of each constituent that can be applied to the site in accordance with Section 200.100.B.1.a.i (cumulative loading rate shall not exceed the cumulative constituent loading rate).

h. Manure application shall not exceed the agronomic rate of application for plant available nitrogen (PAN) for the intended crop(s) on an annual basis. For those years that fertilizer is land applied, manures in combination with the fertilizer shall not exceed the agronomic rate of nutrient utilization of the intended crop(s).

2. Any producer who confines animals shall ensure that the applicable requirements in this part are met when the animal manure and other animal by-products are applied to the land.

3. Animal manure and other animal by-products shall not be applied to land that is saturated from recent precipitation, flooded, frozen, or snow-covered. Animal manure and other animal by-products shall not be applied during inclement weather or when a significant rain event is forecasted to occur within forty-eight (48) hours, unless approved by the Department in an emergency situation.

4. Animal manure and other animal by-products shall not be placed directly in groundwater.

5. ~~The~~All land application equipment, when used once or more per year, shall be calibrated at least annually by the ~~producer~~person land applying. A permit may require more frequent calibrations to ensure proper application rates. The two (2) most recent calibration records should be retained by the producer and made available for Department review upon request. If the land application equipment has not been used in over a year, the equipment shall be calibrated prior to use.

6. ~~No producer shall apply a~~Animal manure and other animal by-products shall not be applied to the land except in accordance with the requirements in this part.

7. A producer who supplies animal manure and other animal by-products to another person for land application shall provide the person who will land apply the manure and other animal by-products with the concentration of plant available nitrogen, phosphorus, potassium, and the concentration of all other constituents listed in the permit. The producer shall also supply the person who will land apply the manure with a copy of the crop management plan included in their Animal Facility Management Plan ~~or a copy of the Land Application Requirements brochure approved by the Department which outlines the land application requirements and responsibility for proper management of animal manure~~.

8. Animal manure and other animal by-products shall not be applied to or discharged onto a land surface when the vertical separation between the ground surface and the seasonal high water table is less than 1.5 feet at the time of application unless approved by the Department. For special cases, no land application can occur when the vertical separation from the ground surface to the water table is less than 1.5 feet at the time of application unless a situation is deemed an emergency with ~~d~~Departmental concurrence.

9. Soil sampling (usually 6 to 8 inch depth) shall be conducted for each field prior to manure application to determine the appropriate application rate. Each field should be sampled at least once per year. If manure application frequency ~~shall~~will be less than once per year, then at least one (1) soil sample shall be taken prior to returning to that field for land application. All new manure utilization areas shall be evaluated using the NRCS-CPS to determine the suitability for application and the limiting nutrient (nitrogen or phosphorus). However, fields that are high in phosphorus may also be required to incorporate additional runoff control or soil conservation features as directed by the Department. Additional soil sampling may be required by the Department on a case-by-case basis to ensure there is no potential for groundwater contamination

10. Soil sampling to a depth of ~~eighteen~~ 18 inches ~~shall~~may be required by the Department to be performed within forty-five (45) calendar days after each application of animal manure, but no more than two (2) times per year if the application frequency is more than twice per year. This sampling shall be performed for at least three (3) years after the initial application on at least one (1) representative manure utilization area for each crop grown to verify the estimated calculated manure application rates for the utilization areas. The date of manure application and the date of sampling shall be carefully recorded. The sampling shall be conducted at depths of ~~zero to six~~ 0 to 6 inches, ~~six to twelve~~ 6 to 12 inches, and ~~twelve to eighteen~~ 12 to 18 inches with nitrates and phosphorus being analyzed.

11. The results of the pre-application and post-application sampling shall be used by the ~~producer~~crop farmer to adjust as necessary, the amount of animal manure to be applied to a manure utilization area to meet the agronomic application rate for the crop(s) to be grown. These results shall be submitted to the Department at the time of application for permit renewal.

12. Additional soil sampling to greater depths may be required by the Department on a case-by-case basis to ensure there is no potential for groundwater contamination. ~~The permit shall give the appropriate depth and frequency for all soil sampling.~~

13. The permittee shall obtain the following information needed to comply with the requirements in this part~~.~~:

a. Manure transfer contracts shall be developed for the producer to use with any person who is accepting manure in quantities greater than 12 tons per recipient per year. The contract should contain, at a minimum, the following information:

i. Name, address, county, and telephone number of the person who is purchasing or accepting animal manure and other animal by-products;

ii. Manure nutrient composition (pounds per ton of plant available nitrogen, phosphorus, and potassium to be filled in or provided by the producer. This information shall be obtained from three (3) manure analysis results and the producer shall provide this information on the manure transfer contract;

iii. Land application field information;

iv. Physical description (acreage, crop soil type);

v. Soil test results (phosphorus, zinc, and copper in pounds/acre); and

vi. Recommended application rates (nitrogen, phosphorus, and potassium in pounds/acre as reported on a soil test).

b. Attach a copy of a soils map, topographic map, county tax map, plat, FSA map, or a site plan sketch that includes the following information:

i. Manure application areas with setbacks outlined:

ii. Known water supply wells within 100 feet of property lines;

iii. Adjacent surface waters, including ditches, streams, creeks, and ponds; and

iv. Identification of roads and highways to indicate location.

c. Description of application equipment and name of person to land apply manure;

d. Signed agreement that informs the landowner that he or she is responsible and liable for land applying the animal manure and other animal by-products in accordance with this regulation; and

e. A copy of the land application requirements shall be provided to the recipient of the manure.

14. All persons who routinely accept manure from a producer, in quantities greater than ~~twelve~~ 12 tons per recipient per year, shall be listed in the approved Animal Facility Management Plan. The Animal Facility Management Plan shall include the appropriate manure utilization area information for the sites routinely used by other persons. The producer shall inform the ~~recipient~~applier of their responsibility to properly manage the land application of manure to prevent discharge of pollutants to Waters of the State (including ephemeral and intermittent streams). A manure transfer contract must be signed. The person

accepting the manure may be required by the Department to have an Animal Facility Management Plan and a permit for their manure utilization areas.

15. All persons who accept manure from a producer, ~~regardless of whether the land is included in the waste management plan~~in quantities less than 12 tons per recipient per year, are responsible for land applying the manure in accordance with ~~these~~this requirement~~s~~ and must have a signed agreement with the producer explaining their responsibility to comply with the regulation. The Department may require the person(s) land applying the manure to correct any problems that result from the application of manure.

16. Animal manure shall not be applied to cropland more than thirty (30) calendar days before planting or during dormant periods for perennial species, unless otherwise approved by the Department in an emergency situation.

17. ~~When the Department receives nuisance complaints on a land application site, the Department may restrict land application of animal manure on weekends.~~ If the Department receives complaints on a land application site, the Department may restrict land application of animal manure on this site completely or during certain time periods.

18. The Department may require manure~~, spread on cropland,~~ to be disked in immediately.

19. Manure (solid or liquid) shall only be applied when weather and soil conditions are favorable and when prevailing winds are blowing away from nearby dwellings. Animal manure should not be applied to land when the soil is saturated, flooded, during rain events, or when a significant rain event is forecasted to occur within forty-eight (48) hours~~.~~, unless otherwise approved by the Department in an emergency situation.

20. Manure shall not be spread in the floodplain if there is danger of a major runoff event, unless the manure is incorporated during application or immediately after application.

21. If the manure is stockpiled ~~more than three (3) days~~outside, the manure shall be stored on a concrete pad or other approved pad (such as plastic or clay lined) and covered with an acceptable cover to prevent odors, vector attraction, and runoff on a daily basis (unless otherwise specified in the permit). The cover should be properly vented with screen wire to let the gases escape. The edges of the cover should be properly anchored.

22. If a ~~P~~producer~~s~~ who contracts to transfer the animal manure and other animal by-products produced at their facility ~~a manure broker shall obtain and submit for approval an updated Animal Facility Management Plan if they discontinue using the designated broker or if the manure broker goes out of the manure brokering business~~ changes brokers/land appliers, he or she must submit notification and a new broker/land applier contract for approval to the Department.

23. The body of vehicles transporting manure shall be wholly enclosed and, while in transit, be kept covered with a canvas cover provided with eyelets and rope tie-downs, or any other approved method which shall prevent blowing or spillage of loose material or liquids. Should any spillage occur during the transportation of the manure, the owner/operator shall take immediate steps to clean up the manure.

C. Setbacks for manure utilization areas.

1. The minimum separation distance ~~in feet~~ required between a manure utilization area and a residence is 300 feet. If there are no residences within 300 feet of the manure utilization area, manure may be applied up to the property line. The 300-foot setback is waived with the consent of the owner of the residence. If

the application method is injection or immediate incorporation, manure may be applied up to the property line. The setbacks are imposed at the time of application. The Department may impose these setbacks on previously approved sites to address problems on a case-by-case basis.

2. The minimum separation distance ~~in feet~~ required between a manure utilization area and Waters of the State (including ephemeral and intermittent streams) located down slope from the area is 100 feet when spray application is the application method or when the manure is spread on the ground surface, 75 feet when incorporation is the application method, and 50 feet when injection is the application method. When incorporation is accomplished within twenty-four (24) hours of the initial application, the distance can be reduced to 50 feet.

3. The minimum separation distance ~~in feet~~ required between a manure utilization area and ditches and swales, located down slope from the area, that discharge to Waters of the State including ephemeral and intermittent streams is 50 feet.

4. The minimum separation distance ~~in feet~~ required between a manure utilization area and a potable drinking water well is ~~100~~200 feet.

5. The Department may establish, in permits, additional application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainage ways, and surface water (including ephemeral and intermittent streams) as deemed necessary to protect public health and the environment. Factors taken into consideration in the establishment of additional setbacks would be animal manure application method, adjacent land usage, public access, aerosols, runoff prevention, adjacent groundwater usage, aquifer vulnerability, and potential for vectors and odors.

6. Water (pond) that is completely surrounded by land owned by the applicant and has no connection to surface water is excluded from the setback requirements outlined in this part.

D. The Department may establish additional permitting restrictions based upon soil and groundwater conditions to ensure protection of the groundwater and surface Waters of the State (including ephemeral and intermittent streams). Criteria may include, but is not limited to, soil permeability, clay content, depth to bedrock, rock outcroppings, aquifer vulnerability, proximity to a State Approved Source Water Protection Area, and depth to the seasonal high groundwater table.

E. The Department may establish permit conditions to require that animal manure and other animal by-products application rates remain consistent with the lime and fertilizer requirements for the cover, feed, food, and fiber crops based on Southeastern land grant universities' ~~(in the southeast)~~ published lime and fertilizer recommendations ~~(~~,such as the Lime and Fertilizer Recommendations, Clemson Extension Services~~, Circular 476)~~.

F. The Department may establish minimum requirements in permits for soil and/or groundwater monitoring, for manure utilization areas. Factors taken into consideration in the establishment of soil and groundwater monitoring shall include groundwater depth, operation flexibility, application frequency, type of animal manure and other animal by-products, size of manure utilization area, aquifer vulnerability, ~~and~~ proximity to a State Approved Source Water Protection Area, and loading rate.

1. The Department may establish pre-application and post-application site monitoring requirements in permits for limiting nutrients or limiting constituents as determined by the Department.

2. The Department may establish permit conditions, which require the permittee to reduce, modify, or eliminate the animal manure and other animal by-products applications based on the results of this monitoring data.

3. The Department may modify, revoke and reissue, or revoke a permit based on the monitoring data.

G. The Department may require manure to be treated for odor control (i.e., composting or lime stabilizing for dry operations) prior to land application if the manure is not incorporated into the soil at the time of land application or if odors exist or are suspected to exist at an undesirable level. Manure, which has a very undesirable level of odor before treatment, such as turkey manure, shall not normally be permitted to be land applied on land near residences without appropriate treatment for odor control.

200.110. Spray Application System Requirements.

A. Spray application of liquid animal manure using irrigation equipment. This includes all methods of surface spray application, including, but not limited to, fixed gun application, traveling or mobile gun application, or center pivot application.

B. Manure utilization area slopes shall not exceed ten percent (10%) ~~percent~~ unless approved by the Department. The Department may require that slopes be less than ten percent (10%) based on site conditions.

C. Animal manure distribution systems shall be designed so that the distribution pattern optimizes uniform application.

D. Hydraulic Application Rates.

1. Application rates shall normally be based on the agronomic rate for the crop to be grown at the manure utilization area. As determined by soil conditions, the hydraulic application rate may be reduced below the agronomic rate to ensure no surface ponding, runoff, or excessive nutrient migration to the groundwater occurs.

2. The hydraulic application rate may be limited based on constituent loading including any constituent required for monitoring under this regulation.

E. Animal manure and other animal by-products shall not be ~~land~~ applied ~~or discharged onto a land surface~~ when the vertical separation between the ground surface and the seasonal high water table is less than 1.5 feet at the time of application, unless approved by the Department on a case-by-case basis. For special cases, no land application can occur when the vertical separation from the ground surface to the water table is less than 1.5 feet at the time of application unless a situation is deemed an emergency with ~~d~~Departmental concurrence.

F. Conservation measures, such as terracing, strip cropping, etc., may be required in specific areas determined by the Department as necessary to prevent potential surface runoff from entering or leaving the manure utilization areas. The Department may consider alternate methods of runoff controls that may be proposed by the applicant, such as berms.

G. For an animal facility, ~~A~~a system for monitoring the quality of groundwater may also be required for the proposed manure utilization areas. The location of all the monitoring wells shall be approved by the Department. The number of wells, constituents to be monitored, and the frequency of monitoring shall be

determined on a case-by-case basis based upon the site conditions such as type of soils, depth of water table, aquifer vulnerability, proximity to State Approved Source Water Protection Area, etc.

H. If an adverse trend in groundwater quality is identified, further assessment and/or corrective action may be required. This may include an alteration to the permitted application rate or a cessation of manure application on the impacted area.

I. Spray application systems should be designed and operated in such a manner to prevent drift of liquid manure onto adjacent property.

200.120. Frequency of Monitoring for Animal Manure.

A. The producer and/or integrator shall be responsible for having representative samples, based on Clemson Extension Service recommendations, of the animal manure collected and analyzed at least once per year and/or when the feed composition significantly changes. The constituents to be monitored shall be given in the permit. The analyses should be used to determine the amount of animal manure to be land applied. In order to ensure that the permitted application rate (normally the agronomic rate) is met, the application amount shall be determined using a rolling average of the previous analyses. The Department shall establish minimum requirements for the proper method of sampling and analyzing of animal manure. Facilities with permits that do not specify which constituents to monitor shall monitor for Ammonium-Nitrogen, Total Kjeldahl Nitrogen (TKN), Organic Nitrogen (Organic Nitrogen = TKN - Ammonium Nitrogen), P_2-O_5, and K_2O.

B. The Department may require nitrogen, potassium, phosphorus, the constituents listed in Table 1 and Table 2 of Section 200.100, and any other constituent contained in a permit to be monitored prior to each application.

C. Permittees do not have to analyze for any constituent that they can demonstrate to the satisfaction of the Department is not present in their animal manure.

D. All monitoring shall be done in accordance with collection procedures in Standard Methods for Analysis of Water and Wastewater or other Department guidelines. Analysis shall be conducted by Clemson University Extension Service, or a laboratory certified by the Department. This laboratory shall have and maintain certification for the constituents to be analyzed.

200.130. Dead Animal Disposal Requirements.

A. Dead animal disposal shall be done as specified in the approved Animal Facility Management Plan. The Dead Animal Disposal Plan should include the following:

1. Primary Method for the handling and disposal of normal mortality at the facility.

2. Alternate Method for the handling and disposal of excessive mortality ~~on the farm~~ at the facility. The normal method of disposal may not be sufficient to handle an excessive mortality situation. Each producer ~~should~~shall have ~~an~~a Department-approved emergency or alternate method to dispose of excessive mortality. Excessive mortality burial sites shall be preapproved by the Department prior to utilization.

B. Burial. (For existing facilities permitted prior to January 2023 with a burial site approved by the Department) Facility permits issued after January 2023 or facilities permitted prior to January 2023 without an approved burial site from the Department must find an alternate method for daily and emergency dead animal disposal. After January 2023 burial sites will be approved by the Department for an emergency that

is declared by the South Carolina State Veterinarian, Clemson Livestock Poultry Health charged with protecting animal health through control of endemic, foreign, and emerging diseases in livestock and poultry and protecting the health of S.C. consumers.

1. Burial pits may be utilized for emergency conditions, as determined by the Department, when the primary method of disposal is not sufficient to handle excessive mortality.

2. Burial pits shall not be located in the 100-year floodplain.

3. Soil type shall be evaluated for leaching potential.

4. Burial pits shall not be located or utilized on sites that are in areas that may adversely impact surface or groundwater quality or further impact impaired water bodies.

5. The bottom of the burial pit may not be within 2 feet of the seasonal high groundwater ~~level~~table.

6. No burial site shall be allowed to flood with surface water.

7. Animals placed in a burial site shall be covered daily with sufficient cover (6 inches per day minimum) to prohibit exhumation by feral animals.

8. When full, the burial site should be properly capped (minimum 2 feet) and grassed to prohibit erosion.

9. Proposed burial pit sites shall be approved by the Department. The Department may conduct a geologic review of the proposed site prior to approval.

10. The Department may require ~~the~~any new or existing producer to utilize another method of dead animal disposal if burial is not managed according to the Dead Animal Disposal Plan or repeated violations of these burial requirements occur or adverse impact to surface or groundwater is determined to exist.

11. The Department may require groundwater monitoring for dead animal burial pits on a case-by-case basis. The Department shall consider all of the facts including, but not limited to, the following: depth to the seasonal high water table; aquifer vulnerability; proximity to a State Approved Source Water Protection Area; groundwater use in the area; distance to adjacent surface waters; number of dead animals buried; and frequency of burial in the area.

C. Incinerators.

1. For animal facilities proposing an incinerator for dead animal disposal, either a permit for the air emissions shall be obtained from the Department's Bureau of Air Quality before the incinerator can be built or the following criteria shall be met in order to qualify for an exemption from an air permit:

a. The emission of particulate matter shall be less than ~~one~~ 1 pound per hour at the maximum rated capacity;

b. The incinerator shall be a package incinerator ~~and have a rated capacity of 500 pounds per hour or smaller which burns virgin fuel only~~that meets the requirements from the Department’s Bureau of Air Quality; and

c. The incinerator shall not exceed an opacity limit of ten percent (10%).

2. Incinerators used for dead animal disposal shall be properly operated and maintained. Operation shall be as specified in the owner's manual provided with the incinerator. The owner's manual shall be kept on site and made available to Department personnel upon request.

3. The use of the incinerator to dispose of waste oil, hazardous, or any other waste chemical is prohibited. The use of the incinerator shall be limited to dead animal disposal only unless otherwise approved by the Department’s Bureau of Air Quality.

D. Composters. Composters used for dead animal disposal shall be designed by a professional engineer or an NRCS representative and operated in accordance with the approved Animal Facility Management Plan. Packaged composters shall be approved on a case-by-case basis.

E. Disposal of dead animals in a municipal solid waste landfill shall be in accordance with ~~Regulation~~R.61- 107.~~258~~19.

F. Disposal of animal carcasses or body parts into manure lagoons, ~~manure~~ treatment systems, ~~manure~~ storage ponds, ~~w~~Waters of the State, ephemeral and intermittent streams, ditches, and swales is prohibited.

G. Disposal of animal carcasses or body parts by rendering shall be approved by the Department and include a signed contract with the rendering company.

~~G~~H. Other methods of dead animal disposal that are not addressed in this regulation may be proposed in the Dead Animal Disposal Plan.

200.140. Other Requirements.

A. There shall be no discharge of pollutants from the operation into surface Waters of the State (including ephemeral and intermittent streams). There shall be no discharge of pollutants into groundwater, which could cause groundwater quality not to comply with the groundwater standards established in ~~South Carolina Regulation~~R.61-68.

B. On a case-by-case basis, the Department may impose additional or more stringent requirements for the management, handling, treatment, storage, or utilization of animal manure and other animal by-products.

C. The following cases shall be evaluated for additional or more stringent requirements:

1. Source water protection. Facilities and manure utilization areas located within a state-approved source water protection area.

2. 303(d) Impaired Water Bodies List. Facilities and manure utilization areas located upstream of an impaired waterbody.

3. Proximity to Outstanding Resource Waters, trout waters, shellfish waters, or potential to adversely affect a federally listed endangered or threatened species, its habitat, or a proposed or designated critical habitat.

4. Aquifer Vulnerability Area, an area where groundwater recharge may affect an aquifer.

D. If an adverse impact to the Waters of the State, ~~(~~including ephemeral and intermittent streams or groundwater~~),~~ from animal manure and other animal by-products handling, storage, treatment, or utilization practices are documented, through monitoring levels exceeding the standards set forth in ~~Regulation~~R.61-68, or a significant adverse trend occurs, the Department may require the producer responsible for the animal manure and other animal by-products to conduct an investigation to determine the extent of impact. The Department may require the producer to remediate the water to within acceptable levels as set forth in ~~Regulation~~R.61-68.

E. No manure may be released from the premises of an animal facility to Waters of the State, ~~(~~including ephemeral and intermittent streams~~) unless a permit pursuant to Section 402 or 404 of the CWA has been issued by the Department~~.

F. Animal medical waste cannot be disposed into animal lagoons, treatment systems, or manure storage ponds, or land applied with animal manure and other animal by-products.

G. In the event of a discharge from an animal facility or an animal lagoon, treatment system, or manure storage pond, the ~~owner or operator~~permittee is required to notify the Department immediately, within twenty-four (24) hours of the discharge.

H. When the Department determines that a nuisance exists at an animal facility, the permittee shall take action to correct the nuisance to the degree and within the time frame designated by the Department.

I. Permittees shall maintain all-weather access roads to their facilities at all times.

~~J. The body of vehicles transporting manure shall be wholly enclosed and while in transit, be kept covered with a canvas cover provided with eyelets and rope tie-downs, or any other approved method which shall prevent blowing or spillage of loose material or liquids. Should any spillage occur during the transportation of the manure, the owner/operator shall take immediate steps to clean up the manure.~~

200.150. Odor Control Requirements.

A. The Animal Facility Management Plan shall contain an odor abatement plan for the animal facility, lagoon, treatment system, manure storage pond, and manure utilization areas, which ~~may~~ shall consist of the following:

1. Operation and maintenance practices which are used to eliminate or minimize undesirable odor levels in the form of a Best Management Plan for Odor Control;

2. Use of treatment processes for the reduction of undesirable odor levels;

~~3. Additional setbacks from property lines beyond the minimum setbacks given in this part;~~

~~4~~3. Other methods as may be appropriate; or

~~5~~4. Any combination of these methods.

B. Producers shall utilize Best Management Practices normally associated with the proper operation and maintenance of an animal facility, lagoon, treatment system, manure storage pond, and any manure utilization area to ensure an undesirable level of odor does not exist.

C. No producer may cause, allow, or permit emission into the ambient air of any substance or combination of substances in quantities that an undesirable level of odor is determined to result unless preventive measures of the type set out below are taken to abate or control the emission to the satisfaction of the Department. When an odor problem comes to the attention of the Department through field surveillance or specific complaints, the Department shall determine if the odor is at an undesirable level.

D. ~~After determining an undesirable level of odor exists, the Department shall require remediation of the undesirable level of odor.~~ If the Department determines an undesirable level of odor exists, the Department may require these abatement or control practices, including, but not limited to, the following:

~~E. The Department may require these abatement or control practices, including, but not limited to the following:~~

1. Remove or dispose of odorous materials;

2. Methods in handling and storage of odorous materials that minimize emissions;

a. Dry manure to a moisture content of fifty percent (50%) or less;

b. Solids separation from liquid manure, and composting of solids;

~~b~~c. Disinfection to kill microorganisms present in manure;

~~c~~d. Aeration manure;

~~d~~e. Composting of solid manure and other animal by-products; and/or

~~e~~f. Odor ~~C~~control ~~A~~additives.

3. Prescribed standards in the maintenance of premises to reduce odorous emissions;

a. Filtration (biofilters or other filter used to remove dust and odor) of ventilation air;

b. Keep animals clean ~~or~~and separate from manure;

c. Adjust number of animals confined in the pens or paddocks in accordance with Clemson University Animal Space Guidelines.

d. ~~Increase the~~Frequen~~cy~~t manure removal from animal houses;

e. ~~Keep f~~Feeding areas should be kept dry, and minimize waste feed accumulation;

f. Maintaining feedlot surfaces in a dry condition (twenty-five to forty percent (25~~%~~ to 40%) moisture content), with effective dust control;

g. ~~Maintain~~ Proper maintenance of the dead animal disposal system;

h. Covering or reduc~~e~~ing the surface area of manure and other animal by-products storage. (Vents shall be provided for the release of pressure created by manure gases if completely sealed covers are used);

i. ~~Plant trees around or downwind of the manure and other animal by-products storage and treatment~~

facilities;Planting trees around or downwind of the manure and other animal by-products storage and treatment facilities (Trees shall not be planted within 25 feet of the toe of the dike.);

j. Incorporateion of manure and other animal by-products immediately after land application; and/or

k. Selection of appropriate times for land application.

4. Best Available Technology to reduce odorous emissions.

E. Nothing in this section prohibits an individual or group of persons from bringing a complaint against a facility including problems at lagoons, treatment systems, manure storage ponds, and manure utilization areas.

F. If the permittee fails to control or abate the odor problems at a land application sitean animal facility, lagoon, treatment system, manure storage pond, and any manure utilization area to the satisfaction and within a time frame determined by the Department, the permit may be revoked. If the permittee fails to control or abate the odor problems at land application sites, approval for land application of manure on the manure utilization area in question may be revoked. Additional land may be required to be added to the Animal Facility Management Plan, if necessary, to provide a sufficient amount of land for manure utilization.

200.160. Vector Control Requirements.

A.Vector Abatement Plan. The Vector Abatement Plan shall, at a minimum, consist of the following:

1. NormalBest management practices used at the animal facility, lagoon, treatment system, manure storage pond, and manure utilization areas to ensure there is no accumulation of organic or inorganic materials to the extent and in such a manner as to create a harborage for rodents or other vectors that may be dangerous to public health.

2. A list of specific actions to be taken by the producer if vectors are identified as a problem at the animal facility, lagoon, treatment system, manure storage pond, or any manure utilization area. These actions should be listed for each vector problem, e.g., actions to be taken for fly problems, actions to be taken for rodent problems, etc.

B. No producer and or land applier may cause, allow, or permit vectors to breed or accumulate in quantities that result in a nuisance level, as determined by the Department.

C. The Department shall require remediation of the problem to the satisfaction of the Department, after determining a vector problem exists.For an existing facility, if the Department determines a vector problem exists, the Department may require these abatement of control practices, including, but not limited to, the following:

D.The Department may require abatement or control practices, including, but not limited to the following:

1. Remove and properly dispose of vector infested materials;

2. Methods in handling and storage of materials that minimize vector attraction;

a. Remove spilled or spoiled feed from the house as soon as practicably possible not to exceed forty-eight (48) hours, unless otherwise approved by the Department;

b. Remove and properly dispose of dead animals as soon as practicably possible not to exceed twenty-four (24) hours, unless otherwise approved by the Department;

c. Increase the frequency of manure removal from animal houses;

d. Prevent solids buildup in the pit storage or on the floors or walkways;

e. Remove excess manure packs along walls and curtains;

f. Compost solid manure and other animal by-products;

g. Appropriately use vector control chemicals, poisons, or insecticides (take caution to prevent insecticide resistance problems);

h. Utilize traps, or electrically charged devices;

i. Utilize biological agents;

j. Utilize Integrated Pest Management;

k. Incorporate manure and other animal by-products immediately (within twenty-four (24) hours) after land application.; and/or

l. Contact Clemson Extension Service for appropriate measures to control a vector problem.

3. Prescribed standards in the maintenance of premises to reduce vector attraction;

a. Remove ~~any~~ standing water that may be a breeding area for vectors;

b. Keep animals clean or separated from manure;

c. Keep facility clean and free from trash or debris;

d. Properly utilize and service bait stations;

e. Keep feeding areas dry, and minimize waste feed accumulation;

f. Keep grass and weeds mowed around the facility and manure storage or treatment areas;

g. Properly maintain the dead animal disposal system;

h. Cover or reduce the surface area of manure and other animal by-products storage. (Vents shall be provided for release of pressure created by manure gases if completely sealed covers are used);

i. Properly store feed and feed supplements;

j. Conduct a weekly vector monitoring program;

k. Be aware of insecticide resistance problems, and rotate use of different insecticides;

l. Prevent and repair leaks in waterers, water troughs, or cups; and/or

m. ~~Provide~~Ensure proper grading and drainage around the buildings to prevent rain water from entering the buildings or ponding around the buildings.

4. Utilize the best available control technology to reduce vector attraction and breeding.

200.170. Record Keeping.

A. A copy of the approved Animal Facility Management Plan, including approved updates, and a copy of the permit(s) issued to the producer shall be retained by the permittee for as long as the animal facility is in operation.

B. All application information submitted to the Department shall be retained by the permittee for eight (8) years. However, if the facility was permitted prior to June 26, 1998, and the permittee has previously discarded these documents since there was no requirement to maintain records at that time, this requirement shall not apply.

C. Records shall be developed for each manure utilization area. These records shall be kept for eight (8) years. The records shall include the following:

1. For each time animal manure and other animal by-products are applied to the site, the amount of animal manure and other animal by-products applied (in gallons per acre or pounds per acre, as appropriate), the date and time of application, and the location of application~~.~~;

2. All sampling results for animal manure that is land applied;

3. All soil monitoring results;

4. All groundwater monitoring results, if applicable; and

5. Crops grown.

D. Records for the facility to include the following on a monthly basis:

1. ~~Monthly a~~Animal count and the normal production animal live weight; and

2. Mortality count and method of disposal.

E. Records for lagoon, treatment system, or manure storage pond operations to include the following:

1. Monthly water levels of the lagoon, treatment system, and manure storage pond; and

2. ~~All g~~Groundwater monitoring results, if applicable.

F. All records retained by the producer shall be kept at either the facility, an appropriate business office, or other location as approved by the Department.

G. All records retained by the producer shall be made available to the Department during normal business hours for review and copying, upon request by the Department.

200.180. Reporting.

A. Large and X-large animal facilities ~~(greater than 500,000 pounds normal production live weight)~~ are required to submit an annual report, on a form approved by the Department. The Department may establish reporting requirements in permits as it deems appropriate. These reporting requirements may include the following:

1. All manure sampling results for the last year and the latest rolling average concentration for the land limiting constituent;

2. All soil monitoring results, if applicable;

3. All groundwater monitoring results, if applicable;

4. Calculated ~~(permitted application rate)~~ application rates for all manure utilization areas; and

5. The adjusted application rates, if applicable, based on the most recent animal manure sampling, soil samples, and crop yield(s). The application rate change could also be due to a change in field use, crop grown, or other factors.

B. The Department may require small animal facilities ~~(500,000 pounds or less of normal production live weight)~~ to submit annual reports on a case-by-case basis.

C. The Department may establish permit conditions to require a facility to complete and submit a comprehensive report every five (5) years. The Department shall review this report to confirm that the permitted nutrient application rates have not been exceeded. Based on the results of the review, additional soil and/or groundwater monitoring requirements, permit modification, and/or corrective action may be required.

200.190. Training Requirements.

A. An owner/operator of an animal facility or manure utilization area shall attend a training program on the operation of animal manure management under the program created and operated by Clemson University.

B. Owners/Operators of new and existing animal facilities ~~and large animal facilities (greater than 500,000 pounds normal production live weight)~~ shall be required to obtain certification under the program created and operated by Clemson University. ~~The Department may also require existing operators with documented violations to obtain certification under Clemson's program.~~

C. The ~~training and~~ certification program shall be completed by owners/operators of new facilities within one (1) year of the effective date of the issued permit.

D. The ~~training and/or~~ certification program shall be completed by owners/operators of existing facilities within ~~two years~~one (1) year of the effective date of this regulation.

E. ~~Training and/or c~~Certification shall be maintained as long as the facility remains in operation. All facilities must have a CAMM certified operator at all times.

F. Failure to obtain the ~~training and/or~~ certification as provided in this Section shall be deemed a violation of this regulation and the permit may be revoked.

G. An owner/operator of a cattle stockyard shall be exempt from attending the training program on the operation of animal manure management under the program created and operated by Clemson University (CAMM).

200.200. Violations.

A. Persons who violate this regulation or any permit issued under this regulation are subject to the penalties in Sections 48-1-320 (Criminal Penalties) and 48-1-330 (Civil Penalties) of the South Carolina Pollution Control Act.

B. Any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required by the Department to be maintained as a condition in a permit, or who alters or falsifies the results obtained by such devices or methods, shall be deemed to have violated a permit condition and shall be subject to the penalties provided for pursuant to Sections 48-1-320 and 48-1-330 of the S.C. Code of Regulations.

PART 300
INNOVATIVE AND ALTERNATIVE TECHNOLOGIES.

300.10. General.

A. The Department supports and encourages the use of appropriate innovative and alternative technologies.

B. When innovative or alternative technology is proposed for an agricultural facility for manure and other animal by-products handling, treatment, storage, processing, or utilization, a meeting should be held with the Department prior to the submittal of the project. The purpose of the meeting is for the applicant and the Department to go over the proposed project and the purpose and expected benefits from the use of the innovative or alternative technology.

300.20. Submittal Requirements.

A. When innovative or alternative technology is proposed for an agricultural facility for manure and other animal by-products handling, storage, treatment, processing, or utilization, the applicant shall provide to the Department the submittal information contained in Sections 100.50 or 200.50, as appropriate, and a detailed project report which explains the innovative or alternative technology and the purpose and expected benefits of the proposal.

300.30. Requirements in Lieu of Requirements Under Part 100 or Part 200 of This Regulation.

A. When the Department determines that appropriate alternative or innovative technology is being proposed, the specific requirements given in Part 100 and 200 of this regulation, which deal with the purpose or expected benefits of the technology, may not have to be met except when required by a specific statute or the Department after review of the project. Requirements in Part 100 that apply to X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall not be reduced or waived.

B. The Department shall review the project and determine the purpose or benefits of the proposed innovative or alternative technology and determine which requirements under Part 100 or 200 do not have to be met and the appropriate requirements to be used in lieu of the requirements in Part 100 or 200.

C. When an alternative or innovative technology is proposed, the review criteria shall be established on a case-by-case basis by the Department when the project is received.

D. When alternative or innovative technology is utilized at an animal facility, the setbacks given in Part 100 or 200 may be reduced by the Department as appropriate. Requirements in Part 100 that apply to large or X-large swine facilities ~~with 1,000,000 pounds or more normal production live weight~~ shall not be reduced or waived.

300.40. Innovative and Alternative Treatment Technologies.

A. The following is a list of innovative or alternative technologies for agricultural facilities to consider. This list is not exhaustive. Other processes exist and new technologies are being developed.

1. Aerobic treatment systems or combination aerobic/anaerobic systems;

2. Artificial (constructed) wetlands use for treatment;

3. Use of steel tanks;

4. Use of solid separators;

5. Methane Gas Recovery Systems;

~~6. Surface Water Discharge Systems;~~

~~7.~~6. Composting manure solids;

~~8.~~7. Bioreactors;

~~9.~~8. Covered liquid or slurry manure storage;

~~10.~~9. Air Scrubbers;

~~11.~~10. Ozonation; and

~~12.~~11. Alternative Fuels.

B. At a minimum, the preparer of the agricultural Animal Facility Management Plan should consider the technologies given in 300.40.A for use at a proposed agricultural facility when the Animal Facility Management Plan is being developed.

C. When odors exist or are reasonably expected to exist at an undesirable level, the Department may require the use of appropriate innovative or alternative treatment technology to eliminate the odors or the potential for odors.

D. When the Department determines under Section 100.70.G. (Permit Decision Making Process) that there is reasonable potential for cumulative or secondary impacts due to methane gas from facilities, the Department may require the use of methane gas recovery systems or other appropriate technology to eliminate the potential impacts.

300.50. Exceptional Quality Compost.

A. When the Department determines that the composting of solid animal manure and other animal by-products is performed in such a manner that the odor and vector attraction potential is reduced and the controlled microbial degradation of the organic manure and other animal by-products has been accomplished, this material may be considered ~~e~~Exceptional ~~q~~Quality ~~c~~Compost. Exceptional ~~q~~Quality ~~c~~Compost may be sold or distributed without regulation by the Department, if it meets the requirements of this part and the standards established by Penn State University. The Department shall review and approve the composter design and proposal for operation and distribution of the composted product. Composting systems shall be designed by a professional engineer or an engineer with the Natural Resources Conservation Service.

B. Composting can be subject to nuisance problems such as odors, dusts, and vector attraction. Therefore, the composting facility shall incorporate measures to control such conditions. An Odor and Vector Abatement Plan shall be developed for a composting facility.

C. Compost Product Quality Standards.

1. Product Standards are necessary to protect public and environmental health and to ensure a measure of commercial acceptability.

a. Based on EPA standards for pathogen reduction, the time/temperature conditions required are equivalent to an average of 128 degrees Fahrenheit (°F) (53 degrees Celsius (°C)) for five (5) consecutive days, 131°F (55°C) for 2.6 consecutive days, or 158°F (70°C) for thirty (30) minutes.

b. The composted product shall meet or exceed the minimum standard of mature or very mature compost as set forth in the USDA Test Methods for the Examination of Composting and Compost (TMECC) Section 05.02-G CQCC Maturity Index. A maturity rating shall be given based upon the Maturity Assessment Matrix given in this method.

c. When land applied, the compost shall adhere to requirements for constituent concentrations and loading rates as outlined in Part 100.100, Part 200.100, or Part 400.60.

2. Compost products which meet these standards and also comply with pathogen quality and vector attraction standards are considered to be of ~~e~~Exceptional ~~q~~Quality and can be used without regulatory oversight, other than the compliance of agronomic application rates based on product analysis.

3. If the Department determines that the composting system is not being operated properly or that the composted product is not of an Exceptional Quality, the composted product shall be handled in accordance with the land application requirements of Part 100, 200, or 400 (as applicable) of ~~these~~this regulation~~s~~.

4. An operable thermometer capable of measuring temperatures within a compost pile shall be kept at the composting facility for monitoring the temperature of each compost pile or batch. A written log of the daily temperature reading should be kept for each batch of compost. Temperatures shall not be allowed to rise above 180°F (82°C), which may cause combustion in the compost pile and start a fire.

5. The composted product shall be analyzed by Clemson University or another Department approved laboratory. The composted product content information along with recommended application rates shall be distributed with the product. The consumer shall be advised that the composted product shall be applied at an agronomic rate.

300.60. Public Notice Requirements.

~~A.~~ When the Department permits an alternative or innovative technology, the notice on the issuance of the permit required under Sections 100.60.H. or 200.60.H. shall contain a general description of the innovative or alternative process and a summary of the expected benefits.

PART 400
MANURE BROKER/LAND APPLIER OPERATIONS~~.~~

400.10. Purpose and Applicability.

A. Purpose.

1. To protect the environment and the health and welfare of citizens of the State from pollutants generated by the processing, treatment, and land application of dry animal manure and other animal by-products.

2. To establish standards, which consist of general requirements, constituent limits, management practices, and operational standards, for the use of dry animal manure and other animal by-products generated at animal facilities. Standards are included in this part for dry animal manure and other animal by-products applied to the land.

3. To establish standards for the frequency of monitoring and record keeping requirements for brokers/land appliers who operate dry animal manure and other animal by-products handling businesses.

4. To establish standards for the proper operation and maintenance of dry animal manure and other animal by-products treatment and storage facilities associated with manure brokering/land applying operations.

5. To establish criteria for dry animal manure and other animal by-products storage facilities' and manure utilization areas' locations as they relate to protection of the environment and public health. The location of dry animal manure and other animal by-products storage facilities and manure utilization areas as they relate to zoning in an area~~,~~ is not covered in this regulation. Local county or municipal governments may have zoning requirements and ~~these~~this regulation~~s~~ neither interferes with nor restricts such zoning requirements. Permit applicants should contact local municipal and county authorities to determine any local requirements that may be applicable.

B. Applicability.

1. This part applies to:

a. All new and ~~expanding~~renewing dry manure brokering/land applying operations;

b. All dry animal manure and other animal by-products treatment or storage facilities operated by brokers/land appliers; and

c. Permanent manure utilization areas added to a manure broker/land applier management plan.

2. This part applies to all dry animal manure and other animal by-products taken, bought, given, handled, or sold by a manure broker.

3. This part applies to all land where dry animal manure and other animal by-products bought, given, taken, handled, or sold by a manure broker/land applier is applied.

4. This part applies to out-of-state and in-state based manure brokers/land appliers who accept manure and other animal by-products from agricultural animal facilities located in the State.

5. This part applies to all manure brokers/land appliers who bring animal manure and other animal by-products from other states into ~~the state of~~ South Carolina.

6. Part 200.80.C. (Dry Animal manure and other animal by-products Treatment and Storage Facility Siting Requirements) of this regulation applies to dry animal manure and other animal by-products treatment or storage facilities proposed by brokers/land appliers.

7. If a manure broker/land applier proposes to handle, process, treat, or store liquid animal manure as a part of the operation, the requirements of this part shall be met, at a minimum. However, the Department may require that the applicant meet additional requirements applicable to liquid manure that are included in Part 100 and Part 200.

~~8. Existing brokers that hold a valid permit from the Department are deemed permitted under this regulation, and do not need to apply for a new permit. The deemed permitted brokers shall meet all the requirements of this part.~~

400.20. Permits and Compliance Period.

A. Permit Requirement. Animal manure and other animal by-products from an animal facility with dry manure handling can only be handled, stored, treated, processed, or land applied in the State in accordance with a permit issued by the Department. The handling, storage, treatment, and final utilization of animal manure and other animal by-products from a manure broker/land applier operation shall be permitted under the provisions of this part before the broker/land applier can operate in the State.

B. Notification Requirements. The permittee shall notify the Department in writing and receive written Departmental approval, prior to any change in operational procedures in a permitted broker/land applier operation, including, but not limited to, the following:

1. Change in operations or in manure and other animal by-products treatment, storage, handling, or utilization;

2. Change in contracts routinely used in manure and other animal by-products transfers; or

3. Termination of operations.

400.30. Relationship to Other Regulations.

The following regulations are referenced throughout this part and may apply to facilities covered under this regulation.

~~A.Nuisances are addressed in Regulation 61-46.~~

~~B~~A. Application and annual operating fees are addressed in ~~Regulation~~ R.61-30, Environmental Protection Fees.

~~C~~B. The proper closeouts of wastewater treatment facilities are addressed in ~~Regulation~~ R.61-82, Proper Closeout of Wastewater Treatment Facilities. This regulation includes animal manure treatment lagoons and manure storage ponds.

~~D. Permitting requirements for concentrated animal feeding operations as defined by Regulation 61-9 are contained in Regulation 61-9.~~

~~E~~C. Setbacks and construction specifications for potable water wells and ~~M~~monitoring wells shall be in accordance with ~~Regulation~~ R.61-71, Well Standards.

~~F~~D. Permits for air emissions from incinerators are contained in ~~Regulation~~ R.61-62, Air Pollution Control Regulations and Standards.

~~G~~E. Disposal of animal manure in a municipal solid waste landfill unit is addressed in ~~Regulation~~ R.61-107.~~258~~19, Solid Waste Management: Solid Waste Landfills and Structural Fill.

~~H~~F. Disposal of animal manure with domestic or industrial sludge is addressed in ~~Regulation~~ R.61-9, Water Pollution Control Permits, and permitted under R.61-9.

~~I. Procedures for contested cased are addressed in Regulation 61-72 and the Rules of the State's Administrative Law Judge Division.~~

~~J~~G. Laboratory ~~C~~certification is addressed in ~~Regulation~~ R.61-81, State Environmental Laboratory Certification Program.

~~K~~H. Water Classifications and Standards are addressed in ~~Regulation~~ R.61-68.

400.40. Permit Application Procedures (Broker/Land Applier Management Plan Submission Requirements).

A. A ~~broker~~person who proposes to operate as a ~~dry animal manure brokering operation or expand an existing operation~~broker/land applier shall ~~make~~ submit an application for a permit under this part ~~using an application form as designated by the Department~~. The following information shall be included in the application package.

1. A complete~~d~~ application form provided by the Department.

2. A Broker/Land Applier Management Plan prepared by qualified Natural Resources Conservation Service personnel, an S.C. registered professional engineer, or other qualified individuals, such as certified soil scientists or S.C. registered professional geologists. The Broker/Land Applier Comprehensive Nutrient Management Plan shall, at a minimum, contain:

a. Brokering/land applying ~~O~~operation name, address, email, telephone number, county, and permit number (if applicable) and CAMM number (or if applicable, date of CAMM class);

b. Applicant's name, address, email, and telephone number (if different from above);

c. Broker's/land applier's name;

d. Dry Animal manure and other animal by-products Storage or Treatment Facility Information (if applicable):

i. Description of animal manure and other animal by-products storage and storage capacity;

ii. Description of animal manure and other animal by-products treatment (if any);

iii. Facility location description and the zoning or land use restrictions in this area (this information should be obtained from the county). ~~Facility shall meet the siting requirements outlined in Section 200.80.C of this regulation;~~The minimum separation distance required between a dry animal manure and other animal by-products treatment or storage facility operated by a manure broker/land applier and the lot line of real property owned by another person is 200 feet and 1,000 feet to the nearest residence. However, the Department shall evaluate each proposed site to consider increasing distances, when the amount of manure stored, treated, or processed at this facility is significant.

e. Animal manure and other animal by-products handling and application information shall be included as follows:

i. A ~~general~~ crop management plan which includes the optimum time of year of the animal manure and other animal by-products application and how it relates to crop type, crop planting, and harvesting schedule (if applicable) ~~in general~~ for manure utilization areas in the State. This information should be used as a guide in the absence of more accurate information. The Plan Preparer may need to include this information for the different regional areas of ~~T~~the State, as necessary, to provide the broker/land applier with ~~general~~ crop information for the entire State;

ii. Type of equipment used to transport and/or spread the animal manure and other animal by-products ~~(if applicable)~~;

iii. Description of services provided by the broker/land applier (clean-out houses, transport manure and other animal by-products, drop-off only, land application, incorporation of manure and other animal by-products into field, stacking or storing manure and other animal by-products, manure and other animal by-products treatment, etc.);

iv. Example of the contract or letter of intent to buy or accept animal manure and other animal by-products between the broker/land applier and the producer who is supplying the animal manure and other animal by-products; and

v. Example of the manure transfer contract to be used for the transfer of animal manure and other animal by-products between the broker and the person(s) who is accepting or purchasing the animal manure and other animal by-products. The Department has developed a Manure transfer contract that can be used or the broker may develop his own contract as long as it contains the minimum information outlined in part 400.60.B.12.

3. The Broker/Land Applier Management Plan shall contain an odor abatement plan for the dry animal manure and other animal by-products storage or treatment facility or manure utilization areas, as appropriate.

4. A Vector Abatement Plan shall be developed for the dry animal manure and other animal by-products storage or treatment facility or land application areas~~,~~ (if applicable).

5. ~~Soil Monitoring Plan.~~A soil monitoring plan shall be developed for all broker/land applier operations.

6. Plans and specifications for the construction and operation of all manure and other animal by-products treatment or storage structures, such as composters or manure storage sheds that are to be owned and operated by the brokering/land applying operation.

7. Adjoining property owners written agreement for reduction of setbacks for any manure storage and/or treatment facilities (if applicable).

8. Application fee and first year's operating fee as established by ~~Regulation~~R.61-30.

B. The Department may request an applicant to provide any additional information deemed necessary to complete or correct deficiencies in the broker/land applier operation permit application prior to processing the application or issuing, modifying, or denying a permit.

C. Applicants shall submit all required information in a format acceptable to the Department.

D. Incomplete submittal packages ~~may~~shall be returned to the applicant by the Department. An application package for a permit is complete when the Department receives all of the required information~~, which has been completed to its satisfaction~~.

E. Application packages for permit modifications only need to contain the information applicable to the requested modification.

400.50. Permit Decision Making Process.

A. No permit shall be issued before the Department receives a complete application for a permit.

B. After the Department has received a complete application package, a technical review shall be conducted by the Department. The Department may request any additional information or clarification from the applicant or the preparer of the Broker/Land Applier Management Plan to help with the determination on whether a permit should be issued or denied. If a permit application package meets all applicable requirements of this part, a permit may be issued.

C. A site inspection of any proposed sites for dry animal manure and other animal by-products storage or treatment facilities shall be made by the Department before a permit decision is made.

D. For permit issuances, the Department~~, at the expense of the applicant,~~ shall publish a notice of issuance of a permit to operate a dry animal manure brokering operation on the Department's website~~in a local newspaper of general circulation in the area of the broker's base of operations~~.

E. For permit denials, the Department shall give the permit applicant a written explanation, which outlines the specific reason(s) for the permit denial.

~~F. The appeal of a permit decision is governed by the SC Administrative Procedures Act, Regulation61-72, and the Rules of the State's Administrative Law Judge Division.~~

~~G~~F. When a permit is issued, it shall contain an issue date and an effective date. The effective date shall be at least ~~twenty (20)~~ fifteen (15) calendar days after the issue date to allow for any appeals. If a timely appeal is not received, the permit is effective.

~~H~~G. Permits issued under this part for broker/land applier operations shall be renewed ~~at least~~ every five (5) years. However, subsequent to the issuance of a permit, if the broker/land applier operation is not in operation or production for two (2) consecutive years, the permit is no longer valid and a new permit shall be obtained. If the Broker/Land Applier does not apply for permit renewal or does not fulfill the requirements of the permit renewal, the permit is terminated. Should the broker/land applier allow his or her permit to expire and apply for a new permit within the two (2) years, the broker/land applier will be required to update the management plan before the permit is re-issued.

~~I~~H. An expired broker/land applier operation permit which was issued under this part continues in effect until a new permit is effective only if the permittee submits a complete application, to the satisfaction of the Department, at least one hundred twenty (120) calendar days before the existing permit expires. The Department may grant permission to submit an application later than the deadline for submission stated above, but no later than the permit expiration date. If the facility has been closed for any two (2) consecutive years since the last permit was issued, the provision for the expiring permit remaining in effect does not apply since the permit is no longer valid. Permittees shall notify the Department in writing when they go out of business.

~~J~~I. At the time of the broker/land applier's renewal application, ~~T~~the Department shall review ~~all~~the yearly Animal Waste Balance Reporting Form, for every year of the current permit. ~~Broker operation records for permit renewal at the time of application.~~ The Department may request additional documentation based on the review of the Animal Waste Balance Reporting Form. The ~~Department may require that~~broker/land applier is required to add routine application sites ~~are added~~ to ~~the~~ an updated ~~broker~~ management plan at the time of renewal. These manure utilization areas that are added to the broker management plan shall meet all the requirements for manure utilization areas included in Part 200 of ~~these~~this regulation~~s~~.

~~K~~J. The brokering/land applying operation can only be built (if a manure storage or treatment facility was included) or operated when the permit is effective~~ with no appeals pending~~. The dry animal manure and other animal by-products treatment or storage facility cannot be placed into operation until the Department grants ~~written authorization to begin operations~~an ATO.

~~L~~K. For manure brokers/land appliers who do not have any constructed facilities associated with their operations, the Department shall issue a permit ~~to operate~~ with an effective date. Once this permit is effective~~, with no appeals pending,~~ the broker/land applier may begin operations. No additional written ~~authorization~~approval from the Department shall be required.

~~M~~L. For manure brokers/land appliers who are permitted to construct a storage or treatment facility associated with the brokering/land applying operation, ~~authorization~~approval to begin operations shall be obtained prior to operation. To receive ~~authorization~~approval to begin operations, the broker/land applier shall have the preparer of the Broker/Land Applier Management Plan submit to the Department written certification that the construction of the dry animal manure and other animal by-products treatment or storage facility has been completed in accordance with the approved Broker/Land Applier Management Plan and the requirements of this regulation.

~~N~~M. The Department ~~may~~shall conduct a final inspection of any dry animal manure and other animal by-products treatment or storage facilities before granting ~~authorization~~approval to a broker/land applier to begin operations (if applicable).

~~O~~N. The Department shall grant written ~~authorization~~approval for the broker/land applier to begin operations of the dry animal manure and other animal by-products treatment or storage facility after it has received the certification statement in 400.50.M and the results of the final inspection, if conducted, are satisfactory.

400.60. Manure Utilization Area Requirements.

A. Application Rates. The Department shall approve a Broker/Land Applier Management Plan that establishes application rates based upon the limiting constituent (a nutrient or other constituent as given in item 400.60.B). The limiting constituent shall be ~~N~~nitrogen, unless the soil test results exceed the limits for phosphorus. More information on maximum allowable constituent concentrations are outlined in item 400.60.B and item 400.60.C.

B. Constituent Limits for Land Application of Dry Animal manure and other animal by-products and Operational Practices for Land Application.

1. Dry animal manure and other animal by-products. When the animal manure analysis indicates there are high levels of arsenic, copper, zinc, or other constituent of concern, the producer shall comply with the following criteria:

a. Constituent Limits. If animal manure and other animal by-products subject to a constituent limit is applied to land, either:

i. The cumulative loading rate for each constituent shall not exceed the loading rate in Table 1 of Section 400.60; or

ii. The concentration of each constituent in the animal manure and other animal by-products shall not exceed the concentration in Table 2 of Section 400.60.

b. Constituent concentrations and loading rates - animal manure and other animal by-products.

i. Cumulative constituent loading rates.

TABLE 1 OF SECTION 400.60 - CUMULATIVE CONSTITUENT LOADING RATES		
Cumulative Constituent Loading Rate		
Constituent	(kilograms per hectare)	(pounds per acre)
Arsenic	41	37
Copper	1500	1339
Zinc	2800	2499

ii. Constituent concentrations.

TABLE 2 OF SECTION 400.60 - CONSTITUENT CONCENTRATIONS	
Monthly Average Concentrations	
Constituent	Dry weight basis (milligrams per kilogram)
Arsenic	41
Copper	1500
Zinc	2800

iii. Annual constituent loading rates.

TABLE 3 OF SECTION 400.60 - ANNUAL CONSTITUENT LOADING RATES		
Annual Constituent Loading Rate		
	(kilograms per hectare	(pounds per acre per
Constituent	per 365-day period)	365-day period)
Arsenic	2.0	1.8
Copper	75	67
Zinc	140	125

c. Additional constituent limits may be required, from the application information or subsequent monitoring in a permit thereafter, but such needs shall be assessed on an individual project basis.

d. No person shall apply animal manure and other animal by-products to land if any of the loading rates in Table 1 of Section 400.60.B.1 have been reached.

e. No person shall apply animal manure and other animal by-products to land during a 365-day period after the annual application rate in Table 3 of Section 400.60.B.1 has been reached.

f. If animal manure and other animal by-products have not been applied to the site, the cumulative amount for each constituent listed in Table 2 of Section 400.60.B.1 may be applied to the site in accordance with Section 400.60.B.1.a.i (cumulative loading rate shall not exceed the cumulative constituent loading rate).

g. If animal manure and other animal by-products have been applied to the site and the cumulative amount of each constituent applied to the site in the animal manure and other animal by-products is known, the cumulative amount of each constituent applied to the site shall be used to determine the additional amount of each constituent that can be applied to the site in accordance with Section 400.60.B.1.a.i (cumulative loading rate shall not exceed the cumulative constituent loading rate).

h. Manure application shall not exceed the agronomic rate of application for plant available nitrogen (PAN) for the intended crop(s) on an annual basis. For those years that fertilizer is land applied, manures in combination with the fertilizer shall not exceed the agronomic rate of nutrient utilization of the intended crop(s).

2. Any person who land applies animal manure and other animal by-products shall ensure that the applicable requirements in this part are met when the animal manure and other animal by-products are applied to the land.

3. If the Department receives complaints on a land application site, the Department may restrict land application of animal manure on this site completely or during certain time periods.

C. Requirements for the land application of animal manure and other animal by-products.

1. ~~Animal manure and other animal by-products shall not be applied to land that is saturated from recent precipitation, flooded, frozen, or snow-covered. Animal manure and other animal by-products shall not be applied during inclement weather, or when a significant rain event is forecasted to occur within 48 hours.~~Manure (solid or liquid) shall only be applied when weather and soil conditions are favorable and when prevailing winds are blowing away from nearby dwellings. Animal manure and other animal by-products should not be applied to land when the soil is saturated, flooded, during rain events, or when a significant rain event is forecasted to occur within forty-eight (48) hours.

2. Animal manure and other animal by-products shall not be placed directly in groundwater.

3. Animal manure and other animal by-products shall not be applied to cropland more than thirty (30) calendar days before planting or during dormant periods for perennial species, unless otherwise approved by the Department in an emergency situation.

4. ~~The land application equipment, when used once or more per year, shall be calibrated at least annually by the person who land applies animal manure; more frequent calibrations may be required in a permit to ensure that proper application rates are being attained. If the land application equipment has not been used in over a year, the equipment shall be calibrated prior to use.~~The land application equipment, when used once or more per year, shall be calibrated at least annually by the applicator. A permit may require more frequent calibrations to ensure proper application rates. The two (2) most recent calibration records should be retained by the broker/land applier and made available for Department review upon request. If the land application equipment has not been used in over a year, the equipment shall be calibrated prior to use.

5. If the broker chooses to offer manure analysis as a service, the manure shall be analyzed at least once per year. If the broker does not perform manure analysis, the animal producer shall provide the broker with a copy of the most recent manure analysis. Dry animal manure information (as appropriate) shall be included as follows:

a. Dry animal manure shall be analyzed for the following:

i. Nutrients (on a dry weight basis).

(a) Total Kjeldahl Nitrogen (mg/kg).

(b) Total inorganic nitrogen (mg/kg).

(c) Total ammonia nitrogen (mg/kg) and Total nitrate, nitrogen (mg/kg).

(d) P_2O_5 (mg/kg).

(e) K_2O (mg/kg).

(f) Calcium Carbonate equivalency (if animal manure is alkaline stabilized).

ii. Constituents (on a dry weight basis).

(a) Arsenic (mg/kg).

(b) Copper (mg/kg).

(c) Zinc (mg/kg).

b. Name, address, email, and telephone number of the laboratory conducting the analyses.

c. Analysis shall be conducted by Clemson University Extension Service or a laboratory certified by the Department. This laboratory shall have and maintain certification for the constituents to be analyzed.

6. Permittees do not have to analyze for any constituent that they can demonstrate, to the satisfaction of the Department, is not present in their manure.

7. No person(s) accepting or purchasing manure or other animal by-products from a manure broker shall apply animal manure and other animal by-products to the land except in accordance with the requirements in this part. The broker shall inform the recipient of their responsibility to properly manage the land application of manure to prevent discharge of pollutants to Waters of the State (including ephemeral and intermittent streams) and ditches that lead to Waters of the State.

8. An animal producer who supplies animal manure to a broker/land applier shall provide the broker/land applier with the concentration of plant available nitrogen, phosphorus, potassium, and the concentration of all other constituents listed in the permit. ~~Unless~~If the broker/land applier is providing an additional service of ~~performing the manure analysis,~~ collecting the manure samples to be analyzed, which shall be agreed upon up-front in the manure transfer contract, the analysis shall identify the name of the farm where the manure originated.

9. Animal manure and other animal by-products shall not be applied to or discharged onto a land surface when the vertical separation between the manure and other animal by-products and the seasonal water table is less than 1.5 feet at the time of application. For special cases, no land application can occur when the vertical separation from the ground surface to the water table is less than 1.5 feet at the time of application unless a situation is deemed an emergency with departmental concurrence.

10. Soil sampling (6-8 inches depth) shall be conducted for each field prior to manure application to determine the appropriate application rate. Each field should be sampled once per year. If manure application frequency will be less than once per year, at least one (1) soil sample should be taken prior to returning to that field for land application ~~again~~. This sample shall not be more than one (1) year old. All new manure utilization areas shall be evaluated using the NRCS-CPS to determine the suitability for application and the limiting nutrient (nitrogen or phosphorus). This information shall be obtained from person(s) accepting dry animal manure and other animal by-products prior to the delivery or land

application of animal manure and other animal by-products by the broker/land applier. Soil phosphorus shall be addressed according to NRCS-CPS in the broker management plan. However, fields that are high in phosphorus may also be required to incorporate additional runoff control or soil conservation features as directed by the Department. The Department may require additional limits on soil phosphorus in the permit conditions. Additional soil sampling may be required by the Department on a case-by-case basis to ensure there is no potential for groundwater contamination.

11. The permittee shall obtain information needed to comply with the requirements in this part.

12. A Manure Transfer Contract shall be developed for the ~~B~~broker to use with any person who is accepting manure in quantities greater than ~~twelve (~~12~~)~~ tons per recipient per year. The contract should contain, at a minimum, the following information:

a. Name, address, email, county, and telephone number of the person who is purchasing or accepting animal manure and other animal by-products;

b. Name, address, email, CAMM number, county, and telephone number of the broker who is selling or providing animal manure and other animal by-products;

~~b~~c. Manure nutrient composition (pounds per ton of ~~P~~plant ~~A~~available ~~N~~nitrogen, ~~P~~phosphorus, and ~~P~~potassium) to be filled in or provided by the broker/land applier. This information shall be obtained from the manure analysis results and the broker shall provide this information on the manure transfer contract;

~~c~~d. Land Application Field Information:

i. Physical Description (acreage, crop, soil type);

ii. Soil Test Results (nitrogen, phosphorus, potassium, zinc, and copper in pounds/acre); and

iii. Recommended Application Rates (~~N~~nitrogen, ~~P~~phosphorus, and ~~P~~potassium in pounds per acre as reported on a soil test).

~~d~~e. Attach a copy of a soils map, topographic map, county tax map, plat, FSA map, ~~OR~~or a site plan sketch which includes the following information:

i. Manure application area with setbacks outlined;

ii. Known water supply wells within 100 feet of the property line;

iii. Adjacent surface waters, including ditches, streams, creeks, and ponds; and

iv. Identification of roads and highways to indicate location.

~~e~~f. Description of application equipment and name of person to land apply manure;

~~f~~g. Signed agreement that informs the land owner/applier that he is responsible and liable for land applying the animal manure and other animal by-products in accordance with ~~these~~this regulation~~s~~; and

~~g~~h. A copy of the land application requirements shall be provided to the recipient of the manure.

13. All persons who routinely accept animal manure and other animal by-products, in quantities greater than ~~twelve~~ 12 tons per recipient per year, from a broker shall be listed in the approved Broker Management Plan at the time of permit renewal. The Broker Management Plan shall include the appropriate manure utilization area information for the sites routinely used by other persons. The person accepting the manure may be required by the Department to have a Management Plan and a permit for their manure utilization areas.

14. Dead animals shall be removed from ~~dry manure~~animal manure and other animal by-products prior to land application. The livestock producer is responsible for removing all dead animals from the manure prior to transfer. Manure brokers/land appliers may not accept manure that contains dead animals, unless the broker/land applier plans to separate out the dead animals and handle the dead animals in accordance with a dead animal disposal plan approved by the Department.

15. ~~When~~If the Department receives ~~nuisance~~ complaints on a land application site, the Department may restrict land application of animal manure on the site completely or during certain time periods.

16. The Department may require ~~manure~~animal manure and other animal by-products, spread on cropland, to be disked in immediately.

17. ~~Manure (solid or liquid) shall only be applied when weather and soil conditions are favorable and when prevailing winds are blowing away from nearby opposite dwellings.~~ Manure (solid or liquid) shall only be applied when weather and soil conditions are favorable and when prevailing winds are blowing away from nearby dwellings. Animal manure should not be applied to land when the soil is saturated, flooded, during rain events, or when a significant rain event is forecasted to occur within forty-eight (48) hours.

18. Any ~~manure~~animal manure and other animal by-products that contain fly larvae and fly pupae shall be disked into the ground immediately or treated with an approved and effective fly control method. If the manure utilization on a land application area creates a fly problem for the community, the owner and/or applicator shall be responsible for the control of all flies resulting from the application of the manure. Assistance in fly control and fly problem prevention can be obtained through contact with the local Clemson Extension Service Office.

19. ~~Manure~~Animal manure and other animal by-products shall not be spread in the floodplain if there is danger of a major runoff event, unless the manure is incorporated during application or immediately after application.

20. ~~Should the manure be stockpiled more than three (3) days,~~If the manure is stockpiled outside, the manure shall be stored on a concrete pad and/or other ~~acceptable means~~approved pad and covered with an acceptable cover to prevent odors, vectors, and runoff on a daily basis (unless otherwise stated in the permit). The cover should be properly vented with screen wire to let the gases escape. The edges of the cover should be properly anchored.

21. Manure Brokers/Land Appliers and other manure transporters shall use all sanitary precautions in the collection, storage, transportation, and spreading of ~~manures~~animal manure and other animal by-products. The body of all vehicles transporting manure shall be wholly enclosed, or shall at all times, while in transit, be kept covered with an appropriate cover provided with eyelets and rope tie-downs, or any other approved method which shall prevent blowing or spillage of loose material or liquids. Should any spillage occur during the transportation of the ~~manure~~animal manure and other animal by-products, the owner/operator shall take immediate steps to clean up the ~~manure~~animal manure and other animal by-products.

D. Setbacks for manure utilization areas.

1. The minimum separation distance ~~in feet~~ required between a manure utilization area and a residence ~~is located~~ is 300 feet. If there are no residences within 300 feet of the manure utilization area, manure may be utilized up to the property line. The setback may be waived with the written consent of the owner of the residence. If the application method is injection or immediate incorporation (same day), manure can be utilized up to the property line.

2. The minimum separation distance ~~in feet~~ required between a manure utilization area and Waters of the State (including ephemeral and intermittent streams) is 100 feet when dry manure is spread on the ground surface, 75 feet when incorporation is the application method, and 50 feet when injection is the application method. When incorporation is accomplished within twenty-four (24) hours of the initial application, the distance can be reduced to 50 feet.

3. The minimum separation distance ~~in feet~~ required between a manure utilization area and ditches and swales that discharge to Waters of the State including ephemeral and intermittent streams is 50 feet.

4. The minimum separation distance ~~in feet~~ required between a manure utilization area and a potable drinking water well is ~~100~~200 feet.

5. The Department may establish additional application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainage ways, and surface water (including ephemeral and intermittent streams) as deemed necessary to protect public health and the environment. Factors taken into consideration in the establishment of additional setbacks would be animal manure application method, adjacent land usage, public access, aerosols, runoff prevention, adjacent groundwater usage, and potential for vectors and odors.

E. The Department may establish additional permitting restrictions based upon soil and groundwater conditions to ensure protection of the groundwater and surface Waters of the State (including ephemeral and intermittent streams). Criteria may include, but is not limited to, soil permeability, clay content, depth to bedrock, rock outcroppings, ~~and depth to groundwater~~aquifer vulnerability, proximity to a State Approved Source Water Protection Area, and depth to the seasonal high groundwater table.

F. The Department may establish permit conditions to require that animal manure and other animal by-products application rates remain consistent with the lime and fertilizer requirements for the cover, feed, food, and fiber crops based on Southeastern land grant universities' ~~(in the southeast)~~ published lime and fertilizer recommendations ~~(~~, such as the Lime and Fertilizer Recommendations, Clemson Extension Services~~, Circular 476)~~.

G. The Department may establish minimum requirements in permits for soil and/or groundwater monitoring, for manure utilization areas. Factors taken into consideration in the establishment of soil and groundwater monitoring shall include groundwater depth, operation flexibility, application frequency, type of animal manure and other animal by-products, size of manure utilization area, aquifer vulnerability, proximity to a State Approved Source Water Protection Area, and loading rate.

1. The Department may establish pre-application and post-application site monitoring requirements in permits for limiting nutrients or limiting constituents as determined by the Department.

2. The Department may establish permit conditions, which require the permittee to reduce, modify, or eliminate the animal manure and other animal by-products applications based on the results of this monitoring data.

3. The Department may modify, revoke and reissue, or revoke a permit based on the monitoring data.

H. The Department may require manure to be treated for odor control (i.e., composting or lime stabilizing for dry operations) prior to land application if the manure is not incorporated into the soil at the time of land application or if odors exist or are suspected to exist at an undesirable level. Manure, which has a very undesirable level of odor before treatment, such as turkey manure, shall not normally be permitted to be land applied on land near residences without appropriate treatment for odor control.

400.70. Other Requirements.

A. On a case-by-case basis, the Department may impose additional or more stringent requirements for the management, handling, treatment, storage, or utilization of animal manure and other animal by-products.

B. The following cases shall be evaluated for additional or more stringent requirements:

1. Source water protection. Facilities and manure utilization areas located within a ~~s~~State ~~a~~Approved ~~s~~Source ~~w~~Water ~~p~~Protection ~~a~~Area.

2. 303(d) Impaired Waterbodies List. Facilities and manure utilization areas located upstream of an impaired waterbody.

3. Proximity to Outstanding Resource Waters, trout waters, shellfish waters, or would adversely affect a federally listed endangered or threatened species, its habitat, or a proposed or designated critical habitat.

4. Aquifer Vulnerability Area, an area where groundwater recharge may affect an aquifer.

C. If an adverse impact to the Waters of the State, ~~(~~including ephemeral and intermittent streams and groundwater,~~)~~ from animal manure and other animal by-products handling, storage, treatment, or utilization practices are documented, through monitoring levels exceeding the standards set forth in ~~Regulation~~R.61-68 or a significant adverse trend occurs, the Department may require the person responsible for the animal manure and other animal by-products to conduct an investigation to determine the extent of impact. The Department may require the person to remediate the water to within acceptable levels as set forth in ~~Regulation~~R.61-68.

D. Animal manure shall not be released to Waters of the State, ~~(~~including ephemeral and intermittent streams~~)~~.

E. Animal medical waste shall not be land applied with animal manure and other animal by-products.

F. Animal manure and other animal by-products shall not be removed by a manure broker from a quarantined farm, until that quarantine has been lifted by the State Veterinarian.

G. Animal manure and other animal by-products that are quarantined for noxious weed seed contamination shall not be removed by a manure broker unless approved by Clemson Plant Industry.

H. If the Department determines that a complaint exists, the broker/land applier shall take action to correct the nuisance to the degree and within the time frame designated by the Department.

400.80. Odor Control Requirements.

A. An odor abatement plan shall be included, which may consist of the following:

1. Operation and maintenance practices which are used to eliminate or minimize undesirable odor levels in the form of a Best Management Plan for Odor Control;

2. Use of treatment processes for the reduction of undesirable odor levels;

3. Additional setbacks from property lines beyond the minimum setbacks given in this part;

4. Other methods as may be appropriate; or

5. Any combination of these methods.

B. Person(s) who transport, treat, store, or land apply manure and other animal by-products shall utilize Best Management Practices normally associated with the proper operation and maintenance of an animal manure and other animal by-products treatment or storage facility and any manure utilization area to ensure an undesirable level of odor does not exist.

C. No person(s) who transport, treat, store, or land apply manure and other animal by-products may cause, allow, or permit emission into the ambient air of any substance or combination of substances in quantities that an undesirable level of odor is determined to result unless preventive measures of the type set out below are taken to abate or control the emission to the satisfaction of the Department. When an odor problem comes to the attention of the Department through field surveillance or specific complaints, the Department shall determine if the odor is at an undesirable level.

D. ~~After determining an undesirable level of odor exists, the Department shall require remediation of the undesirable level of odor. For an existing facility, i~~If the Department determines an undesirable level of odor exists, the Department may require these abatement or control practices, including, but not limited to, the following:

~~E. The Department may require these abatement or control practices:~~

1. Remove or dispose of odorous materials;

2. Methods in handling and storage of odorous materials that minimize emissions;

a. Dry manure to a moisture content of fifty percent (50%) or less;

b. Use disinfection to kill microorganisms present in manure;

c. Aerate manure;

d. Compost solid manure and other animal by-products; and/or

e. Utilize ~~O~~odor ~~C~~control ~~A~~additives.

3. Prescribed standards in the maintenance of premises to reduce odorous emissions;

a. Cover or reduce the surface area of manure and other animal by-products storage. (Vents shall be provided for release of pressure created by manure gases if completely sealed covers are utilized);

b. Plant trees around or downwind of the manure and other animal by-products storage and treatment facilities;

c. Incorporate manure and other animal by-products immediately, within twenty-four (24) hours after land application;

d. Select appropriate times for land application.

4. Best available control technology to reduce odorous emissions.

~~F~~E. If the permittee fails to control or abate the odor problems at a land application site to the satisfaction and within a time frame determined by the Department, the broker permit may be revoked. If the permittee fails to control or abate the odor problems at land application sites, approval for land application of manure on the manure utilization area in question may be revoked. Additional land may be required to be added to the ~~animal facility~~broker management plan, if necessary to provide a sufficient amount of land for manure utilization.

400.90. Vector Control Requirements.

A. A Vector Abatement Plan shall be developed for the dry animal manure and other animal by-products storage or treatment facility or land application areas~~,~~ (if applicable). The Vector Abatement Plan shall, at a minimum, consist of the following:

1. Normal management practices used at the dry animal manure and other animal by-products storage or treatment facility to ensure there is no accumulation of organic or inorganic materials to the extent and in such a manner as to create a harborage for rodents or other vectors that may be dangerous to public health.

2. A list of specific actions to be taken by the broker/land applier if vectors are identified as a problem at the dry animal manure and other animal by-products storage or treatment facility or land application site. These actions should be listed for each vector problem, e.g., actions to be taken for fly problems, actions to be taken for rodent problems, etc.

3. If the broker is not performing land application, but is only transferring the manure to a person who is accepting responsibility for handling the manure in accordance with ~~these~~this regulation~~s~~, the person accepting the manure shall be responsible for correcting any nuisance problems resulting from the land application of manure.

B. No broker/land applier may cause, allow, or permit vectors to breed or accumulate in quantities that result in a nuisance level, as determined by the Department.

C. ~~After determining a vector problem exists, the Department shall require remediation of the problem to the satisfaction of the Department.~~ For an existing broker/land applier, if the Department determines a vector problem exists, the Department may require these abatement or control practices, including, but not limited to, the following:

~~D.The Department may require abatement or control practices, including, but not limited to the following:~~

1. Remove and properly dispose of vector infested materials;

2. Methods in handling and storage of materials that minimize vector attraction;

a. Compost solid manure;

b. Appropriately use vector control chemicals, poisons, or insecticides (take caution to prevent insecticide resistance problems);

c. Utilize traps, or electrically charged devices;

d. Utilize biological agents;

e. Utilize Integrated Pest Management; and/or

f. Incorporate manure and other animal by-products immediately, within twenty-four (24) hours after land application.

3. Prescribed standards in the maintenance of premises to reduce vector attraction;

a. Remove any standing water that may be a breeding area for vectors;

b. Keep storage and/or treatment facilities clean and free from trash or debris;

c. Properly use and service bait stations;

d. Keep grass and weeds mowed around the manure storage and/or treatment areas;

e. Cover or reduce the surface area of manure and other animal by-products storage. (Vents shall be provided for release of pressure created by manure gases if completely sealed covers are used);

f. Conduct a weekly vector monitoring program;

g. Be aware of insecticide resistance problems, and rotate use of different insecticides; and/or

h. Ensure proper grading and drainage around the buildings to prevent rain water from entering the buildings or ponding around the buildings.

4. Utilize the best available control technology to reduce vector attraction and breeding.

400.100. Record Keeping.

A. A copy of the approved Broker/Land Applier Management Plan, including approved updates, and a copy of the permit(s) issued to the broker/land applier shall be retained by the permittee for as long as the broker is in operation.

B. All application information submitted to the Department shall be retained by the permittee for eight (8) years. ~~However, if the facility was permitted prior to the effective date of this regulation, and the~~

~~permittee has previously discarded these documents since there was no requirement to maintain records at that time, this requirement shall not apply.~~

C. Animal ~~m~~Manure Records. These records shall be kept for ~~four~~five (5) years. The records shall include the following:

1. Name, address, email, county, and phone number of all producers from whom the broker/land applier purchases or accepts animal manure;

2. Sampling results for the animal manure;

3. Amount (in tons) of animal manure obtained from each producer; and

4. Date of transfer.

D. All completed Manure Transfer contracts, including soil analysis results, between the broker and the person(s) purchasing or accepting animal manure, shall be kept by the broker for eight (8) years.

E. All records retained by the broker/land applier shall be kept at an appropriate business office, or other location, as approved by the Department.

F. All records retained by the broker/land applier shall be made available to the Department during normal business hours for review and copying, upon request by the Department.

400.110. Reporting.

A. The Department may establish reporting requirements in permits as it deems appropriate. These reporting requirements may include ~~the following:~~a

~~1.~~ Manure Balance Sheet~~. Listing,~~ which lists the producer/farm name and amount (tons) of manure provided and a listing of all person(s) who bought or accepted animal manure and the amount (tons) accepted. Any manure that is currently in storage or treatment structures at the broker/land applier facility shall be accounted for in this report.

B. The Department may require on a case-by-case basis any of the required records, as outlined in section 400.100, to be reported on an annual basis.

400.120. Training Requirements.

A. An owner/operator of a manure brokering/land applying business shall be trained and certified on the operation of animal manure management under the poultry version of the certification program created and operated by Clemson University (CAMM). The certification shall be obtained within one (1) year of the effective date of the issued permit.

B. The certification program shall be completed by owners/operators of existing brokerage/land applier businesses within one (1) year of the effective date of this regulation or of a transfer of ownership approval.

~~B~~ C. Failure to obtain the ~~training~~ certification and education as provided in this Section shall be deemed a violation of this ~~R~~regulation and a violation of the permit.

400.130. Violations.

~~A.~~ Persons who violate this regulation or any permit issued under this regulation are subject to the penalties in Sections 48-1-320 (Criminal Penalties) and 48-1-330 (Civil Penalties) of the South Carolina Pollution Control Act.

PART 500
INTEGRATOR REGISTRATION PROGRAM~~.~~

500.10. General.

A. The Department encourages Integrators to be involved with the permitting and compliance of their growers.

B. The Department encourages Integrators to assist growers in the disposal of dead animals and the proper utilization of animal manure.

C. Integrating companies shall inform each prospective grower that they are required by State law to obtain a permit to construct and an approval to operate from the Department, and a certification of construction from the engineering company or NRCS. The Department recommends that growers verify an exemption status from the Department prior to construction of an agricultural animal facility.

500.20. Submittal Requirements.

A. Each integrating company that contracts with animal producers that operate facilities located within the State shall submit to the Department a Request for Registration form, as provided by the Department. The ~~i~~Integrator shall work with the Department to identify growers that are unpermitted. The Department may schedule an annual inspection in order to review grower lists and identify unpermitted farms. The integrator shall provide the Department any additional information needed to contact unpermitted growers contracting with their company. ~~Existing Integrators or integrating companies shall submit a request form to the Department no later than one year after the effective date of these regulations.~~

B. Animal Manure Analysis Information. If the producers that contract with the integrator use the same feed rations and have dry animal manure analyses that come out to be consistently the same, they may qualify to use one (1) analysis for their individual testing requirement. However, if any of these producers utilize a different feed ration, utilize a significant amount of medications as compared to the others, or use any other inconsistent bedding materials, animal manure treatments, or vector treatments, they shall be required to run a separate and individual analysis on their animal manure. The Integrator is responsible for notifying the Department of any significant feed composition changes. This benefit shall not be available to liquid manure handling systems, since other factors specific to each site, such as rainfall, could affect the nutrient analysis of the manure.

C. If an integrating company can certify through general feed composition reports that a certain constituent, such as arsenic, is not present in their feed or medications, the producers that contract with that integrator may be exempt from testing for that constituent. The integrator shall submit a written request,

along with general feed composition reports, and a list of growers who are using this feed ration. The Department shall approve this report in writing before the constituent can be removed from the analysis requirements. Each grower who is included in this exemption shall be notified in writing by the Department.

D. Swine Integrators must submit a plan addressing cumulative environmental and public health impacts of their contracted facilities with their first request for integrator certification. The plan must cover the integrator's existing contract growers and the projected three (3) year increase in the number of permitted facilities and swine. The plan must include:

1. The general area served by the integrator;

2. The number of existing swine facilities under contract;

3. The number of swine grown (broken down by facility);

4. The number of projected new facilities (broken down by facility size) with the total number of swine;

5. The integrating company's: procedures, protocols, policies, programs, required manure treatment and utilization technologies, etc. to ensure the cumulative impacts from their contracted facilities do not cause any adverse impact to the environment or public health; and

6. An assessment of the adverse environmental or public impact, if any, from the existing and proposed swine facilities under contract with the integrator.

~~E.~~ 7. The Swine Integrator must also provide to the Department any other supplemental information that may reasonably be required by the Department to assess cumulative adverse environmental or public health impacts.

~~F.~~ 8. The environmental and public health impact assessment plan must be approved by the Department before integrator certification can be granted. Once approved, the integrator may update the plan at any time. Also, the Department may require the plan be updated from time to time.

~~G~~E. All permits for growers under contract with the integrator must be in accordance with the integrator's approved plan.

F. All integrators are required to submit, on an annual basis by December 31st of each year, a list of active and inactive growers that have been added and/or released from their contracts.

500.30. Certificate of Integrator Registration.

A. The Department shall issue a certificate of integrator registration to integrators or integrating companies that meet all the requirements of this part.

B. All integrators or integrating companies shall hold a valid certificate of registration to operate in the State.

C. Certificates of integrator registration issued under this part do not have any administrative procedures for public notice under ~~these~~this regulation~~s~~.

D. The certificate of integrator registration may be modified, revoked, or reissued if the requirements of this part are not met by the integrator or integrating company.

500.40. Reporting.

A. The Department may establish reporting requirements for integrators as it deems appropriate. These reporting requirements may include the following:

1. General feed composition reports. Feed composition reports provided in accordance with this section shall be exempt from disclosure under the Freedom of Information Act; and

2. A list of any special treatments or chemicals added to the manure or manure storage structure that are required by the integrator.

500.50. Other Requirements.

A. An integrator or integrating company shall not knowingly provide animals to an animal facility that does not hold a valid agricultural permit and an approval to operate from the Department. Any existing, unexpired contracts may be fulfilled, but the integrator may not renew the contract until the facility has obtained a valid permit and approval to operate. ~~The Department shall allow a grace period of at least one year for existing unpermitted farms.~~ If an integrator knowingly provides animals to an animal facility that does not hold a valid permit, the Department may require the integrator to remove the animals from the facility and be subject to Part 500.60.

B. The integrator or integrating company shall take reasonable steps to ensure that the animal facilities that are under contract with the company are certified, trained, and educated on compliance with their permit to include the following:

1. Notify growers of their responsibility to update their Animal Facility Management Plan and permit if changes are made in the operation of the farm; and

2. Provide information on technical assistance to its growers on compliance and assist the producers in selecting a corrective action.

500.60. Violations.

~~A.~~ Persons who violate this regulation or any permit issued under this regulation are subject to the penalties in Sections 48-1-320 (Criminal Penalties) and 48-1-330 (Civil Penalties) of the South Carolina Pollution Control Act.

~~**Part 600. Severability**~~

PART 600
SEVERABILITY

~~A.~~ Should a section, paragraph, sentence, clause, phrase, or other part of this regulation be declared invalid for any reason, the remainder shall not be affected.

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-60, 44-1-65, 46-45-80, and 48-1-10 et seq.

Notice of Drafting:

The Department of Health and Environmental Control ("Department" or "DHEC") proposes amending R.61-43, Standards for the Permitting of Agricultural Animal Facilities. Interested persons may submit comment(s) on the proposed amendment to Charles Williams of the Bureau of Water; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; williacj@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on July 27, 2020, the close of the draft comment period.

Synopsis:

Pursuant to R.61-43, Standards for the Permitting of Agricultural Animal Facilities, the Department permits facilities for the growing or confining of animals that have a lagoon and/or over 30,000 pounds of animals to ensure the proper processing of animal waste and by-products. The Department proposes amending R.61-43 to incorporate the following statutory changes made by the General Assembly through passage of Act No. 139, which took effect March 12, 2018:

1. The General Assembly amended Section 44-1-65 to establish specific requirements for the review and appeal of decisions by DHEC regarding the permitting, licensing, certification, or other approval of poultry and other animal facilities (except swine facilities);

2. The General Assembly amended Section 44-1-60 to revise and clarify procedures for reviewing permits for poultry and other animal facilities (except swine facilities); and

3. The General Assembly amended Section 46-45-80 regarding setback distances for poultry and other animal facilities (except swine facilities) to prohibit DHEC from requiring additional setback distances if established distances are achieved, to allow waiver of the established setback distances in certain circumstances, and other purposes.

The Department may also include changes such as corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 10, 2020

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

From: Office of Ocean and Coastal Resource Management

Re: Notice of Proposed Regulation Amending R.30-1, Statement of Policy, and R.30-12 Specific Project Standards for Tidelands and Coastal Waters

I. Introduction

The Office of Ocean and Coastal Resource Management proposes the attached Notice of Proposed Regulation amending R.30-1, *Statement of Policy*, and R.30-12, *Specific Project Standards for Tidelands and Coastal Waters*, for publication in the September 25, 2020, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 48-39-10 *et seq.*, which instructs the Department to implement policies to promote the economic and social welfare of the citizens of the state while protecting the sensitive and fragile areas in the coastal counties and promoting sound development of coastal resources. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed new regulations.

II. Facts

1. The Department proposes new sections R.30-1.D(31) and R.30-12.Q to provide a definition and add project standards for living shorelines. Coastal property owners and other stakeholders in South Carolina have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance. The proposed new sections will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. The proposed new sections will also help ensure a project's design will accomplish its intended goals.

2. The Department had a Notice of Drafting published in the April 24, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments during the public comment period.

3. In 2015, the Department commenced a Living Shoreline initiative in partnership with the South Carolina Department of Natural Resources and South Carolina's two National Estuarine Research Reserves to evaluate the performance of different living shoreline methods over time and under a range of environmental conditions. As a result of this collaboration, a technical report was produced in 2019 to provide science-based information to guide living shoreline project standards in South Carolina.

4. The Department convened a Living Shorelines Working Group that includes members of federal, state, and local governments, as well as nongovernment organizations (NGOs). The Working Group met four times between February 2017 and May 2019 to provide input on various aspects of living shorelines including regulatory guidance, research, and education and outreach. The Working Group will continue to meet in the future to assist in educational and training opportunities associated with living shorelines.

5. In February 2020, the Department held an inter-agency coordination meeting with key agencies involved in the living shorelines process from permitting through the installation phase. Specific agencies included the U.S. Army Corps of Engineers, U.S. Coast Guard, U.S. Fish and Wildlife Service, NOAA National Marine Fisheries Service, SC Department of Natural Resources, DHEC Shellfish Program, and DHEC Bureau of Water. Representatives from local governments and NGOs also participated in the discussion.

6. Appropriate Department staff conducted an internal review of the proposed amendments on August 21, 2020.

III. Request for Approval

The Office of Ocean and Coastal Resource Management respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 25, 2020, *State Register*.

Elizabeth B. von Kolnitz
Chief, Ocean and Coastal Resource Management

Myra C. Reece
Director of Environmental Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the April 24, 2020, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.30-1, Statement of Policy, and R.30-12, Specific Project Standards for Tidelands and Coastal Waters

September 10, 2020

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 30
Statutory Authority: 1976 Code Sections 48-39-10 et seq.

30-1. Statement of Policy.
30-12. Specific Project Standards for Tidelands and Coastal Waters.

Preamble:

Pursuant to the S.C. Coastal Zone Management Act, S.C. Code Sections 48-39-10 et seq., the Department of Health and Environmental Control ("Department") proposes amending R.30-1 and R.30-12 to provide a definition and add project standards for living shorelines. Coastal property owners and other stakeholders in South Carolina have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance. Proposed new sections R.30-1.D(31) and R.30-12.Q will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. The proposed new sections will also help ensure a project's design will accomplish its intended goals.

The Department developed the proposed new sections using scientific data and monitoring results from existing living shoreline installations in South Carolina and with input from state, local, and federal agencies, the Living Shoreline Working Group, and additional stakeholder engagement.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the April 24, 2020, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

R.30-1.D(31). Add new definition to specify characteristics and functions associated with a living shoreline.

R.30-12.Q. Add new section to provide description of living shorelines and project standards to be evaluated.

R.30-12.Q(1). Add new subsection to specify that living shorelines must be associated with waterfront parcels or lots.

R.30-12.Q(2). Add new subsection to specify that living shorelines must be installed within extended property lines and provide for exceptions.

R.30-12.Q(3). Add new subsection to specify how living shorelines must be aligned.

R.30-12.Q(4). Add new subsection to specify minimum creek width requirements for installation.

R.30-12.Q(5). Add new subsection to specify what components and material may be used in the construction of a living shoreline.

R.30-12.Q(6). Add new subsection to specify living shorelines design and construction criteria.

R.30-12.Q(7). Add new subsection to clarify restrictions on tideland critical area impacts.

R.30-12.Q(8). Add new subsection to specify maintenance and monitoring for living shorelines.

R.30-12.Q(9). Add new subsection to provide criteria for when removal of a living shoreline may be required.

R.30-12.Q(10). Add new subsection to specify that living shorelines may be rebuilt if destroyed by a natural event.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Tara Maddock of the Office of Ocean and Coastal Resource Management; S.C. Department of Health and Environmental Control, 1362 McMillan Avenue, Suite 400, Charleston, S.C. 29405; maddoctc@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 26, 2020, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 10, 2020, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agenda.

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

Preliminary Fiscal Impact Statement

The Department estimates no additional cost incurred by the state or its political subdivisions as a result of the promulgation, approval, and implementation of these proposed amendments. The Department will use existing staff and resources to implement these amendments.

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: 30-1, Statement of Policy, and 30-12, Specific Project Standards for Tidelands and Coastal Waters

Purpose: These proposed amendments are based on interest from coastal property owners and other stakeholders in South Carolina who have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance. The proposed amendments will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. The proposed new sections will also help ensure a project's design will accomplish its intended goals.

Due to this citizen interest, the Department commenced a Living Shoreline initiative and worked in partnership with the South Carolina Department of Natural Resources and South Carolina's two National Estuarine Research Reserves to evaluate the performance of different living shoreline methods over time and under a range of environmental conditions. The Department developed the proposed amendments using scientific data and monitoring results from existing living shoreline installations in South Carolina and with input from state, local, and federal agencies, the Living Shoreline Working Group, and additional stakeholder engagement.

Legal Authority: 1976 Code Sections 48-39-10 et seq.

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

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

The Department proposes adding new sections R.30-1.D(31) and R.30-12.Q to provide a definition and add project standards for living shorelines. Coastal property owners and other stakeholders in South Carolina have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance.

The proposed amendments are reasonable and necessary to manage the long-term health and sustainability of the state's tidelands critical area. The proposed amendments will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. By providing living shorelines as an alternative method of estuarine shoreline stabilization, additional benefits to water quality, tidal wetland resiliency, and oyster stock may also be realized.

DETERMINATION OF COSTS AND BENEFITS:

The Department does not anticipate additional cost to the state resulting from administration of these proposed amendments. Benefits to the state would include improved management of coastal resources by providing standards for alternative natural shoreline stabilization approaches. The proposed amendments will allow for a more efficient authorization process for the state and the regulated public. The Department does not anticipate additional cost to the regulated community as a result of these proposed new regulations.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of the proposed amendments seeks to benefit the environment by providing more clarity to the Department's Coastal Division statutory directives to manage the state's tideland critical areas. Living shorelines benefit the state's tideland ecosystems by maintaining, restoring, or enhancing natural estuarine processes that improve water quality, reduce shoreline erosion, protect property, and enhance aquatic habitats.

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

There is no anticipated detrimental effect on the environment and/or public health associated with these proposed amendments. Not implementing these amendments will continue to result in longer permitting review times for proposed living shoreline installations and continued uncertainties about living shoreline project performance. The proposed amendments will allow for a more efficient authorization process to encourage the use of living shorelines as an alternative to traditional hardened erosion control structures.

Statement of Rationale:

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

Coastal property owners and other stakeholders in South Carolina have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance.

The proposed amendments will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. This will help ensure a project's design will accomplish its intended goals. The Department developed the proposed amendments using scientific data and monitoring results from existing living shoreline installations in South Carolina and with input from state, local, and federal agencies, the Living Shoreline Working Group, and additional stakeholder engagement.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

30-1. Statement of Policy.
30-12. Specific Project Standards for Tidelands and Coastal Waters.

Statutory Authority: S.C. Code Sections 48-39-10 et. seq

Add New 30-1.D(31), definition of "Living Shoreline" to read as follows and renumber remaining definitions:

(31) Living Shoreline - A shoreline stabilization approach utilized in intertidal wetland environments that maintains, restores, and/or enhances natural estuarine processes through the strategic placement of native vegetation and/or use of green infrastructure as described in 30-12.Q. Living shorelines promote wetland resiliency and water quality, and enhance the diverse intertidal habitat.

(3~~1~~2) Major Development Activity - any construction activity that is not a Minor Development Activity.

(3~~2~~3) Marinas - a marina is any of the following:

(a) locked harbor facility;

(b) any facility which provides fueling, pump-out, maintenance or repair services (regardless of length);

(c) any facility which has effective docking space of greater than 250 linear feet or provides moorage for more than 10 boats;

(d) any water area with a structure which is used for docking or otherwise mooring vessels and constructed to provide temporary or permanent docking space for more than ten boats, such as a mooring field; or

(e) a dry stack facility.

(3~~3~~4) Master Plan - a document or a map prepared by a developer or a city as a policy guide to decisions about the physical development of the project or community.

(3~~4~~5) Minor Development Activity - the construction, maintenance, repair or alteration of any private pier or erosion control structure, the construction of which does not involve dredging.

(3~~5~~6) Nonwater-dependent - a facility which cannot demonstrate that dependence on, use of, or access to coastal waters is essential to the functioning of its primary activity.

(3~~6~~7) Normal Maintenance and Repair - work performed on any structure within the critical area as part of a routine and ongoing program to maintain the integrity of the structure provided that the structure is still generally intact and functional in its present condition and the work only extends to the original dimensions of the structure. See R.30-5(D).

(3~~7~~8) OCRM - the South Carolina Department of Health and Environmental Control's Office of Ocean and Coastal Resource Management.

(3~~8~~9) Offshore Breakwater - a structure which is designed to protect an area from wave action, is generally built parallel to the shore, may or may not be submerged, and may be built singly or in series. Breakwaters may interfere with natural wave action and wave induced currents.

(~~39~~40) Party - each person or agency named or admitted as a party or properly seeking and entitled to be admitted as a party, including a license or permit applicant.

(~~40~~1) Planned Development - a development plan which has received local approval for a specified number of dwelling and other units. The siting and size of structures and amenities are specified or restricted within the approval. This term specifically references multi-family or commercial projects not otherwise referenced by the terms master plan or planned unit development.

(~~41~~2) Planned Unit Development - a residential, commercial, or industrial development, or all three, designed as a unit and approved in writing by local government.

(~~42~~3) Pool - a structure designed and used for swimming and wading.

(~~43~~4) Primary Oceanfront Sand Dunes - those dunes that constitute the front row of dunes adjacent to the Atlantic Ocean. For the purposes of establishing the jurisdictional baseline, the dune must have a minimum height of thirty-six (36) inches, as measured vertically from the seaward toe to the crest of the dune. The dune must also form a nearly continuous dune ridge for 500 shore parallel feet and may exhibit minimal breaks such as those resulting from pedestrian or emergency vehicle access points. This dune typically exhibits the presence of stable, native vegetation, and is not scarped, eroded, or overtopped by the highest predicted astronomical tides. However, this dune may be inundated by storm surge which normally accompanies major coastal storm events.

(~~44~~5) Public Interest - As used within these Rules and Regulations, public interest refers to the beneficial and adverse impacts and effects of a project upon members of the general public, especially residents of South Carolina who are not the owners and/or developers of the project. To the extent that, in the opinion of the Department, the value of such public benefits is greater than the public costs embodied in adverse environmental, economic and fiscal effects, a proposed project may be credited with net public benefits.

(~~45~~6) Setback Area - the area located between the setback line and the baseline.

(~~46~~7) Setback Line - the line landward of the baseline that is established at a distance which is forty times the average annual erosion rate as determined by historical and other scientific means and adopted by the Department in the State Comprehensive Beach Management Plan. However, all setback lines shall be established no less than twenty feet landward of the baseline, even in cases where the shoreline has been stable or has experienced net accretion over the past forty years.

(~~47~~8) Significant Dune - A dune located completely seaward of the setback line, which because of its size and/or location is necessary to protect the beach/dune system of which it is a part.

(~~48~~9) Special Geographic Circumstances - physical characteristics and land uses of surrounding uplands and waters may warrant additional consideration toward dock sizes. Special Geographic Circumstances identified by OCRM include: tidal ranges of greater than 6 feet; lots with greater than 500 feet of water frontage; and no potential access via dockage from the opposite side of the creek. At the discretion of Department staff, one or more of these circumstances may be applied to dock applications, which may allow up to an additional fifty percent (50%) to what is allowed in 30-12.A(2)(c).

(~~49~~50) Standard Erosion Zone - a segment of shoreline which is subject to essentially the same set of coastal processes, has a fairly constant range of profiles and sediment characteristics, and is not directly influenced by tidal inlets or associated inlet shoals.

(5~~0~~1) Tidelands - all areas which are at or below mean high tide and coastal wetlands, mudflats, and similar areas that are contiguous or adjacent to coastal waters and are an integral part of the estuarine systems involved. Coastal wetlands include marshes, mudflats, and shallows and means those areas periodically inundated by saline waters whether or not the saline waters reach the area naturally or through artificial water courses and those areas that are normally characterized by the prevalence of saline water vegetation capable of growth and reproduction. Provided, however, nothing in this definition shall apply to wetland areas that are not an integral part of an estuarine system. Further, until such time as the exact geographic extent of this definition can be scientifically determined, the Department shall have the authority to designate its approximate geographic extent.

(5~~1~~2) Transmittal Form - the official form prepared by the agency with subject matter jurisdiction that is filed with the division notifying it of a request by any person for a contested case hearing.

(5~~2~~3) Water-dependent - a facility which can demonstrate that dependence on, use of, or access to coastal waters is essential to the functioning of its primary activity.

(5~~3~~4) Waterfront property - For purposes of these regulations, waterfront property will generally be defined as upland sites where a straight-line extension of both, generally shore perpendicular, upland property lines reaches a navigable watercourse within 1000' of the marsh critical line. Waterfront property may also be identified via an approved dock master plan where designated corridors differing from upland property line extensions are delineated.

Add New 30-12.Q to read:

Q. Living Shorelines: Living shorelines, as defined in 30-1.D, are encouraged as an alternative to traditional hardened erosion control structures in estuarine environments because they provide an environmental benefit and reduce the environmental impacts associated with hardened structures. Living shoreline methods involve planting of native vegetation and/or the installation of other green infrastructure. Green infrastructure includes softer approaches to protecting estuarine shorelines and consists of materials including, but not limited to, oyster shells or coir logs, that promote growth of native biological components and maintain continuity of the natural land-water interface. Environmental conditions of a site will be considered in the evaluation of living shoreline applications including whether the type of living shoreline has demonstrated success. Demonstrated success can include an increase in the presence of native vegetation and/or oysters, and an increase in elevation on the landward side of the living shoreline installation.

The following standards are applicable for all living shoreline installations:

(1) Living shorelines are limited to waterfront parcels or lots as defined in R.30-1.D.

(2) Living shorelines must be constructed within extended property boundaries of the permittee for individual projects. One application may be submitted for a living shoreline installation that involves more than one adjoining waterfront parcel. The Department may consider an alternative alignment on a site-by-site basis if site-specific characteristics warrant such an alignment.

(3) Living shorelines must be shore parallel and aligned to conform to the natural contours of the shoreline to the maximum extent feasible.

(4) Living shorelines must not be installed in creeks less than twenty (20) feet in width as measured from marsh vegetation on each side unless special geographic circumstances exist. In all cases, the Department will consider any navigational concerns when evaluating the siting of living shoreline projects.

(5) All living shoreline applications must demonstrate that the installations are designed to promote growth of native biological components. Living shoreline installations must be composed of Department approved materials. Approval of materials by the Department may require the applicant to submit a certified letter from the supplier of the source material.

(6) The size and extent of the living shoreline must be limited to that which is reasonable for the intended purpose. All living shoreline applications must demonstrate that the living shoreline is designed and constructed in a manner that:

(a) does not restrict the reasonable navigation or public use of state lands and waters;

(b) does not prohibit water flow;

(c) maintains, restores, and/or enhances shoreline ecological processes;

(d) maintains continuity of the natural land-water interface; and

(e) prevents the installation from being displaced which can result in marine debris.

(7) Filling or excavation of vegetated tidelands for the construction of a living shoreline is prohibited. Minimal impacts to non-vegetated tidelands may be permitted to achieve a successful installation only if no feasible alternative exists. Projects with proposed non-vegetated tideland impacts must provide sufficient evidence that no feasible alternative exists and must demonstrate avoidance and minimization of impacts. Living shoreline installations must not be constructed in a manner that results in the creation of upland.

(8) Living shorelines must be maintained by the permittee (as well as future upland property owners) such that the installation is generally intact and functional. The Department may require the permittee (as well as future upland property owners) to monitor the living shoreline subject to the critical area permit to determine whether the installation is functioning as intended, results in marine debris, or impedes navigation or public use of state lands and waters.

(9) The Department may require remediation or removal of a living shoreline for reasons that include, but are not limited to:

(a) the installation is no longer generally intact and functional;

(b) the installation has resulted in marine debris;

(c) the installation impedes navigation or public use of state lands and waters; or

(d) the installation is not accomplishing the intended purpose of the living shoreline.

(10) If a living shoreline is destroyed by natural events, the installation may be rebuilt to its previously permitted configuration so long as reconstruction is completed within one (1) year of the date of the event unless there are extenuating circumstances justifying more time.

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 30

Statutory Authority: 1976 Code Sections 48-39-10 et seq.

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.30-1, Statement of Policy, and R.30-12, Specific Project Standards for Tidelands and Coastal Waters, the Department's Coastal Division regulations. Interested persons may submit comment(s) on the proposed amendments to Tara Maddock of the Office of Ocean and Coastal Resource Management; S.C. Department of Health and Environmental Control, 1362 McMillan Avenue, Suite 400, Charleston, S.C., 29405; or by email at maddoctc@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on May 26, 2020, the close of the draft comment period.

Synopsis:

Pursuant to R.30-1 through 30-18, Coastal Division Regulations, the Department seeks to implement the policies of the S.C. Coastal Zone Management Act (S.C. Code Section 48-39-10 et seq.) to promote the economic and social welfare of the citizens of this State while protecting the sensitive and fragile areas in the coastal counties and promoting sound development of coastal resources. The Department proposes amending R.30-12.C and adding new sections R.30-1.D(31) and R.30-12.Q to provide a definition and add project standards for living shorelines. Coastal property owners in South Carolina have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance. The proposed amendments will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. This will help ensure a project's design will accomplish intended goals.

The proposed amendments will be developed using scientific data and monitoring results from existing living shoreline installations in South Carolina and input from state and federal agencies, stakeholder working groups, and other interested parties. By providing living shorelines as an alternative method of estuarine shoreline stabilization, additional benefits to water quality and oyster stock may also be realized.

The Department may also include stylistic changes, such as corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

Date: September10, 2020

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

From: Bureau of Land and Waste Management

Re: Public Hearing for Notice of Final Regulation Amending R.61-63, *Radioactive Materials (Title A)*, Document No. 4958

I. Introduction

The Bureau of Land and Waste Management ("Bureau") proposes the attached Notice of Final Regulation amending R.61-63, *Radioactive Materials (Title A*) for publication in the September 10, 2020, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Section 13-7-70, which designates the Department of Health and Environmental Control ("Department") as the agency responsible for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as they are for compliance with federal law. The amendments will take legal effect as of the September 25, 2020, publication in the *State Register*.

II. Facts

1. Pursuant to R.61-63, *Radioactive Materials (Title A)*, the Department requests approval to ensure state standards comply with the Nuclear Regulatory Commission's ("Commission") regulatory updates. The federal Atomic Energy Act of 1954 enables the Commission to enter into agreements with governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. *Id*. To renew South Carolina's ongoing agreement with the Commission, the Department of Health and Environmental Control ("Department") amends R.61-63 for compliance with the Commission's federal regulatory updates. The proposed amendments add clarification and corrections to Part II of the regulation. Additionally, the proposed amendments authorize the Department to review general licensees' quality assurance programs for the use of Commission-approved Type B Packaging for transportation of radioactive material as required in NRC regulation Title 10, Code of Federal Regulations ("CFR") Part 71.

2. The Department had a Notice of Drafting published in the October 25, 2019, *State Register*.

3. The Bureau held a stakeholder meeting on November 14, 2019, to discuss the schedule and implementation process for the proposed amendments.

4. The Bureau submitted draft text of the proposed amendments to the Technical Advisory Radiation Control Council ("TARCC") on January 7, 2020, for review. The Bureau received no comments from TARCC resulting from the review.

5. Appropriate Department staff conducted an internal review of the proposed amendments on January 14, 2020.

5. The Department had a Notice of Proposed Regulation published in the February 28, 2020, *State Register*. The Department received no public comments by the March 30, 2020, close of the public comment period.

6. The Bureau also submitted copies of the proposed amendments to the Commission for compatibility review on June 7, 2017. The Commission responded with comments dated July 25, 2017. The Bureau integrated these comments into the proposed amendments where applicable.

6. The Bureau also submitted copies of the proposed amendments to the Commission for compatibility review on June 7, 2017. The Commission responded with comments dated July 25, 2017. The Bureau integrated these comments into the proposed amendments where applicable.

III. Request for Approval

The Bureau respectfully requests the Board to find need and reasonableness of the attached proposed amendment of R.61-63, *Radioactive Materials (Title A)*, for legal effect as of September 25, 2020, publication in the *State Register*.

Henry J. Porter
Bureau Chief

Myra C. Reece
Director

Attachments:
A. Notice of Final Regulation

ATTACHMENT A

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

September 10, 2020

Document No. 4958
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 13-7-70

61-63. Radioactive Materials (Title A).

Synopsis:

The federal Atomic Energy Act of 1954 enables the United States Nuclear Regulatory Commission ("Commission") to enter into agreements with governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. *Id*. To renew South Carolina's ongoing agreement with the Commission, the Department of Health and Environmental Control ("Department") amends R.61-63 for compliance with the Commission's federal regulatory updates. The amendments add clarifications and corrections to Part II of the regulation. Additionally, the amendments authorize the Department to review their general licensees' quality assurance programs for the use of Commission-approved Type B packaging for transportation of radioactive material as required in NRC Regulation Title 10, Code of Federal Regulations ("CFR") Part 71.

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 October 25, 2019, *South Carolina State Register*.

Instructions: Amend R.61-63 pursuant to each individual instruction provided with the text of the amendments below.

~~Indicates Matter Stricken~~
Indicates New Matter

Text:

61-63. Radioactive Materials (Title A).

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

Add 2.22.5 and subparagraphs 2.22.5.1 through 2.22.5.5 as shown.

2.22.5 General License: NRC-approved package.[12]

2.22.5.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a Certificate of Compliance (CoC), or other approval has been issued by the NRC.

2.22.5.2 This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of subpart H of 10 CFR 71.

2.22.5.3 Each licensee issued a general license under 2.22.5.1 of this section shall:

2.22.5.3.1 Maintain a copy of the NRC-issued CoC, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2.22.5.3.2 Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of 10 CFR 71; and

2.22.5.3.3 Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportations, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number, and the package identification number specified in the package approval.

2.22.5.4 This general license applies only when the package approval authorizes use of the package under this general license.

2.22.5.5 For a Type B package or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

[12] Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in §71.19.

Add 2.22.6 and subparagraphs 2.22.6.1 through 2.22.6.4.2 as shown.

2.22.6 General License: Use of foreign-approved package.

2.22.6.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

2.22.6.2 Except as otherwise provided in this section, the general license applies only to a licensee having a quality assurance program approved by the Department as satisfying the applicable provisions of subpart H of 10 CFR 71.

2.22.6.3 This general license applies only to shipments made to or from locations outside the United States.

2.22.6.4 Each licensee issued a general license under 2.22.6.1 of this section shall:

2.22.6.4.1 Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the CoC, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

2.22.6.4.2 Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of 10 CFR 71.

Add 2.22.7 and subparagraphs 2.22.7.1 through 2.22.7.2 as shown.

2.22.7 Records.

2.22.7.1 The licensee shall make available to the Department for inspections, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

2.22.7.2 The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 10 CFR 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three (3) years after the life of the packaging to which they apply.

Add 2.22.8 and subparagraphs 2.22.8.1 through 2.22.8.3 as shown.

2.22.8 Quality assurance requirements.

2.22.8.1 Purpose. This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, "Quality Assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

2.22.8.2 Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

2.22.8.3 Approval of program. Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: South Carolina Department of Health and Environmental Control, Division of Waste Management, 2600 Bull Street, Columbia, South Carolina 29201.

Add 2.22.9 and subparagraph 2.22.9.1.

2.22.9 Quality assurance organization.

2.22.9.1 The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

Add 2.22.10 and subparagraphs 2.22.10.1 through 2.22.10.3 as shown.

2.22.10 Changes to quality assurance program.

2.22.10.1 Each quality assurance program licensee shall submit a description of a proposed change to its Department-approved quality assurance program that will reduce commitments in the program description as approved by the Department. The quality assurance program approval holder shall not implement the change before receiving Department approval.

2.22.10.1.1 The description of a proposed change to the Department-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of 10 CFR 71.

2.22.10.1.2 Reserved.

2.22.10.2 Each quality assurance program licensee may change a previously approved quality assurance program without prior Department approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Department. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Department every twenty-four (24) months. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

2.22.10.2.1 The use of a quality assurance standard approved by the Department that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the change;

2.22.10.2.2 The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

2.22.10.2.3 The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

2.22.10.2.4 The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

2.22.10.2.5 Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

2.22.10.3 Each quality assurance program approval holder shall maintain records of quality assurance program changes.

Add 2.22.11 and subparagraph 2.22.11.1 as shown.

2.22.11 Quality assurance records.

2.22.11.1 The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by 2.22.10 of this part, the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications or personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for three (3) years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures, or instructions is superseded, the licensee shall retain the superseded material for three (3) years after it is superseded.

Statement of Need and Reasonableness:

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

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

Purpose: The Department amends R.61-63 for compliance with federal regulatory updates to 10 CFR Part 71. The Department promulgates these amendments in order to renew South Carolina's ongoing agreement with the Commission.

Legal Authority: 1976 Code Section 13-7-70.

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. 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 Department amends R.61-63 for compliance with the Commission's federal regulatory updates. The federal Atomic Energy Act of 1954 enables the Commission to enter into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. The amendments are needed in order to renew South Carolina's ongoing agreement with the Commission. The amendments are beneficial in that they ensure state oversight of required standards.

DETERMINATION OF COSTS AND BENEFITS:

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

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

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

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

None. Federal requirements will apply to all affected users. The amendments eliminate possible duplicative or redundant requirements.

South Carolina Board of Health and Environmental Control
Final Review Conference
September 10, 2020

Final Review Conference - Docket No. 20-RFR-44, Grey Ghost Properties, LLC, Issuance of an amendment to permit 2008-0066-1IT-P for the authorization of wet slips, side-tie dockage, a drystack, drystack storage launch pier, drystack storage queuing docks, a wave attenuator, a harbor masters building and the reconfiguration of the existing shrimp docks.

Counsel of Record –

Mary D. Shahid for Grey Ghost Properties, LLC
Brad Churdar for SCDHEC

Table of Contents

Note: Page #s for this record are located on the bottom of the page.