

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

October 8, 2020

- () ACTION/DECISION
(X) INFORMATION

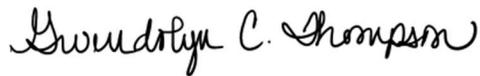
I. TITLE: Healthcare Quality Administrative and Consent Orders.

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

III. FACTS: For the period of August 1, 2020 through August 31, 2020, Healthcare Quality reports one Administrative Order and one Consent Order totaling \$1,885 in assessed monetary penalties. No 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 Healthcare Professionals	Emergency Medical Technician	1	0	0	\$0
Bureau of Radiological Health	Dental Facility	0	1	0	\$1,885
TOTAL		1	1	0	\$1,885

Submitted By:



Gwen C. Thompson
Director of Healthcare Quality

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

October 8, 2020

Bureau of Healthcare Professionals

Provider Type	Total # of Certified Providers
Emergency Medical Technician (EMT)	6,735

1. Trevor G. Sizemore – EMT

Inspections and Investigations: The Department has found that the EMT failed to comply with requirements set forth in a November 2018 Consent Order and subsequently remains in violation of statutory and regulatory requirements.

Violations: The Department determined that Mr. Sizemore violated the Emergency Medical Services (EMS) Act and Regulation 61-7, *Emergency Medical Services*, by failing to comply with remedial training as directed by the Department as a result of a previous investigation and findings. The EMT was ordered to complete a National Association of Emergency Medical Technicians' Principles of Ethics and Personal Leadership (PEPL) course within 12 months of his November 2018 Consent Order being executed. The Department granted extensions for the EMT to take the course when he initially failed to take the course within the instructed 12 months. To date, the EMT has yet to successfully complete the required course.

Enforcement Action: The Department has decided to resolve the matter with an Administrative Order. In August 2020, the Department executed an Administrative Order suspending Mr. Sizemore's EMT Certification for two years. The EMT is also ordered to take the National Association of Emergency Medical Technicians' PEPL course and provide evidence of its completion to the Department. Should Mr. Sizemore fail to take the required PEPL course by the end of the two-year period, the suspension will remain in effect until such time as Mr. Sizemore provides evidence to the Department of having successfully completed a PEPL course.

Remedial Action: Mr. Sizemore is currently serving the two-year suspension of his EMT Certification. He has not taken the required PEPL course.

Prior Enforcement Actions: The EMT agreed to a Consent Order in November 2018.

Bureau of Radiological Health

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

2. James Mark Lawhon, DMD – Florence, SC

Inspections and Investigations: The Department conducted a routine inspection in June 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 and failing to provide documentation that facility specific operator training had occurred.

Enforcement Action: The parties agreed to resolve the matter with a Consent Order. In August 2020, the parties executed a Consent Order imposing a civil monetary penalty of \$1,885 against the registrant. The registrant was required to pay \$285 of the assessed penalty within 30 days of executing the Consent Order. The remaining \$1,600 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
 October 8, 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 August 1, 2020, through August 31, 2020.
3. **FACTS:** For the reporting period of August 1, 2020, through August 31, 2020, the Office of Environmental Affairs issued forty-three (43) Consent Orders with total assessed civil penalties in the amount of fifty-five thousand, four hundred thirty dollars (\$55,430.00). Also, eight (8) Administrative Orders were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	0	0	0	0
Aboveground Tanks	0	0	0	0
Solid Waste	0	0	1	\$500.00
Hazardous Waste	0	0	0	0
Infectious Waste	0	0	0	0
Mining	0	0	0	0
SUBTOTAL	0	0	1	\$500.00
Water				
Recreational Water	0	0	31	\$29,980.00
Drinking Water	0	0	1	\$4,000.00
Water Pollution	0	0	4	\$1,700.00
Dam Safety	0	0	0	0
SUBTOTAL	0	0	36	\$35,680.00
Air Quality				
SUBTOTAL	0	0	1	\$14,000.00
Environmental Health Services				
Food Safety	1	0	3	\$4,250.00
Onsite Wastewater	7	0	2	\$1,000.00
SUBTOTAL	8	0	5	\$5,250.00
OCRM				
SUBTOTAL	0	0	0	0
TOTAL	8	0	43	\$55,430.00

Submitted by:

Myra C. Reece

Myra C. Reece
 Director of Environmental Affairs

**ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
October 8, 2020**

BUREAU OF LAND AND WASTE MANAGEMENT

Solid Waste Enforcement

- 1) Order Type and Number: Consent Order 20-21-SW
 Order Date: August 27, 2020
 Individual/Entity: **Mary Hunt-Miller**
 Facility: Hunt-Miller Landfill
 Location: 1226 Chime Bell Church Road
 Aiken, SC 29803

 Mailing Address: Same
 County: Aiken
 Previous Orders: None
 Permit/ID Number: 022725-1701
 Violations Cited: Solid Waste Policy and Management Act of
 1991, S.C. Code Ann. 44-96-440 *et seq.* (Rev. 2018 & Supp. 2019); Solid Waste
 Management: Solid Waste Landfills and Structural Fill R.61-107.19 (Supp. 2018),
 Part III.B.7.

Summary: Mary Hunt-Miller (Individual/Entity) owns and operates a Class One landfill in Aiken County, South Carolina. A fire was reported to the Department on February 22, 2020, and multiple inspections were conducted between February 25, 2020, and May 12, 2020. The Individual/Entity has violated the Solid Waste Policy and Management Act and the Solid Waste Management: Solid Waste Landfills and Structural fill Regulation as follows: failed to implement corrective action measures as appropriate to extinguish the fire and prevent it from smoldering in the 30-day parameter provided by the Department and as requested by the Department.

Action: The Individual/Entity is required to: notify the Department which option will be performed: Option a) cover all exposed waste with soil; and ensure the fire is completely extinguished with no smoldering. The Department has assessed a total civil penalty in the amount of five thousand, nine hundred dollars (\$5,900.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (\$500.00) and pay a suspended penalty in the amount of five thousand, four hundred dollars (\$5,400.00) should any requirement of Option a) in the Order not be met; or Option b) close the landfill in accordance with the Regulation and Permit by: immediately posting signs that state that the facility is no longer in operation; apply a two (2) foot thick final earth cover; test for certification of cap closure at a rate of two thickness tests per acre; send in a closure report completed by a professional engineer; seed the finished surface of

the disposal area with native grasses; notify the Department that the landfill has been properly closed in accordance with the requirements specified in the General Permit; and record a notation in the record of ownership of the property with the appropriate Register of Deeds or another instrument normally examined during a title search, that will notify any potential purchaser of the property that the land has been filled. The Department has assessed a total civil penalty in the amount of five thousand, nine hundred dollars (\$5,900.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand, nine hundred dollars (**\$5,900.00**) should any requirement of Option b) in the Order not be met.

Updates: The Individual/Entity has chosen to meet the requirements in Option b; therefore they will need to meet the requirements to properly close the landfill by November 25, 2020, and pay the suspended penalty of five thousand, nine hundred dollars (\$5,900.00) should any requirement of Option b not be met.

BUREAU OF WATER

Recreational Waters Enforcement

2) <u>Order Type and Number:</u>	Consent Order 20-009-RW
<u>Order Date:</u>	August 3, 2020
<u>Individual/Entity:</u>	Royal Estates Homeowners Association, Inc.
<u>Facility:</u>	Royal Estates
<u>Location:</u>	4389 Mandi Avenue Little River, SC 29566
<u>Mailing Address:</u>	Same
<u>County:</u>	Horry
<u>Previous Orders:</u>	19-003-RW (\$680.00)
<u>Permit/ID Number:</u>	26-H25-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Royal Estates Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 9, 2020, and July 8, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the depth marker tiles on the deck were broken; a ladder was missing bumpers; the deck was uneven with sharp edges; there was no drinking water fountain; the chlorine and pH levels were not within the acceptable range of water quality standards; and, the bound and numbered log book was not maintained on a daily basis.

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

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

- 3) Order Type and Number: Consent Order 20-010-RW
Order Date: August 3, 2020
Individual/Entity: **Vision Hotels, LLC**
Facility: Tru by Hilton
Location: 2140 West Lucas Street
Florence, SC 29501
Mailing Address: P.O. Box 7537
Florence, SC 29502
County: Florence
Previous Orders: None
Permit/ID Number: 21-1032B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Vision Hotels, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Florence County, South Carolina. The Department conducted inspections on February 13, 2020, and June 17, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; there were non-pool related items stored in the equipment room; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the life ring did not have a permanently attached rope; 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**).

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

- 4) Order Type and Number: Consent Order 20-011-RW
Order Date: August 3, 2020
Individual/Entity: **Pinebrook Homeowners Association, Inc.**
Facility: Pinebrook
Location: 3878 Pinebrook Circle
Little River, SC 29566
Mailing Address: P.O. Box 26844

Charlotte, NC 28221

<u>County:</u>	Horry
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	26-F38-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Pinebrook 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 July 1, 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 deck was chipped; a skimmer lid was broken; the bathrooms were not accessible; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; and, the bound and numbered log book was not maintained on a daily basis.

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

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

5) <u>Order Type and Number:</u>	Consent Order 20-012-RW
<u>Order Date:</u>	August 4, 2020
<u>Individual/Entity:</u>	Drayton Athletic Association
<u>Facility:</u>	Drayton Athletic Association
<u>Location:</u>	2378 Brevard Road Charleston, SC 29414
<u>Mailing Address:</u>	Same
<u>County:</u>	Charleston
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	10-026-2
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Drayton Athletic Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Charleston County, South Carolina. The Department conducted inspections on June 9, 2020, and June 29, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; the bathrooms did not have toilet paper; the kiddie pool entry door did not self-close and latch; the pH level was not within the acceptable range of water quality standards; the bound and numbered log book was not available for review on the first inspection; and, the bound and numbered log book was not maintained on a daily basis on the second inspection.

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

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

- 6) Order Type and Number: Consent Order 20-013-RW
Order Date: August 4, 2020
Individual/Entity: **Tri-Springs Homeowners Association**
Facility: Tri-Springs
Location: 200 Spring Tyme Court
Lexington, SC 29073
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-197-1 & 32-198-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Tri-Springs Homeowners Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Lexington County, South Carolina. The Department conducted inspections on May 28, 2020, and July 1, 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 chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated; the pool rules sign was not completely filled out; a ladder was missing non-slip tread inserts; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record on the first inspection; and, the bound and numbered log book was not maintained on a daily basis on the second inspection.

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

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

- 7) Order Type and Number: Consent Order 20-014-RW
Order Date: August 4, 2020
Individual/Entity: **Wyboo Plantation Owners Association, Inc.**
Facility: Wyboo Plantation
Location: 100 Recreation Drive

Mailing Address: Manning, SC 29102
200 Recreation Drive
Manning, SC 29102
County: Clarendon
Previous Orders: None
Permit/ID Number: 14-038-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Wyboo Plantation Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Clarendon County, South Carolina. The Department conducted inspections on June 15, 2020, and July 1, 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 water level was too high; a skimmer was missing a weir; the life ring was deteriorated; there was no shepherd's crook; the emergency notification device was not accessible; the bound and numbered log book was not available for review on the first inspection; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection; the disinfection equipment was not accessible; and, the recirculation and filtration system was not accessible.

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**).

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

8) Order Type and Number: Consent Order 20-015-RW
Order Date: August 10, 2020
Individual/Entity: **JDHQ Hotels, LLC**
Facility: Residence Inn by Marriott
Location: 5035 International Boulevard
Charleston, SC 29405
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1073B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: JDHQ Hotels, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 27, 2020, and July 2, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing a step; a ladder was missing bumpers; the pool furniture was not at least four feet from the edge of the

pool; skimmers were missing weirs; non-pool related items were stored in the pool equipment room; the chlorine level was not within the accept range of water quality standards; the life ring did not have a permanently attached rope; the shepherd's crook was missing a bolt and was not permanently attached to the handle; the pool rules sign was not completely filled out; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; the bound and numbered log book was not maintained on a daily basis, and it was not maintained a minimum of three times per week by the pool operator of record; the facility could not produce current valid documentation of pool operator certification; and, the drinking water fountain 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**).

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

9) <u>Order Type and Number:</u>	Consent Order 20-016-RW
<u>Order Date:</u>	August 10, 2020
<u>Individual/Entity:</u>	Views on Pelham Property Holdings, LLC
<u>Facility:</u>	Park at Sondrio
<u>Location:</u>	3500 Pelham Road Greenville, SC 29615
<u>Mailing Address:</u>	Same
<u>County:</u>	Greenville
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	23-191-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Views on Pelham Property Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on June 12, 2020, and July 27, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the drinking water fountain was not operating properly; the "Shallow Water – No Diving Allowed" signs posted did not have the correct wording or the correct size letters; the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted did not have the correct size letters; the cyanuric acid level was not being recorded weekly in the bound and numbered log book; and, the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record.

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**).

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

10) <u>Order Type and Number:</u>	Consent Order 20-017-RW
<u>Order Date:</u>	August 11, 2020
<u>Individual/Entity:</u>	Kalpana, Inc.
<u>Facility:</u>	Best Western
<u>Location:</u>	2470 Prospect Drive North Charleston, SC 29406
<u>Mailing Address:</u>	Same
<u>County:</u>	Charleston
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	10-1141B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Kalpana, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 17, 2020, and July 13, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmer lids were cracked; skimmers did not have weirs; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the United States Coast Guard approved life ring was deteriorated; the emergency notification device was not operational; 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**).

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

11) <u>Order Type and Number:</u>	Consent Order 20-018-RW
<u>Order Date:</u>	August 13, 2020
<u>Individual/Entity:</u>	Orencel Tamarind, LLC
<u>Facility:</u>	Tamarind at Stoneridge
<u>Location:</u>	143 Stoneridge Drive Columbia, SC 29210
<u>Mailing Address:</u>	Same
<u>County:</u>	Richland
<u>Previous Orders:</u>	17-164-RW (\$680.00)
<u>Permit/ID Number:</u>	40-206-1

Violations Cited:

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

Summary: Orencel Tamarind, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 23, 2020, and July 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the pool floor was dirty; there was debris in the skimmer baskets; the chlorine and pH levels were not within the acceptable range of water quality standards; the bound and numbered log book was not available for review; a ladder was broken; the gate did not self-close and latch; there were no “Shallow Water – No Diving Allowed” signs posted; and, there were no “No Lifeguard On Duty – Swim At Your Own Risk” signs posted.

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**).

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

- 12) Order Type and Number: Consent Order 20-020-RW
Order Date: August 18, 2020
Individual/Entity: **Sejwad Hospitality, LLC**
Facility: Holiday Inn Express Columbia –
Two Notch
Location: 8300 Two Notch Road
Columbia, SC 29223
Mailing Address: 8105 Two Notch Road
Columbia, SC 29223
County: Richland
Previous Orders: None
Permit/ID Number: 40-390-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sejwad Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on May 26, 2020, and June 26, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was algae on the pool floor; the gate did not self-close and latch; the bound and numbered log book was not maintained on a daily basis; only one “No Lifeguard On Duty - Swim At Your Own Risk” sign was posted; the bathrooms were not accessible; and, the chlorine level was not within the acceptable range of water quality standards.

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

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

13) Order Type and Number: Consent Order 20-022-RW
Order Date: August 18, 2020
Individual/Entity: **Atlantic Paradise, LLC**
Facility: Atlantic Paradise Resort
Location: 1401 South Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: 1403 South Ocean Boulevard
Myrtle Beach, SC 29577
County: Horry
Previous Orders: 18-244-RW (\$2,040.00)
Permit/ID Number: 26-394-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J) &
61-51(K)(1)(c)

Summary: Atlantic Paradise, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 9, 2020, and July 16, 2020, and violations were issued for failure to properly operate and maintain and for operating prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing rungs; there was no drinking water fountain; the pool equipment room was not locked; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; there was no life ring; the emergency notification device was not operational; the pool rules sign was not legible; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review on the first inspection and the bound and numbered log book was not maintained on a daily basis on the second inspection; and, the pool was operating prior to receiving Department approval.

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

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

14) Order Type and Number: Consent Order 20-023-RW
Order Date: August 18, 2020
Individual/Entity: **Mystic Sea, Inc.**
Facility: Mystic Sea
Location: 2101 South Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: 2105 South Ocean Boulevard
Myrtle Beach, SC 29577
County: Horry
Previous Orders: None
Permit/ID Number: 26-J22-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Mystic Sea, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Horry County, South Carolina. The Department conducted inspections on June 16, 2020, and July 17, 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 chlorine and pH levels were not within the acceptable range of water quality standards; and, the spa temperature was too high.

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

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

15) Order Type and Number: Consent Order 20-024-RW
Order Date: August 18, 2020
Individual/Entity: **Tara of Greenville, LLC**
Facility: Hyatt Place Greenville
Location: 128 E Broad Street
Greenville, SC 29601
Mailing Address: 8832 Blakeney Professional Drive Suite 202
Charlotte, NC 28277
County: Greenville
Previous Orders: None
Permit/ID Number: 23-1276B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Tara of Greenville, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on June 2, 2020, and July 2, 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 chlorine and pH levels were not within the acceptable range of water quality standards; the shepherd's crook was missing a bolt; and, the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record.

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**).

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

16)	<u>Order Type and Number:</u>	Consent Order 20-025-RW
	<u>Order Date:</u>	August 18, 2020
	<u>Individual/Entity:</u>	Vista Commons, L.P.
	<u>Facility:</u>	Vista Commons Apartments
	<u>Location:</u>	1100 Pulaski Street Columbia, SC 29201
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Richland
	<u>Previous Orders:</u>	None
	<u>Permit/ID Number:</u>	23-1276B
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Vista Commons, L.P. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 15, 2020, and July 23, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operational; the bound and numbered log book was not maintained on a daily basis; the current pool operator of record information was not posted to the public; and, the facility address was not posted at the emergency notification device.

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

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

17)	<u>Order Type and Number:</u>	Consent Order 20-021-RW
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<u>Order Date:</u>	August 19, 2020
<u>Individual/Entity:</u>	Belair at Carolina Lakes Homeowners Association, Inc.
<u>Facility:</u>	Belair at Carolina Lakes
<u>Location:</u>	3225 Dunbar Lane Indian Land, SC 29707
<u>Mailing Address:</u>	Same
<u>County:</u>	Lancaster
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	29-1012B & 29-1013C
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Belair at Carolina Lakes Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Lancaster County, South Carolina. The Department conducted inspections on June 16, 2020, and July 17, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; the drinking water fountain was not operating; the life ring rope was deteriorated; the shepherd's crook was missing a bolt; the pool rules sign was not completely filled out; only one "Shallow Water – No Diving Allowed" sign was posted; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; there was a leak in the pool equipment room; the water level was too high on the first inspection, and the water level was too low on the second inspection; a skimmer basket was floating; the flow meter was not operating; the chlorine level was not within the acceptable range of water quality standards; a ladder was not tight and secure; and, there was debris in the skimmer baskets.

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

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

18) <u>Order Type and Number:</u>	Consent Order 20-019-RW
<u>Order Date:</u>	August 20, 2020
<u>Individual/Entity:</u>	GS Crossings, LLC
<u>Facility:</u>	Livingston Place Subdivision
<u>Location:</u>	418 North Cobia Court Irmo, SC 29063
<u>Mailing Address:</u>	90 North Royal Tower Drive Irmo, SC 29063
<u>County:</u>	Richland
<u>Previous Orders:</u>	None

Permit/ID Number: 40-1192B
Violations Cited: S.C. Code Ann. Regs. 61-51(B)(2)

Summary: GS Crossings, LLC (Individual/Entity) owns and is responsible for obtaining from the Department a permit to construct a pool located in Richland County, South Carolina. The Department conducted an inspection of the site on June 25, 2020 and determined that the pool was being constructed and 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: complete the construction in accordance with the permit. The Department has assessed a total civil penalty in the amount of three hundred dollars (\$300.00). The Individual/Entity shall pay a civil penalty in the amount of three hundred dollars (**\$300.00**).

Update: Prior to the issuance of the Order, a permit application was submitted, and a permit was issued. The civil penalty has been paid.

19) Order Type and Number: Consent Order 20-026-RW
Order Date: August 21, 2020
Individual/Entity: **Airport Properties, Inc.**
Facility: Sandcastle North
Location: 1802 North Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: P.O. Box 1362
Myrtle Beach, SC 29578
County: Horry
Previous Orders: None
Permit/ID Number: 26-J86-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Airport Properties, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 12, 2020, and July 16, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the chlorine and pH levels were not within the acceptable range of water quality standards; the main drain grates were not visible; and, the life ring was deteriorated.

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**).

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

20) Order Type and Number: Consent Order 20-027-RW
Order Date: August 21, 2020
Individual/Entity: **Pelican Pass Homeowners Association, Inc.**
Facility: Pelican Pass
Location: 612 South Ocean Boulevard
Surfside Beach, SC 29575
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 26-821-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Pelican Pass 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 2, 2020, and June 30, 2020, and violations were issued for failure to properly operate and maintain and for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the waterline tiles were not clean; a skimmer basket was floating; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operating properly; the pool rules sign was not completely filled out; the “Shallow Water – No Diving Allowed” and “No Lifeguard On Duty – Swim At Your Own Risk” signs posted did not have the correct wording; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; and, the pool re-opened prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, twenty dollars (\$1,020.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, twenty dollars (**\$1,020.00**).

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

21) Order Type and Number: Consent Order 20-028-RW
Order Date: August 26, 2020
Individual/Entity: **Graybul Cotton Mill Commons, LLC**
Facility: Cotton Mill Commons
Location: 6001 Spindle Circle
Simpsonville, SC 29681

Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 23-1294B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Graybul Cotton Mill Commons, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on July 6, 2020, and August 6, 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 pH level was not within the acceptable range of water quality standards; the “Shallow Water – No Diving Allowed” signs did not have the correct wording; only one “No Lifeguard On Duty – Swim At Your Own Risk” sign was posted; 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**).

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

22) Order Type and Number: Consent Order 20-029-RW
Order Date: August 26, 2020
Individual/Entity: **Raldex II, Inc.**
Facility: Staybridge Suites
Location: 150 Westpark Drive
Florence, SC 29501
Mailing Address: 780 Woody Jones Boulevard
Florence, SC 29501
County: Florence
Previous Orders: None
Permit/ID Number: 21-1029B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Raldex II, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Florence County, South Carolina. The Department conducted inspections on June 12, 2020, and July 14, 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 skimmer baskets were floating; and, the chlorine and pH levels were not within the acceptable range of water quality standards.

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

Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**).

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

23) Order Type and Number: Consent Order 20-030-RW
Order Date: August 26, 2020
Individual/Entity: **Centre Pointe Hotel, LLC**
Facility: Towne Place Suites North Charleston
Location: 5001 Fashion Avenue
North Charleston, SC 29418
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1307B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Centre Pointe Hotel, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 26, 2020, and June 24, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was a loose tile on the deck posing a trip hazard; a skimmer was missing a weir; the chlorine and pH levels were not within the acceptable range of water quality standards; there was no pool rules sign; there were no “Shallow Water – No Diving Allowed” signs posted; 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**).

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

24) Order Type and Number: Consent Order 20-032-RW
Order Date: August 26, 2020
Individual/Entity: **Sandy Shores III Interval Owners Association, Inc.**
Facility: Sandy Shores III
Location: 1425 N Waccamaw Drive
Murrells Inlet, SC 29576
Mailing Address: 1550 Fawn Vista Drive
Surfside Beach, SC 29575

County: Horry
Previous Orders: None
Permit/ID Number: 26-E51-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sandy Shores III Interval 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 July 9, 2020, and July 29, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool furniture was not at least four feet from the edge of the pool; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the current pool operator of record information was not posted to the public; the depth marker tiles were broken; a ladder was not tight and secure; and, the deck was uneven with sharp edges.

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**).

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

25) Order Type and Number: Consent Order 20-031-RW
Order Date: August 27, 2020
Individual/Entity: **Woodlands of Clemson Condominium Association, Inc.**
Facility: Woodlands of Clemson
Location: 833 Old Greenville Highway
Central, SC 29631
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit/ID Number: 39-1017B, 39-1018B, & 39-1019B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Woodlands of Clemson Condominium Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of three pools located in Pickens County, South Carolina. The Department conducted inspections on June 5, 2020, and July 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 chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; the “No Lifeguard On Duty – Swim At Your Own Risk” signs posted did not have the appropriate size letters on the first inspection, and there was only one sign posted on the second inspection; the depth

marker tiles did not accurately reflect the depth; there was debris in the skimmer baskets; the bound and numbered log book was not maintained on a daily basis; the disinfection equipment was not operating; there were chlorine sticks in the skimmer baskets; the current pool operator of record information was not posted to the public; the cyanuric acid level was not recorded weekly in the bound and numbered log book; and, tiles were missing on the pool wall.

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**).

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

26) <u>Order Type and Number:</u>	Consent Order 20-033-RW
<u>Order Date:</u>	August 27, 2020
<u>Individual/Entity:</u>	Beacon Knoll Homeowners' Association, Inc.
<u>Facility:</u>	Beacon Knoll
<u>Location:</u>	521 Beacon Knoll Lane Fort Mill, SC 29708
<u>Mailing Address:</u>	2764 Pleasant Road Box 10309 Fort Mill, SC 29708
<u>County:</u>	York
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	46-096-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Beacon Knoll Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 15, 2020, and July 14, 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 flow meter was not operating; the chlorine and pH levels were not within the acceptable range of water quality standards; and, the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record.

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

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

27) Order Type and Number: Consent Order 20-034-RW
Order Date: August 27, 2020
Individual/Entity: **HDCC, LLC**
Facility: Darlington Country Club
Location: 125 Country Club Road
Darlington, SC 29540
Mailing Address: Same
County: Darlington
Previous Orders: None
Permit/ID Number: 16-1014B
Violations Cited: S.C. Code Ann. Regs. 61-51.B.7

Summary: HDCC, LLC (Individual/Entity) owns and is responsible for obtaining from the Department final approval to operate a newly constructed pool located in Darlington County, South Carolina. The Department conducted an inspection of the pool on July 9, 2020 and determined that the pool was in operation and final approval had not been issued. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failure to obtain final approval to operate from the Department prior to operating a pool.

Action: The Individual/Entity has corrected the violation. The Department has assessed a total civil penalty in the amount of three hundred dollars (\$300.00). The Individual/Entity shall pay a civil penalty in the amount of three hundred dollars (**\$300.00**).

Update: Prior to the issuance of this Order, final approval to operate the pool was issued. The civil penalty has been paid. This project and Order have been closed.

28) Order Type and Number: Consent Order 20-035-RW
Order Date: August 27, 2020
Individual/Entity: **BRC Fort Mill, LLC**
Facility: Millcrest Apartments
Location: 208 Sedgewick Drive
Fort Mill, SC 29708
Mailing Address: Same
County: York
Previous Orders: None
Permit/ID Number: 46-1074B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: BRC Fort Mill, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 1, 2020, and July 2, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer basket was floating; the flow meter was not operating properly; the chlorine and pH levels were not within the acceptable

range of water quality standards; and, there were chlorine sticks in the recirculation and filtration system pump.

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**).

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

29) Order Type and Number: Consent Order 20-036-RW
Order Date: August 26, 2020
Individual/Entity: **Tani Hospitality, LLC**
Facility: Quality Inn Conway
Location: 3345 Church Street
Conway, SC 29526
Mailing Address: Same
County: Horry
Previous Orders: 19-035-RW (\$680.00)
Permit/ID Number: 26-R03-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Tani Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 12, 2020, and July 16, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight and secure; the chlorine and pH levels were 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 available for review on the first inspection, and was not maintained on a daily basis on the second inspection.

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

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

30) Order Type and Number: Consent Order 20-037-RW
Order Date: August 26, 2020
Individual/Entity: **Pelham Property Holdings, LLC**
Facility: Park at Calabria
Location: 100 Pelham Road

Mailing Address: Greenville, SC 29615
3917 Riga Boulevard
Tampa, FL 33619
County: Greenville
Previous Orders: None
Permit/ID Number: 23-080-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Pelham Property Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on June 2, 2020, and July 7, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight and secure, a ladder was not tight and secure; there were chlorine pucks in the skimmer baskets; the bathrooms did not have toilet paper; the water level was too high; only one “No Lifeguard On Duty - Swim At Your Own Risk” sign was posted; the drinking water fountain was not operating properly; and, the chlorine level was not within the acceptable range of water quality standards.

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

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

31) Order Type and Number: Consent Order 20-038-RW
Order Date: August 26, 2020
Individual/Entity: **Met Property Holdings, LLC**
Facility: Park at Sorrento
Location: 660 Halton Road
Greenville, SC 29607
Mailing Address: 3917 Riga Boulevard
Tampa, FL 33619
County: Greenville
Previous Orders: 16-146-RW (\$680.00);
19-084-RW (\$1,020.00)
Permit/ID Number: 23-292-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Met Property Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on June 8, 2020, and July 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a light in the pool wall was

out of its niche; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; both of the “Shallow Water – No Diving Allowed” signs posted did not have the correct size letters and did not have the correct wording; both of the “No Lifeguard On Duty – Swim At Your Own Risk” signs posted did not have the correct size letters; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; and, the cyanuric acid level was not checked weekly.

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**).

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

32) <u>Order Type and Number:</u>	Consent Order 20-039-RW
<u>Order Date:</u>	August 26, 2020
<u>Individual/Entity:</u>	Twenty5 Pelham Property Holdings, LLC
<u>Facility:</u>	Park at Bonito
<u>Location:</u>	25 Pelham Road Greenville, SC 29615
<u>Mailing Address:</u>	3917 Riga Boulevard Tampa, FL 33619
<u>County:</u>	Greenville
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	23-151-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Twenty5 Pelham Property Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on June 2, 2020, and July 8, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline did not have the required number of floats and the floats were not properly spaced; a light in the pool wall was out of its niche; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; the chlorine level was not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; and, the cyanuric acid level was not checked weekly.

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**).

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

Drinking Water Enforcement

- 33) Order Type and Number: Consent Order 20-020-DW
Order Date: August 20, 2020
Individual/Entity: **Macedonia Water Works, Inc.**
Facility: Macedonia Water Works, Inc.
Location: 3142 Union Highway
Gaffney, SC 29342
Mailing Address: P.O. Box 1955
Gaffney, SC 29342
County: Cherokee
Previous Orders: None
Permit/ID Number: 1120005
Violations Cited: S.C. Code Ann. Regs. 61-58.5.P(2)(b)

Summary: Macedonia Water Works, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Cherokee County, South Carolina. On July 1, 2020, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for total trihalomethanes.

Action: The Individual/Entity is required to: submit a corrective action plan to address the MCL violation. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars (**\$4,000.00**).

Update: The civil penalty has been paid. The corrective action plan has been submitted and approved. The corrective action plan stated automatic flushing devices have been installed within the distribution system to reduce water age, and they are applying for funding to install a tank mixer in the storage tank.

Water Pollution Enforcement

- 34) Order Type and Number: Consent Order 20-024-W
Order Date: August 11, 2020
Individual/Entity: **Altamont Mobile Home Village**
Facility: Altamont Mobile Home Village WWTF

Location: 5716 Old Buncombe Road
Greenville County, SC
Mailing Address: 2518 White Horse Road
Greenville, SC 29611
County: Greenville
Previous Orders: None
Permit/ID Number: SC0028533
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) (2011).

Summary: Altamont Mobile Home Village (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Greenville County, South Carolina. On March 18, 2020, a letter was issued as a result of deficiencies observed by Department staff during an inspection of the WWTF. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: failed to at all times properly operate and maintain the WWTF.

Action: The Individual/Entity is required to: complete clean out of the lagoon. The Department has assessed a total civil penalty in the amount of seven hundred dollars (\$700.00). The Individual/Entity shall pay a civil penalty in the amount of seven hundred dollars (**\$700.00**).

Update: The Individual/Entity has started to clean-out the lagoon and has paid the assessed civil penalty in full.

35) Order Type and Number: Consent Order 20-025-W
Order Date: August 11, 2020
Individual/Entity: **Town of Kingstree**
Facility: Town of Kingstree WWTF
Location: 100 Nelson Boulevard
Williamsburg County, SC
Mailing Address: 401 North Longstreet Street
Kingstree, SC 29556
County: Williamsburg
Previous Orders: 17-035-W (\$6,400.00)
Permit/ID Number: SC0035971
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: The Town of Kingstree (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Williamsburg County, South Carolina. On August 27, 2019, a Notice of Violation was

issued to the Individual/Entity as a result of free cyanide (CN) violations it reported to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations in that it failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for CN.

Action: The Individual/Entity is required to: submit to the Department a corrective action plan addressing sources contributing to free cyanide exceedances.

Update: The Department has not received the corrective action plan from the Individual/Entity and is making contact to determine whether or not submittal has been attempted.

36) Order Type and Number: Consent Order 20-026-W
Order Date: August 18, 2020
Individual/Entity: **McEntire Joint National Guard Base**
Facility: McEntire WWTF
Location: Hwy 378, Eastover
Richland County, SC
Mailing Address: 1325 South Carolina Road
Eastover, SC 29044
County: Richland
Previous Orders: None
Permit/ID Number: SC0000701
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) (2011).

Summary: McEntire Joint National Guard Base (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Richland County, South Carolina. On April 22, 2020, a violation was issued as a result of violations of Escherichia coli (E. coli) 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 to the Department written notification certifying completion of all corrective actions necessary to resolve the E. coli violations. 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 **stipulated penalty** in the amount of two thousand, eight hundred dollars (**\$2,800.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has submitted written certification that corrective actions have been completed to resolve the E. coli violations. These actions included the Individual/Entity performing a smoke test of their collection system, repairing all open

discrepancies identified during the smoke test, replacement of the chlorination and dechlorination pumps, and replacement of certain electrical components with the secondary electrical panel of the WWTF.

37) Order Type and Number: Consent Order 20-027-W
Order Date: August 26, 2020
Individual/Entity: **Town of Jefferson**
Facility: Town of Jefferson WWTF
Location: South Carolina Hwy 265
Jefferson, SC 29718
Mailing Address: P.O. Box 306
Jefferson, SC 29718
County: Chesterfield
Previous Orders: 16-035-W (\$1,400.00)
19-051-W (\$700.00)
Permit/ID Number: SC0024767
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2016), Water Pollution Control Permits, 3 S.C. Code Ann Regs. 61-9.122.21(d) (2011), and NPDES Permit SC0024767

Summary: Town of Jefferson (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 August 3, 2020, a violation was issued for failure to reapply for permit coverage within 180 days prior to the existing NPDES Permit's expiration date. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to submit an application for renewal of the NPDES Permit at least one hundred eighty (180) days before the existing permit expires.

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

Update: The Individual/Entity has submitted an application for renewal of the NPDES Permit. The civil penalty has been paid.

BUREAU OF AIR QUALITY

38) Order Type and Number: Consent Order 20-005-A

Order Date: August 20, 2020
Individual/Entity: **Aryzta LLC**
Facility: Aryzta LLC
Location: 167 Overland Drive
Cayce, SC 29172
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 1560-0155
Violations Cited: EPA Regulations at 40 CFR 68, and 5 South Carolina Code Ann. Regs. 61-62.68, *Chemical Accident Prevention Provisions*

Summary: Aryzta LLC (Individual/Entity), produces baked goods at its facility located in Lexington County, South Carolina. The Department conducted an inspection on August 16, 2018, in response to two reported anhydrous ammonia releases. The Individual/Entity has violated EPA Regulations and South Carolina Air Pollution Control Regulations as follows: failed to provide annual certification demonstrating that its operating procedures were current and accurate for 2016; failed to provide initial training to each employee involved in operating a covered process; failed to provide up to date information regarding piping and instrument diagrams; failed to correct deficiencies in equipment that was outside acceptable limits; and hired a contractor prior to obtaining the contractor's safety performance documentation.

Action: The Individual/Entity is required to: implement and maintain its Risk Management Program in accordance with the requirements of the 112(r) Regulations. The Department has assessed a total civil penalty in the amount of fourteen thousand dollars (\$14,000.00). The Individual/Entity shall pay a civil penalty in the amount of fourteen thousand dollars (**\$14,000.00**).

Updates: The Individual/Entity has provided documentation demonstrating that it has replaced the faulty valve and submitted all required documentation.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

39) Order Type and Number: Administrative Order
Order Date: August 26, 2020
Individual/Entity: **Divya Rai, Jai Rai, and Biva Rai**
D/B/A Anderson Quick Stop
Facility: Divya Rai, Jai Rai, and Biva Rai
D/B/A Anderson Quick Stop

Location: 1701 Pearman Dairy Road
Anderson, SC 29625
Mailing Address: Same
County: Anderson
Previous Orders: 2018-206-01-044 (\$1,600.00)
Permit Number: 04-206-04382
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Anderson Quick Stop (Individual/Entity) is a convenience store located in Anderson, South Carolina. The Department conducted inspections on July 30, 2018, July 8, 2019, July 18, 2019, July 26, 2019, August 5, 2019, August 15, 2019, August 23, 2019, August 30, 2019, September 9, 2019, September 19, 2019, September 27, 2019, October 10, 2019, October 11, 2019, October 21, 2019, October 31, 2019, November 7, 2019, and November 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to pay a civil penalty required pursuant to a Department Order; failed to ensure that the handwashing sinks were accessible at all times; failed to ensure that each handwashing sink or group of two (2) adjacent handwashing sinks was provided with a supply of hand cleaning, liquid, powder or bar soap; failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks; failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles; failed to maintain the premises free of insects, rodents, and other pests; and failed to maintain food safe, unadulterated, and, as specified under 3-601.12.

Action: The Individual/Entity is required to: pay a previously assessed civil penalty in the amount of one thousand dollars (\$1,000.00) in this order. If this previously assessed civil penalty is not paid, the facility must cease and desist their food service operations. The Department has assessed an additional civil penalty in the amount of thirteen thousand, seven hundred fifty dollars (\$13,750.00) for the new violations. The Individual/Entity shall pay a **suspended penalty** in the amount of thirteen thousand, seven hundred fifty dollars (**\$13,750.00**) should any new requirement of the Order not be met.

Update: No Update.

40) Order Type and Number: Consent Order 2020-206-02-013
Order Date: August 21, 2020
Individual/Entity: **Smiley's Acoustic Cafe**
Facility: Smiley's Acoustic Cafe
Location: 111 Augusta Street
Greenville, SC 29601
Mailing Address: 104 Chatman Street
Greer, SC 29650
County: Greenville
Previous Orders: None
Permit Number: 23-206-11055

Violations Cited:

S.C. Code Ann. Regs. 61-25

Summary: Smiley's Acoustic Cafe (Individual/Entity) is a restaurant located in Greenville County, South Carolina. The Department conducted inspections on September 27, 2017, September 11, 2018, June 11, 2019, and January 23, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars (\$1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars (**\$1,600.00**).

Update: The Individual/Entity has entered into a payment plan with the Department and is current on the payments.

41) <u>Order Type and Number:</u>	Consent Order 2020-206-07-003
<u>Order Date:</u>	August 21, 2020
<u>Individual/Entity:</u>	Steel City Pizza
<u>Facility:</u>	Steel City Pizza
<u>Location:</u>	8600 Dorchester Road Summerville, SC 29420
<u>Mailing Address:</u>	Same
<u>County:</u>	Dorchester
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	18-206-08260
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Steel City Pizza (Individual/Entity) is a restaurant located in Dorchester County, South Carolina. The Department conducted inspections on February 7, 2018, February 15, 2018, February 7, 2019, January 22, 2020, and January 30, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand, one hundred fifty dollars (\$2,150.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, one hundred fifty dollars (**\$2,150.00**).

Update: The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

42) Order Type and Number: Consent Order 2020-206-07-004
Order Date: August 21, 2020
Individual/Entity: **Steel City Pizza**
Facility: Steel City Pizza
Location: 1440 Ben Sawyer Boulevard, Suite 1301
Mount Pleasant, SC 29464
Mailing Address: Same
County: Charleston
Previous Orders: 2018-206-07-011 (\$400.00)
Permit Number: 10-206-05442
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Steel City Pizza (Individual/Entity) is a restaurant located in Charleston County, South Carolina. The Department conducted inspections on March 27, 2019, April 4, 2019, and February 14, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of five hundred dollars (\$500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**).

Update: The civil penalty has been paid.

On Site Wastewater Enforcement

43) Order Type and Number: Administrative Order 20-89-OSWW
Order Date: August 11, 2020
Individual/Entity: **Van Stephen Keefe, as personal representative for the estate of Lois Keefe**
Facility: Van Stephen Keefe, as personal representative for the estate of Lois Keefe
Location: 1945 Marley Drive
Columbia, SC 29210
Mailing Address: 1949 Marley Drive
Columbia, SC 29210
County: Richland

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

Summary: Van Stephen Keefe, as personal representative for the estate of Lois Keefe (Individual/Entity) owns property located in Richland County, South Carolina. The Department conducted an investigation on June 16, 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.

Update: The Individual/Entity has met the requirements of the Order.

44) Order Type and Number: Administrative Order 20-90-OSWW
Order Date: August 11, 2020
Individual/Entity: **Franklin Myers**
Facility: Franklin Myers
Location: 1769 Heyward Brockington Road
Columbia, SC 29203
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Franklin Myers (Individual/Entity) owns property located in Richland County, South Carolina. The Department conducted an investigation on June 16, 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.

Update: The Individual/Entity has met the requirements of the Order.

45) <u>Order Type and Number:</u>	Administrative Order 20-91-OSWW
<u>Order Date:</u>	August 11, 2020
<u>Individual/Entity:</u>	Peter and Denise Harding
<u>Facility:</u>	Peter and Denise Harding
<u>Location:</u>	401 Pin Du lac Drive Central, SC 29630
<u>Mailing Address:</u>	Same
<u>County:</u>	Pickens
<u>Previous Orders:</u>	Administrative Order 19-37-OSWW
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Peter and Denise Harding (Individual/Entity) own property located in Pickens County, South Carolina. The Department conducted an investigation on June 12, 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.

Update: The Individual/Entity has made the necessary repairs to the OSWW system.

46) <u>Order Type and Number:</u>	Administrative Order 20-98-OSWW
<u>Order Date:</u>	August 11, 2020
<u>Individual/Entity:</u>	Loyd Dean Kirby
<u>Facility:</u>	Loyd Dean Kirby
<u>Location:</u>	155 Edison Circle Spartanburg, SC 29303

Mailing Address: 406 Floyd Road
Spartanburg, SC 29303
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Loyd Dean Kirby (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on May 18, 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.

Update: On September 28, 2020, the Department issued a legal demand letter giving fifteen (15) days until the case is referred to the Department's Office of General Counsel for filing of a complaint with the Court of Common Pleas.

47) Order Type and Number: Administrative Order 20-100-OSWW
Order Date: August 11, 2020
Individual/Entity: **Mary Ellen Kinard**
Facility: Mary Ellen Kinard
Location: 128 Milam Road
Simpsonville, SC 29681
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Mary Ellen Kinard (Individual/Entity) owns property located in Greenville County, South Carolina. The Department conducted an investigation on July 22, 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.

Update: The Individual/Entity has met the requirements of the Order.

48) <u>Order Type and Number:</u>	Administrative Order 20-96-OSWW
<u>Order Date:</u>	August 26, 2020
<u>Individual/Entity:</u>	Richard Dresher and Denise Dresher
<u>Facility:</u>	Richard Dresher and Denise Dresher
<u>Location:</u>	1394 Suttle Road Lancaster, SC 29720
<u>Mailing Address:</u>	Same
<u>County:</u>	Lancaster
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Richard Dresher and Denise Dresher (Individual/Entity) owns property located in Lancaster County, South Carolina. The Department conducted an investigation on July 9, 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 connect the site to public sewer within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: On September 28, 2020, the Department issued a legal demand letter giving fifteen (15) days until the case is referred to the Department's Office of General Counsel for filing of a complaint with the Court of Common Pleas.

49) Order Type and Number: Administrative Order 20-101-OSWW
Order Date: August 26, 2020
Individual/Entity: **William Pressley**
Facility: William Pressley
Location: Several Sites on Raymond Drive
Chesnee, SC 29323
Mailing Address: 694 Old Island Ford Road
Chesnee, SC 29323
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: William Pressley (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on July 31, 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.

Update: The Individual/Entity has met the requirements of the Order.

50) Order Type and Number: Consent Order 20-67-OSWW
Order Date: August 6, 2020
Individual/Entity: **Timothy McGatha and Reshana McGatha**
Facility: Timothy McGatha and Reshana McGatha
Location: 613 Cliffside Highway
Chesnee, SC 29323
Mailing Address: Same
County: Cherokee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Timothy McGatha and Reshana McGatha (Individual/Entity) owns property located in Chesnee, South Carolina. The Department conducted an investigation on March 6, 2020 and observed a camper on the Site being used as a residence. A cement lined hole with a pipe connected to the OSWW system was being used for collecting the domestic wastewater from the camper and lavatory holding tanks from buses repaired at the Site. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to apply for and receive a permit to construct or upgrade the OSWW system before upgrading the OSWW system and changed the use of a facility such that additions or alterations were proposed that changed the wastewater characteristics and increased wastewater flow without bringing the OSWW system into compliance with the regulation and without applying for and receiving approval for the upgrade/expansion prior to any alterations.

Action: The Individual/Entity is required to cease and desist upgrading the OSWW system without first obtaining a permit from the Department and cease and desist emptying lavatory holding tanks into the existing OSWW system at the Site until a Department issued permit and approval to operate have been issued. The Individual/Entity may apply for a Department issued permit to construct a new OSWW system or upgrade the existing OSWW system to accommodate the increased flow from emptying the lavatory holding tanks into the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Department has not received further complaints about the violations continuing and will continue to monitor for any additional complaints or claims.

51) <u>Order Type and Number:</u>	Consent Order 20-80-OSWW
<u>Order Date:</u>	August 13, 2020
<u>Individual/Entity:</u>	Carter Quality Plumbing
<u>Facility:</u>	Carter Quality Plumbing
<u>Location:</u>	P.O. Box 1391 Lancaster, SC 29721
<u>Mailing Address:</u>	Same
<u>County:</u>	Lancaster
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Carter Quality Plumbing (Individual/Entity) does not possess a Department issued license to construct or repair onsite wastewater systems. The Department conducted an investigation on May 11, 2020 and determined the Individual/Entity had constructed or repaired components of an OSWW system. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: they have engaged in the business of constructing and repairing

onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department.

Action: The Individual/Entity is required to immediately cease and desist constructing and repairing onsite wastewater systems until receiving, and subsequently maintaining, a Department issued license to construct and repair onsite wastewater systems. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**).

Update: On June 19, 2020, the Individual/Entity received a Department issued license to construct and repair OSWW systems.

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

(x) ACTION/DECISION
() INFORMATION

Date: October 8, 2020

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

From: Bureau of Land and Waste Management

Re: Notice of Proposed Regulation Amending R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals.

I. Introduction

The Bureau of Land and Waste Management (“Bureau”) proposes the attached Notice of Proposed Regulation amending R.61-107.4, *Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals*, for publication in the October 23, 2020, *South Carolina State Register* (“*State Register*”). Legal authority resides in the South Carolina Solid Waste Policy and Management Act, S.C. Code Sections 44-96-10 *et seq.*, which requires the Department to promulgate regulations establishing standards for the management of yard trash and land-clearing debris and production of compost. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. Pursuant to S.C. Code Sections 44-96-10 *et seq.*, the Department must establish standards for the management of yard trash and land-clearing debris and production of compost. The proposed amendments improve environmental protection, ensure adequate, but not burdensome, financial assurance to close facilities that cease operating, provide clarity for permit exemptions, update operational criteria, and correct typographical and other similar errors.

2. The Department had a Notice of Drafting published in the May 22, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from two parties by the June 23, 2020, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

3. The Bureau conducted a stakeholder engagement meeting was conducted virtually on August 24, 2020. Participants included representatives of the compost industry, the waste industry, environmental organizations, and city and county government. Additionally, the Bureau provided representatives from Clemson University’s Department of Plant Industry and the U.S. Department of Agriculture copies of the draft and invited to participate and/or comment. The Bureau also invited parties that commented on the Notice of Drafting to participate in this meeting.

4. Appropriate Department staff conducted an internal review of the proposed amendments on September 3, 2020.

III. Request for Approval

The Bureau respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the October 23, 2020, *State Register*.



Henry Porter
Bureau Chief



Myra C. Reece
Director

Attachments:

- A. Notice of Proposed Regulation
- B. Notice of Drafting published in the May 22, 2020, *State Register*
- C. Summary of Public Comments Received and Department Responses

ATTACHMENT A

**STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-107.4, SOLID WASTE MANAGEMENT: COMPOST AND MULCH PRODUCTION
FROM LAND-CLEARING DEBRIS, YARD TRIMMINGS AND ORGANIC RESIDUALS**

October 8, 2020

Document No. _____

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61**

Statutory Authority: 1976 Code Sections 44-96-10 et seq.

R.61-107.4. Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals.

Preamble:

Pursuant to S.C. Code Sections 44-96-10 *et seq.*, it is the responsibility of the Department of Health and Environmental Control (“Department”) to promulgate regulations establishing standards for the management of yard trash and land-clearing debris, and for the production of compost. The proposed amendments improve environmental protection, ensure adequate, but not burdensome, financial assurance to close facilities that cease operating, provide clarity for permit exemptions, update operational criteria, and correct typographical and other similar errors. 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 May 22, 2020, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

The Table of Contents is amended to reflect the proposed revisions made throughout the text of the regulation.

Amended codification and internal citations throughout regulation to reflect repositioning of various provisions and for improved organization and clarity.

Part I. General Provisions.

A. Applicability. References to registered wood-grinding or composting facilities are removed as unnecessary due to most recent revision.

B. Definitions. The definition of and references to “Waters of the U.S.” are removed, and the definitions of “Waters of the State” and “Wetlands” are updated to reflect that wetlands are now included in the category of State waters. A definition is provided for “Hearing” and “Visual Marker.” Typographical corrections are also made for clarity.

D. Prohibitions moved to Part I from Part VI for clarity and consistency. This new section moves the Violations and Penalties and Severability sections to E and F respectively.

Part II. Exempted and Conditionally Exempted Activities.

A. Exempted Activities. A condition is added to Section A that exempted activities must be performed in a manner that does not cause harm to human health or the environment. A change is made to allow specific exempt activities on property under a person's control.

B. Conditionally Exempt Activities. A condition is added to require conditionally exempt activities be performed in a manner that does not cause harm to human health or the environment. A condition is added to require a notice of intent for conditionally exempt activities. A requirement is added that feedstocks be ground or incorporated into a composting mass at least once per year. An additional requirement is added that combustible materials not be stored in piles exceeding 16 feet in height.

Part III. Permitted Facilities.

A. Facility Types. Typographical and grammatical corrections are made for clarity.

B. General Criteria. Typographical and grammatical corrections are made for clarity.

C. Location Criteria. Buffers are clarified for Type Two facilities performing in-vessel composting.

D. Design Criteria. Addition made to allow test pits to be used to determine separation from the seasonal high-water table. Requirement added that visual markers be used to designate operational areas of the facility.

E. General Operating Criteria. Requirements related to open burning, pile sizes, temperature measurements and other material management activities are moved to other parts of the regulation for clarity and consistency. Language is added to clarify that finished compost and mulch are included in annual reporting requirements. Record retention is specified for a minimum of three years. Notification requirements are added to address facility fires or equipment failure.

F. Material Management for Permitted Facilities. In this new section, material management requirements are moved from other sections of the regulation and compiled here for clarity and consistency. New requirements are added to reduce the likelihood of fire, including pile height restrictions for combustible material, management for combustible material piles, requirements for grinding of land-clearing debris, stipulation of appropriate pile spacing, and preventing passive composting.

G. Additional Operating Requirements for Type Two and Type Three Facilities. Addresses standards for operation of Type Two and Type Three facilities. Details allowable composting methods, appropriate methods for temperature measurements, pile size and spacing requirements, and material management guidelines. Addresses employee certification requirements.

H. Quality Assurance and Testing Requirements for Finished Compost. Addresses testing parameters for compost that is to be offered for sale or distribution to the public.

I. Additional Requirements for Permitted Facilities. Corrected for clarity, and for typographical and punctuation errors.

J. Financial Assurance. Modified to clarify that financial assurance must be adequate to perform removal, transport and disposal of all material stored on site in the event of facility closure.

K. Closure. Added requirement that a facility provide a final report upon closure.

L. Permit Suspension or Revocation. Updates Department noticing process for permit revocation to include permit suspension and provides opportunity for response by permittee. Typographical and grammatical corrections are made for clarity.

Part IV Permit Application.

A. Permit Application Process. Updates permit application process and modifies language for clarity.

B. Notice. Updates and reduces noticing requirements for applicants.

C. Application Review and Permit Decision. Typographical and grammatical corrections and modifications to language are made for clarity.

D. Permit Modifications. Language is modified for clarity.

E. Transfer of Ownership. Updates process for permit transfer and modifies language for clarity.

Part V. General Permits.

A. General Permit Issuance. Typographical and grammatical corrections are made for clarity.

B. Application for Coverage under a General Permit. Typographical and grammatical corrections are made for clarity.

C. Corrective Measures and General Permit Revocation. Typographical and grammatical corrections are made for clarity.

Part VI. Prohibitions. Stricken and moved to Part I for clarity and consistency.

Appendix: Feedstock Categories. Added industrial wastes/sludges to allowable feedstocks provided they meet appropriate characterization requirements. Some typographical and grammatical corrections are made for clarity.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Jana White of the Bureau of Land and Waste Management; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; whitejm@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on November 23, 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. Because of ongoing COVID-19 concerns, interested persons who do not wish to appear in person may participate in the public hearing by calling in through an assigned conference line. These participants may register in advance by visiting the DHEC Events webpage (www.scdhec.gov/events) and selecting the appropriate Board meeting date. A link to register will be provided on the accompanying meeting information page. The Department will publish a

meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: <http://www.scdhec.gov/Agenda>.

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

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.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals.

Purpose: The Department proposes amending R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals, to improve environmental protection, to clarify the applicability of regulatory requirements, and to ensure adequate financial resources are available to remove waste and properly close facilities. Changes are proposed to correct typographical errors, to improve the regulation's organizational structure, and provide corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling, to improve the overall text of the regulation.

Legal Authority: 1976 Code Section 44-96-10 et seq., as amended.

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.61-107.4 to clarify the applicability of the regulation, to update definitions, to improve environmental protection by adding fire prevention and material management requirements, and to ensure adequate financial assurance is available to properly close facilities.

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 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 solid waste composting 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 or its political subdivisions resulting from these proposed revisions. Staff time associated with a new requirement for a letter of concurrence for conditionally exempt facilities can be absorbed at current staffing levels.

Changes to the method for calculating closure costs will benefit both the Department and the regulated community by clarifying the amount of financial assurance needed by regulated facilities. This change may result in increased cost estimates for some facilities and decreased cost estimates for others. The requirement for visual markers will also help improve the accuracy of cost estimates. Improving the accuracy of cost estimates may provide a cost savings to the state by helping ensure adequate financial assurance is secured, thus decreasing the likelihood that public funding would be needed to remove waste and properly close a facility, should it cease operating.

Changes to operational requirements will have the benefit of reducing the likelihood of spontaneous combustion of material piles, reducing the need for emergency response by the state and/or its political subdivisions.

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:

The state's authority to adequately oversee solid waste composting and wood-grinding facilities would be compromised if these amendments are not adopted in South Carolina. Without the proposed changes, the state would lack the authority necessary to ensure that facility operators are being adequately protective of the environment, and the state would be unable to ensure that financial resources are available to properly close a facility.

Statement of Rationale:

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

The Department proposes amending R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals, to clarify changes made to the regulation in 2014, to improve environmental protection, and to correct typographical errors, citation errors, and other errors and omissions. These amendments expand and clarify definitions, expand and clarify permit exemptions, expand and clarify operational criteria, improve environmental safety, and help ensure adequate financial assurance will be available to the Department to properly close a facility should it cease operating. The changes improve the regulation's organizational structure, and provide corrections

for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of the regulation.

Text:

~~Indicates Matter Stricken~~

Indicates New Matter

61-107.4. Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals.

Table of Contents

Part I. General Provisions

- A. Applicability
- B. Definitions
- C. Variances
- D. ~~Violations and Penalties~~ Prohibitions
- E. ~~Severability~~ Violations and Penalties
- F. Severability

Part II. Exempted and Conditionally Exempted Activities

- A. Exempted Activities
- B. Conditionally Exempt Activities

Part III. Permitted Facilities

- A. ~~Facilities~~ Types
- B. General Criteria
- C. Location Criteria
- D. Design Criteria
- E. General Operating Criteria
- F. ~~Quality Assurance and Testing Requirements for Finished Compost~~ Material Management for Permitted Facilities
- G. Additional Operating Requirements ~~Permitted for Type Two and Type Three~~ Facilities
- H. ~~Financial Assurance~~ Quality Assurance and Testing Requirements for Finished Compost
- I. ~~Closure~~ Additional Requirements for Permitted Facilities
- J. ~~Permit Violations~~ Financial Assurance
- K. ~~Permit Revocation~~ Closure
- L. Permit Suspension or Revocation

Part IV. Permit Application

- A. Permit Application Process
- B. Notice
- C. Application Review and Permit Decision
- D. Permit Modifications
- E. Transfer of Ownership

Part V. General Permits

- A. General Permit Issuance
- B. Application for Coverage under a General Permit
- C. Corrective Measures and General Permit Revocation

Part VI. Prohibitions

A. Open Dumping

B. Open Burning

61-107.4 Appendix: Feedstock Categories

A. Feedstock Categories

B. Prohibited Feedstocks

Part I. General Provisions.

A. Applicability.

1. The purpose of this regulation is to establish minimum standards for the proper management of yard trimmings, land-clearing debris, and other organic material; to encourage composting and establish standards for the production of compost; and to ensure that operations are performed in a manner that is protective of public health and the environment.

~~2. Registered wood grinding or composting facilities operating on the effective date of this regulation are subject to the following:~~

~~a. Registered facilities operating on the effective date of this amendment shall be subject to all provisions of the amended regulation with the exception of the location criteria outlined in Part III.C. Such an exception shall not apply to facilities that relocate or modify their permit or registration to include feedstocks other than Category One feedstocks, after the effective date of this amendment.~~

~~b. Within 90 days of the effective date of this amended regulation, operators of registered facilities shall send written notification to the Department of their intent to operate in compliance with the regulation or of their intent to cease and close their operations.~~

~~(1) Facilities intending to continue to operate as an exempt or conditionally exempt facility shall include in its notice a statement identifying its eligibility to operate as either an exempt facility or a conditionally exempt facility, a signed certification that activities will be conducted in accordance with this regulation, a request that its registration be terminated and, as appropriate, a request that its financial assurance mechanism be canceled.~~

~~(2) Facilities intending to operate as a permitted facility shall include in its notice a request that its registration, including any modifications approved in writing by the Department prior to the effective date of this amendment, be converted to a permit, and a certification that activities will be conducted in accordance with the regulation.~~

~~(3) Facilities intending to cease wood grinding or composting activities shall provide written notice of intent to close in accordance with Part III.I of this regulation, and a proposed closure date.~~

~~c. Facilities shall achieve compliance with all provisions of this amendment within 270 days of its effective date, or close in accordance with the closure requirements of this regulation, unless otherwise approved by the Department.~~

~~d. In addition to the notice described above, a facility may be required to provide additional information to the Department to determine compliance with this regulation or to facilitate conversion of the registration to a permit.~~

32. The requirements of this regulation are not applicable to the grinding of pallets, packaging, or other industrial sources of wood residuals.

43. The requirements of this regulation are not applicable to sewage sludge or industrial sludge generated and managed on site of a wastewater treatment facility permitted under the authority of R.61-9, Water Pollution Control Permits, including sludges mixed with Category One feedstocks generated off-site of the facility.

B. Definitions.

For the purposes of this regulation, the following terms are defined as follows:

1. “Aerated Static Pile” means a composting process that uses a controlled air distribution system to either blow or draw air through the composting mass. No agitation or turning of the composting mass is performed.

2. “Aerobic” means the biological decomposition of organic substances in the presence of at least five percent oxygen by volume.

3. “Best management practices” (BMP) means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of Waters of the State, ~~Waters of the United States or wetlands.~~

4. “Buffer” means the regulatory minimum separation distance required for wood-grinding equipment, operational areas, storage areas, or boundaries of a wood-grinding or composting site to structures ~~as listed in the regulation.~~

5. “Carbon-to-Nitrogen ratio” (“C:N Ratio”) means the quantity of total carbon (C) in relation to the quantity of total nitrogen (N) in an organic material or composting mass.

6. “Composite sampling” means a single sample for laboratory analysis composed of multiple, well-blended point or sub-samples uniformly distributed throughout the entire volume that, after mixing, accurately represents an average or median value of the property or trait of interest for a batch or general mass of compost.

7. “Compost” means the humus-like product of the process of composting.

8. “Compost stability” refers to a specific stage or state of organic matter during composting as characterized by the inverse measure of the potential for a material to rapidly decompose.

9. “Compostable” means the capability of being decomposed by natural biological processes, ~~and is approved by the Department as an acceptable feedstock.~~

10. “Compostable products” means manufactured items such as cups, plates, and flatware for food service or bags and packaging intended for singular use that undergoes degradation by biological processes ~~at a rate consistent with other known compostable materials and leaves no visually distinguishable or toxic residue.~~ Only the materials that meet the relevant specifications of American Society for Testing Materials (ASTM) D6400 (plastics) or ASTM D6868 (coated papers and natural materials) shall be considered compostable products.

11. "Composting" means the aerobic biological decomposition of organic residuals under managed conditions and minimum time-temperature relationships resulting in compost.

12. "Composting mass" means the result of combining feedstocks in a formulaic recipe to achieve a Carbon-to-Nitrogen ratio, moisture content, and porosity within the mixture that facilitates rapid aerobic decomposition of the materials; the mixture of feedstocks is considered a composting mass until it meets the stability requirements of this regulation.

13. "Control" means having access to a property through part ownership, rental, lease, easement or other access agreement.

14. "Curing" means the process that follows composting in which the compost is matured to meet market conditions.

15. "Department" means the South Carolina Department of Health and Environmental Control (SCDHEC).

16. "Domestic septage" means either liquid or solid material removed from a septic tank, cesspool, portable toilet, Type III marine sanitation device, or similar treatment works that receives only domestic sewage. Domestic septage does not include liquid or solid material removed from a septic tank, cesspool, or similar treatment works that receives either commercial wastewater or industrial wastewater and does not include grease removed from a grease trap at a restaurant.

17. "Domestic sewage" means waste and wastewater from humans or household operations that is discharged to or otherwise enters a treatment works.

18. "Feedstock" means source separated, recovered organic material approved by the Department or listed in the Appendix ~~to~~ of R.61-107.4 to be used in the production of compost, mulch, or other product.

19. "Finished compost" means the product of a composting mass that has met the minimum time and temperature requirements for the composting method chosen and satisfies the stability requirements and applicable quality assurance and testing requirements for finished compost found in Part III.F of this regulation.

20. "Generated on site" means residuals produced on the same single tax map parcel or multiple tax parcels under the same ownership or control, upon which it is managed.

21. "Grinding" means the act of mechanically reducing the size of organic materials.

"Hearing" means a Department proceeding that is conducted after notice by mail has been given to the permittee of facts or conduct that warrant a permit revocation and is a proceeding where the permittee is given an opportunity to show compliance with all lawful requirements for the retention of the permit.

23. "Industrial sludge" means the solid, semi-solid, or liquid residue generated during the treatment of industrial wastewater in a treatment works. Industrial sludge includes, but is not limited to, scum or solids removed in primary, secondary, or advanced wastewater treatment processes, and a material derived from industrial sludge. Industrial sludge does not include ash generated during the firing of industrial sludge in an industrial sludge incinerator or grit and screenings generated during preliminary treatment of industrial wastewater in a treatment works. Industrial sludge by definition does not include sludge covered under 40 CFR 503 or R.61-9.503, Water Pollution Control Permits Standards for the Use or Disposal of Sewage Sludge.

23. “Industrial solid waste” means solid waste generated by manufacturing or industrial processes that is not a hazardous waste regulated under subtitle C of the Resources Conservation and Recovery Act (RCRA). The term does not include employee kitchen or cafeteria residuals, packaging waste or yard-trimmings generated on site of an industrial property.

24. “In-process material” means ground organics ~~which~~that have been incorporated into a composting mass and other material that is in the process of being cured, but has not yet achieved the status of finished compost.

25. “In-vessel composting” means a process in which decomposing organic material is enclosed in a drum, silo, bin, tunnel, or other container for the purpose of producing compost; and in which temperature, moisture and air-borne emissions are controlled, vectors are excluded, and nuisance and odor generation minimized.

26. “Land-clearing debris” means material generated solely from land-clearing activities, including brush, limbs, and stumps, but does not include solid waste from agricultural or silvicultural operations.

27. “Manure” means the fecal and urinary excreta of livestock, poultry, or fish and may also contain bedding, spilled feed, water, soil and other substances incidental to its collection. This definition does not include excreta from household animals such as dogs and cats.

28. “Mulch” means the organic, non-composted product rendered by grinding Category One feedstocks.

29. “Municipal solid waste” means discards from residential, commercial, institutional, and industrial sources ~~which~~that have not been separated at the source for recycling. Industrial process waste is excluded from the wastes that comprise municipal solid waste.

30. “On-site” means activities performed on property under the same ownership or control where the feedstocks were grown, produced, or otherwise generated for recycling.

~~— 31. “Organic” means a substance derived from living organisms.~~

32. “Open burning” is defined to have the same meaning as used in Air Pollution Control Regulations and Standards R.61-62.1, Definitions and General Requirements, or any future amendments, and currently means any fire or smoke-producing process ~~which~~that is not conducted in any boiler plant, furnace, high temperature processing unit, incinerator or flare, or in any other such equipment primarily designed for the combustion of fuel or waste material.

33. “Open dumping” means any unpermitted disposal or landfilling activity except as specifically exempted by regulation.

34. “Operational Area” means the area of a wood-grinding or composting facility where equipment maintenance, material storage, material processing, composting or curing activities are performed, or as otherwise specified by permit.

35. “Operator” means the person responsible for the overall operation of a wood-grinding or composting facility.

“Organic” means a substance derived from living organisms.

36. “Pathogen” means a disease-causing organism, such as fecal coliform, Salmonella bacteria, Ascaris parasite eggs, etc.

37. “Person” means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

38. “Porosity” means the fraction of a material or mass that is void space.

39. “Putrescible” means material that contains organic matter capable of decomposition by microorganisms and of such a character and proportion that it causes obnoxious odors and the capability of attracting or providing food for birds and other animals.

40. “Residence” means any existing structure, all or part of which is designed or used for human habitation, that has received a final permit for electricity, permanent potable water supply, permanent sewage disposal, and, if required by the local government, a certificate of occupancy, ~~if required by the local government~~.

41. “Residuals” means materials that have served their original, intended use and have been source separated and diverted for recycling, grinding, or composting.

42. “Run-off” means any rainwater not absorbed by soil, that flows over land from any part of a facility.

43. “Sewage sludge” means the solid, semi-solid, or liquid residue generated during the treatment of municipal wastewater or domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic or industrial sewage in a treatment works.

44. “Silvicultural” means produced from or pertaining to the care and cultivation of forest trees and timber, including bark and woodchips.

45. “Solid waste” means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

46. “Source separated” means segregated from solid waste at the point of generation to facilitate recycling.

47. “Thermophilic” means a biological stage in the composting process during which microorganisms break down proteins, fats, and complex carbohydrates such as cellulose at relatively high temperatures (ranging from 113 degrees Fahrenheit to 167 degrees Fahrenheit or 45 degrees Celsius to 75 degrees Celsius).

48. “Turn” means to physically manipulate the compost mass in order to aerate, decrease temperatures, and increase evaporation rates.

49. “Unauthorized material” means any feedstock or waste material that due to its feedstock category, characteristics, or volume, causes an exempt, conditionally exempt site, or permitted facility to be in violation of this regulation or the permit conditions approved by the Department.

50. “Untreated wood” means raw wood or lumber that has not been chemically treated or painted.

51. “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.

“Visual marker” means a stationary pole or other apparatus that indicates a boundary of a facility’s operational area and which can be viewed from the area delineated.

~~52. “Waters of the State” means lakes, bays, sounds, ponds, impounding reservoirs, springs, wells, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within the territorial limits of the State, and all other bodies of surface or underground 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.~~
“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 Part.

~~53. “Waters of the United States” means:~~

~~— a. All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;~~

~~— b. All interstate waters, including interstate wetlands;~~

~~— c. All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sand flats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds that the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:~~

~~— (1) Which are or could be used by interstate or foreign travelers for recreational or other purposes;~~

~~— (2) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or~~

~~— (3) Which are used or could be used for industrial purposes by industries in interstate commerce;~~

~~— d. All impoundments of waters otherwise defined as Waters of the United States under this definition;~~

~~— e. Tributaries of waters identified in paragraph a through paragraph f of this definition;~~

~~— f. The territorial sea; and~~

~~—g. Wetlands adjacent to waters (other than waters that are themselves wetlands) identified in paragraph a through paragraph f of this definition.~~

~~—h. Waste treatment systems, including treatment ponds or lagoons designed to meet the requirements of the Clean Water Act, are not waters of the United States.~~

~~54. “Wetlands” means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas; 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.~~

~~55. “Yard trimmings” means residuals consisting solely of vegetative matter resulting from maintenance or alteration of public, commercial, institutional, or residential landscapes and tends to include grass clippings, leaves, discarded plants and weeds, which have been source separated and diverted for recycling.~~

C. Variances.

Any request for a change to the adherence to a provision or provisions of this regulation, or to a permit issued pursuant to or in accordance with this regulation, shall be made in writing to the Department. The Department shall provide a written response to such a request.

D. Prohibitions.

1. Open dumping of land-clearing debris, yard trimmings, and other organics is prohibited.

2. Open burning of land-clearing debris, yard trimmings, and other organics is prohibited except as approved by the Department for emergency storm debris management or as allowed by Air Pollution Control Regulations and Standards R.61-62.2, Prohibition of Open Burning.

~~E.~~ F. Violations and Penalties.

A violation of this regulation, or any permit or order issued pursuant to or in accordance with this regulation, subjects a violator to the issuance of a Department order, a civil enforcement action, or to a criminal enforcement action in accordance with S.C. Code Ann., Section 44-96-100, as amended.

~~E.~~ F. Severability.

If, for any reason, any provision, paragraph, sentence, clause, phrase, or part of this regulation or application thereof, is declared by a court of competent jurisdiction as invalid, or unconstitutional, such judgment shall not affect, impair, or invalidate the remainder of this regulation or its application.

Part II. Exempted and Conditionally Exempted Activities.

The feedstock categories referenced in this part of the regulation are listed and characterized in the Appendix ~~to~~ of R.61-107.4. For the purposes of this Part-H, a “site” shall mean one tax map parcel or multiple contiguous tax parcels under the same ownership.

A. Exempted Activities.

The activities below are exempted from the requirements of this regulation, but shall be performed in a manner to not cause harm to human health or to the environment as determined by the Department:

1. Backyard composting, when feedstocks generated on residential property by the property owner or occupants are composted primarily for use on the same property;

2. Grinding or composting of Category One feedstocks by a person on property under their ownership or control, when the feedstocks are generated ~~at that site~~ on site;

3. Acceptance, storage, grinding, or composting of only Category One feedstocks by a person on property under their ownership or control, when the combined total of unground feedstocks and in-process material on site at any given time is less than 80 cubic yards;

4. Wood grinding activities for maintenance and land-clearing activities by public agencies, public utilities, railroads, or their representatives, upon land ~~they owned~~ or controlled by the public agency, public utility, or railroad;

5. Composting activities using only Category One and Category Two vegetative feedstocks by a person on property under their ownership or control, when the combined total of feedstocks and in-process material on site, at any given time, is less than five cubic yards;

6. Storage, grinding, and composting activities ~~required~~ approved by the Department for emergency storm debris management at sites designated by state, county, ~~and~~ or municipal government;

7. Composting activities or other organics management activities associated with farming operations when the material managed is produced from crops grown on a farm, and when the compost is produced primarily for use on property under the same ownership or control;

8. Limited duration events that involve processing or storage of organic residuals for distribution to the public, to include “Grinding of the Greens” and, as approved by the Department, other programs of a similar nature; and

9. Composting activities by a participant transitioning to or enrolled in the U.S. Department of Agriculture (USDA) National Organic Program, or other programs of a similar nature as approved by the Department, and the compost produced is primarily for use on property under control of the participant.

B. Conditionally Exempt Activities.

1. The following activities are exempt from the permitting requirements of this regulation, but shall comply with all requirements of this Part-H-B:

a. Management of only source separated Category One feedstocks by a person on property under their ownership or control, when the combined total of feedstocks and in-process material on site at any given time is less than 400 cubic yards.

b. Management of only source separated Category Two feedstocks or mixtures of Category One and Category Two feedstocks by a person on property under their ownership or control, when the combined total of feedstocks and in-process material on site at any given time is less than 40 cubic yards.

c. Management of only source separated Category Two feedstocks or mixtures of Category One and Category Two feedstocks generated on site of commercial, industrial, or institutional properties under the same ownership, when the combined total of feedstocks and in-process material on site at any given time is less than 400 cubic yards.

2. All materials shall be managed in a manner to not cause harm to human health or to the environment as determined by the Department.

3. A facility choosing to operate under a conditional exemption shall submit a written notice to the Department stating that it will operate under the conditional exemption requirements. Once submitted, the Department will respond to the notice in writing, either stating concurrence that the facility operation meets the conditional exemption requirements or that it does not.

a. The notice to the Department shall include completion of a Department-issued form and a site map of the facility that demonstrates compliance with required buffers and include information that will allow the Department to confirm that the proposed facility conforms to all other exemption conditions of this Part.

b. The Department shall respond in writing within fifteen (15) calendar days of receiving the notice.

c. Facilities operating prior to the effective date of the most recent amendment to this regulation shall notify the Department within ninety (90) calendar days of that effective date..

24. Conditionally exempt activities shall be performed in accordance with the minimum buffers listed below as measured from the operational area, to the listed entities:

a. A minimum 200-foot buffer shall be required from the operational area to residences, schools, day-care centers, churches, hospitals, and publicly owned recreational park areas unless otherwise waived with documented consent of all property owners within the buffer and made available to the Department upon request;

b. A minimum 50-foot buffer shall be required from property lines unless otherwise waived with documented consent of all property owners within the buffer and made available to the Department upon request;

c. A minimum 100-foot buffer shall be required from public and private drinking water wells.

35. The Department may issue a variance to operate with less restrictive buffers when it determines that the technology and practices of the operation justify the reduction. The request shall be made in writing to the Department and the Department shall respond in writing.

46. All putrescible feedstocks shall be managed to prevent the escape of liquids and to suppress odors by ~~immediately~~ incorporating the feedstocks into the compost mass, an in-vessel composting unit, an air-tight container, or an enclosed building.

57. Best Management Practices shall be utilized to manage stormwater and to prevent impact to Waters of the State.

~~68.~~ No feedstocks or other material piles may be placed or stored in standing water.

~~79.~~ All feedstocks and other material piles on site of the facility shall be monitored and managed to prevent fire.

~~810.~~ Unauthorized and unrecyclable material shall be removed from the facility for proper disposal no less than every seven (7) calendar days, except that putrescible waste shall be placed in an air-tight covered container ~~immediately~~ and removed from the facility within seventy-two (72) hours.

~~911.~~ Compost produced by conditionally exempt facilities using Category Two feedstocks shall not be offered for sale to the public unless it can be demonstrated to meet all applicable standards for compost quality under Part III.F of this regulation.

12. All feedstocks shall be ground and/or incorporated into a composting mass not less than once per year. Conditionally exempt facilities operating prior to the effective date of this regulation shall have one year from the effective date of this regulation revision to comply with this requirement.

13. Piles of combustible material shall not be stored in excess of sixteen (16) feet in height, unless otherwise approved in writing by the Department.

Part III. Permitted Facilities.

The feedstock categories referenced in this part of the regulation are listed and characterized in the Appendix ~~to~~of R.61-107.4.

A. Facility Types.

Facilities described below ~~may~~shall not ~~be~~ operated without a permit, except as specifically exempted in ~~Part II~~ of this regulation:

1. Type One facilities. Type One facilities are facilities that grind or compost only source separated organic residuals described as Category One feedstocks.

2. Type Two facilities. Type Two facilities are ~~those~~ facilities that compost only source separated compostable materials described as Category Two feedstocks or mixtures of Category One and Category Two feedstocks, or any similar items specifically approved in writing by the Department.

3. Type Three ~~F~~ facilities. Type Three facilities are ~~those~~ facilities that:

a. Compost Category Three feedstocks or mixtures of Category Three feedstocks with other feedstock categories ~~from~~listed in the Appendix to of R.61-107.4;

b. Compost feedstocks not listed in the Appendix ~~to~~of R.61-107.4, that pose a level of risk greater than Category Two feedstocks as determined and allowed, on a case-by-case basis, by permit from the Department; or

c. Produce compost using methods not specified in ~~Part III.E.6~~ of this regulation and as allowed on a case-by-case basis by permit from the Department.

B. General Criteria.

1. The siting, design, construction, operation, and closure activities for facilities shall conform to the standards set forth in this regulation, unless otherwise approved by the Department.

2. Facilities shall obtain the appropriate permit or permits from the Department in accordance with ~~Part IV or Part V~~ of this regulation, prior to the construction, operation, expansion, or modification of a facility.

3. The Department may approve a variance from the general, location, design, or operating criteria, based upon the technology and practices of the operation.

4. All facilities shall be subject to inspections and evaluations of operations by a representative of the Department.

C. Location Criteria.

1. All facilities shall comply with the minimum buffers, listed below, from the operational area of the facility; to the listed entities, as they exist at the time the permit application is received by the Department, except that an entity listed here shall be exempt from the buffer requirement to its own buildings.

a. For Type One facilities, for Type Two facilities performing in-vessel composting, or for Type Two facilities performing composting performed in an enclosed building, a minimum 200-foot buffer shall be required from the operational area to residences, schools, day-care centers, churches, hospitals, and publicly owned recreational park areas; for all other Type Two or for all Type Three facilities, a minimum 1,000-foot buffer shall be required.

b. For Type One facilities, a minimum 50-foot buffer shall be required from the operational area to property lines; for Type Two or Type Three facilities, the buffer shall be at least 100 feet;

c. A minimum 100-foot buffer shall be required from the operational area to any Waters of the U.S. State;

d. A minimum 100-foot buffer shall be required from the operational area to public or private drinking water wells; and

~~e. A minimum 100-foot buffer shall be required from isolated wetlands; and~~

~~f. For Type Two or Type Three facilities, a minimum 10,000-foot buffer shall be required from the operational area to any airport runway used by turbojet aircraft and a minimum 5,000-foot buffer from any airport runway used only by piston-type aircraft, unless composting is in an enclosed building.~~

2. The Department may approve, with documented consent of all property owners within the buffer, less stringent buffers than those listed in ~~Part III.C.1.a and Part III.C.1.b of this regulation~~ to residences, schools, day-care centers, churches, hospitals, publicly owned recreational park areas, and property lines.

3. The Department reserves the right to require more stringent buffers if it is determined, based on the site, feedstocks, or operations, that more stringent buffers are necessary to protect health and the environment.

4. The Department's permit decision does not supersede, affect, or prevent the enforcement of a zoning regulation or ordinance within the jurisdiction of an incorporated municipality or county, or by an agency or department of this state.

5. Local governments may require siting criteria and buffer distances that are more stringent than the state regulations.

D. Design Criteria.

1. All facilities shall be designed to divert ~~storm water~~stormwater from running onto the operational areas of a facility.

2. The operational area of all permitted Type One facilities shall ~~ensure~~have at least one foot of separation to groundwater.

3. The operational area of all permitted Type Two and Type Three facilities shall be a hard-packed all-weather surface able to withstand various temperatures and ~~allow for~~be conducive to heavy equipment operation, without damage or failure. The working surface shall be:

a. A naturally occurring or engineered soil mixture with at least two feet separation to the seasonal high-water table; or

b. A surface such as concrete or asphalt pad on an appropriate sub-base intended to support and prevent failure of the surface layer with at least one foot of separation to the seasonal high-water table from the sub-base of the constructed surface; or

c. As otherwise approved by the Department.

4. Facilities may use borings or test pits to determine separation from the seasonal high-water table.

5. The Department may impose more protective design criteria for the operational areas of Type Three facilities to ensure compatibility with the feedstocks in use and the structural integrity needed for the equipment used at the site.

6. Facility design shall ~~ensure~~be structured so that each composting mass can be managed in accordance with the operational requirements of this regulation.

7. Access to all permitted facilities shall be controlled through the use of fences, gates, berms, natural barriers, or other means to prevent unauthorized dumping and access.

8. Each facility must have permanent visual markers that correspond to the approved operating areas shown on the site plan described in this regulation. Markers will be posted a minimum of every 300 feet and delineate the boundaries of areas where material is being stored, where material is being processed through composting, wood grinding, or other activities covered under this regulation, and where finished compost or mulch is stored.

a. Visual markers that are damaged or destroyed must be repaired or replaced within seven (7) calendar days.

b. All operations performed at permitted facilities must be conducted within the boundaries designated by the visual markers, with the exception of transportation services.

E. General Operating Criteria.

1. Site Control and Sign Requirements shall be as follows:

~~a. All permitted facilities shall control receipt of all materials. No incoming waste shall be accepted by the facility unless facility personnel are present to receive the incoming waste.~~

b. All permitted facilities shall post signs in conspicuous places that are resistant to weather and fading of color ~~in direct sunlight~~ that:

- ~~(1) Identify the owner, operator, or a contact person and telephone number in case of emergencies;~~
- ~~(2) Provide the hours during which the facility is open for use; and,~~
- ~~(3) List the valid SCDHEC Facility I.D. number(s) for the facility.~~

~~c. Facilities may accept only those materials as allowed by facility type and category as described listed in the Appendix to of R.61-107.4 or as otherwise specified in their permit application and approved in writing by the Department.~~

d. No material, including feedstocks or in-process material, may be stored at the permitted facility in excess of the maximum capacity allowed by permit.

e. No facility shall accept deliveries of feedstocks or other materials that will result in materials being stored in excess of the maximum capacity allowed by permit.

2. All wood-grinding activities shall assure that no debris is ejected onto neighboring properties.

3. Facilities shall use Best Management Practices to control run-on and run-off. An appropriate permit may be required prior to the discharge of any stormwater.

~~4. Open burning is prohibited except in accordance with Part VI. B of this regulation.~~

~~5. Pile sizes and spacing. All materials shall be maintained in such a way as to:~~

~~a. Allow the measurement of internal pile temperatures of the compost mass as required;~~

~~b. Enable the compost mass to be turned as needed to result in the aerobic, thermophilic decomposition of the solid organic constituents of the feedstock;~~

~~c. Have sufficient space around piles of material to allow access of emergency fire fighting equipment and procedures as described and approved in the facility operational plan;~~

~~d. Provide a safe working environment.~~

~~6. The operation of all composting facilities shall follow acceptable management practices for composting methods that result in the aerobic, thermophilic decomposition of the solid organic constituents of the feedstock. The following composting methods will be allowed:~~

~~a. Passive leaf composting, in which composting leaves collected by local government programs are managed with little manipulation of the materials after they are mixed and piled; turning shall be performed at least quarterly or as needed to prevent odors;~~

~~— b. The windrow composting method, in which the following requirements apply: Aerobic conditions at 131 degrees Fahrenheit or 55 degrees Celsius or greater shall be maintained in the composting mass for at least 15 days. During the high temperature period, the composting mass shall be turned at least five times. The composting mass shall be turned before the internal temperature exceeds 160 degrees Fahrenheit or 71 degrees Celsius.~~

~~— c. The aerated static pile composting method, in which the following requirements apply: Aerobic conditions shall be maintained during the composting process. The temperature of the composting mass shall be maintained at 131 degrees Fahrenheit or 55 degrees Celsius for at least three consecutive days; or~~

~~— d. The in-vessel composting method, in which the temperature of the composting mass shall be maintained at a minimal temperature of 131 degrees Fahrenheit or 55 degrees Celsius for at least three consecutive days.~~

~~— e. The use of other composting methods shall require written Department approval.~~

~~— 7. Temperature measurements shall be as follows:~~

~~— a. The temperature of each composting mass shall be measured daily during the first week of active composting, and not less than weekly thereafter.~~

~~— b. Temperature readings shall be taken every 50 feet along the length of a composting mass and from within the center of the mass.~~

~~— c. In vessel composting systems shall follow the manufacturer's recommendations for monitoring temperatures during active composting.~~

~~— d. Intervals and methods for monitoring temperatures and any alternatives not stated in this regulation must be included in the operational plan and approved in writing by the Department.~~

~~— e. A record of all temperature measurements taken shall be maintained and readily available to the Department upon request.~~

~~— 8. The moisture content in the composting mass shall be monitored regularly and managed to achieve desired results.~~

~~— 9. The working surface of the operational area of all permitted facilities shall be maintained to prevent standing water or uncontrolled releases.~~

~~— 10. Material Management shall occur as follows:~~

~~— a. Grass clippings shall be incorporated into the composting mass within 24 hours of arrival at a ratio of no more than one part grass to three parts chipped or ground carbon rich material by volume.~~

~~— b. Food residuals and other putrescible, nitrogen rich feedstocks shall be incorporated into the compost mass the same day of receipt or stored not more than 72 hours in closed, air tight, and leak proof containers.~~

~~— c. If manure is stored more than three days, the manure shall be stored on a concrete pad or other impervious surface and covered 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.~~

~~— d. Category Three feedstocks shall be incorporated into the compost mass upon receipt or stored in a manner which is described in the operational plan and approved by the Department.~~

~~— e. Source separated feedstocks shall not be combined until incorporated into the compost mass, except as described in the operational plan and approved by the Department.~~

~~— f. Feedstocks shall be thoroughly mixed into the compost mass in accordance with a formulaic recipe that optimizes Carbon to Nitrogen ratios, moisture content and porosity. Feedstocks with excessive moisture content shall be delivered onto a bed of woodchips or sawdust or otherwise managed to prevent escape of the liquids from the compost mass.~~

~~— g. All operations shall be performed to prevent the re-introduction of pathogens into materials that have undergone, or are in the process of, pathogen reduction.~~

~~h4. Unauthorized feedstocks, unrecyclable materials, and waste shall be removed from the facility for proper disposal no less than every seven (7) calendar days unless otherwise approved by the Department. Unauthorized putrescibles shall immediately be placed in ~~an air-tight~~ a covered container ~~immediately~~ and removed from the facility within seventy-two (72) hours of receipt. The area designated for temporary storage of unauthorized waste at the facility shall be identified in the facility operational plan. The Department may require more frequent removal based on the nature or quantity of other unacceptable waste.~~

~~11. All material piles shall be monitored and managed to prevent fire as described in the facility operational plan.~~

~~12. Facilities shall identify any chemical changes to a feedstock, or changes to the chemical ratios of a feedstock, significant enough to alter the composting process or the quality of the compost produced, and shall request appropriate permit modifications from the Department for any operational plan changes required as a result of those changes.~~

~~135. Reporting and Records Retention shall be in accordance with the following:~~

~~a. Not less than once each month, facilities shall measure and record the amounts, in cubic yards, of feedstocks, in-process material, finished compost, and mulch, and waste material on site at that time.~~

~~b. No later than September 1 of each year, all permitted facilities shall submit to the Department, an annual report on a form approved by the Department, for the prior fiscal year beginning on July 1 and ending June 30. The report shall include the following information:~~

~~(1) The total amount in tons, either actual or estimated weight, of in-coming feedstock received yearly for each type of feedstock and the source for each;~~

~~(2) The total amount in tons, either actual or estimated weight, of mulch, compost, or other material that on a yearly basis is:~~

~~(a) Produced;~~

~~(b) Transferred off-site as products such as mulch, compost, or soil amendment;~~

~~(c) Transferred off-site for further processing; and, or~~

(d) Disposed in a landfill and the reason for disposal.

~~c. The following information shall be maintained at all facilities that produce compost for sale or distribution to the public and made available to the Department upon request unless otherwise approved by the Department: Records of weekly temperature readings of mulch piles shall be maintained by all facilities for a period of no less than three (3) years and be made available at all reasonable times for inspection by the Department.~~

~~—— (1) Daily and weekly temperature readings and moisture observations of each composting mass that is formulated;~~

~~—— (2) Start up dates for each composting mass that is formulated and the date for each time a composting mass is remixed or turned while composting;~~

~~—— (3) Number of days required to produce the end product, by type; and~~

~~—— (4) The results of all testing performed in accordance with the Quality Assurance requirements of this regulation and any corrective action taken to improve product quality to the standards in Part III.F.~~

d. ~~Any~~ Changes into telephone numbers, names of responsible parties, addresses, etc. for a permitted facility shall be submitted to the Department within ten (10) business days of the change.

e. Records shall be maintained by all facilities for a period of no less than three (3) years and shall be furnished upon request to the Department or be made available ~~at all reasonable times for~~ during inspections by the Department.

~~14. Any compost produced with Category Two or Category Three feedstocks and offered for sale or distribution to the public is required to meet the physical and biological standards listed in Part III.F.~~

~~156.~~ Operational Plans.

All facilities shall be operated in accordance with this regulation and an operational plan developed specifically for the facility and approved by the Department in writing.

a. Facilities shall maintain an operational plan ~~onsite~~ on site of the facility and it shall be made available for inspection upon request by the Department.

b. Facilities requiring permits shall submit their operational plan to the Department along with the permit application. The Department may require changes to an operational plan when the Department has determined that the operation requires additional measures to protect human health and safety and the environment.

c. Facilities shall address all requirements of this Part III.E and Part F in their operational plan, including at a minimum:

(1) A description of the anticipated source and composition of the incoming feedstocks;

(2) A description of the processes and methods that will be used to grind, compost, cure, store, and otherwise manage material, including a description of production capabilities and equipment to be used;

(3) A description of the procedure for inspecting, measuring, and managing incoming feedstock and unacceptable waste;

(4) A description of the procedures for prevention and control of vector, odor, dust, and litter specific to their geographic location and the types and amounts of feedstocks used in their operation;

(5) A description of the anticipated markets for end products;

(6) A quality assurance and testing plan for finished compost that describes:

(a) All of the parameters and protocols for obtaining, preserving, storing, and transporting samples to a South Carolina certified laboratory;

(b) The frequency of monitoring to assess temperature profiles during composting;

(c) The methods and processes used to determine stability of the compost; and

(d) Other protocols used to achieve quality assurance standards required in ~~Part III.F~~this regulation;

(7) A fire prevention and ~~preparedness document~~response plan which includes:

(a) A description of the processes used to prevent fire, specific to their site design and operating criteria;

(b) A description of the procedures for ~~control of~~responding to a fire specific to their site location, feedstock types, and operating criteria;

(c) The location of emergency equipment and fire suppressant materials; and

(d) The emergency contact information for the local fire protection agency; ~~and,~~

~~_____ (e) Documentation of arrangements with the local fire protection agency to provide fire fighting services.~~

(8) A contingency plan describing facility operations in the event of equipment failure;

(9) A detailed closure plan to meet the requirements of ~~Part III.H~~this regulation, including final closure cost estimate pursuant to this Part III.H.2 of this regulation; ~~and~~

~~_____ (10) A description of the on-site equipment essential for the facility to operate on a day-to-day basis; and,~~

~~(11) Any additional procedures implemented as a requirement of the Department as described in Part III.G~~this regulation.

~~—16. Compost Program Manager Certification shall be secured and maintained as follows:~~

~~— a. Unless otherwise approved by the Department, within 18 months of the effective date of this regulation, all permitted Type Two and Type Three facilities are required to have an operator or one or more employees classified as a manager or supervisor who is duly certified as a compost program manager.~~

~~— b. Persons who have achieved and maintain compost manager certification by the U.S. Composting Council (USCC), the Solid Waste Association of North America (SWANA), or another Department-approved training program shall be deemed certified by the Department.~~

~~— c. Documentation of Compost Program Manager Certification shall be maintained at all permitted Type Two and Type Three facilities and made available to the Department upon request unless otherwise approved by the Department.~~

7. In the event of a fire at a facility, the facility must:

a. Verbally notify the appropriate regional office of the Department within twenty-four (24) hours. A written notification must be sent within seven (7) calendar days;

b. Cease accepting incoming waste until the Department clears the facility as suitable to receive new waste; and

c. Use the methods and equipment outlined in the fire prevention and response plan that is included in the operations plan approved by the Department.

8. In the event of a breakdown or malfunction of essential equipment lasting longer than one (1) day, the facility shall notify the appropriate regional office of the Department within twenty-four (24) hours and cease accepting incoming waste until the equipment is operational.

F. Material Management for Permitted Facilities.

1. Piles of mulch or combustible material shall not be stored in excess of 16 feet in height, unless otherwise approved in writing by the Department. Requests for a variance to the pile height limit must be accompanied by a detailed explanation in the facility operational plan as to how the temperature of the piles will be monitored and managed to prevent fires.

2. All piles of mulch and ground material shall be monitored and managed to prevent fire as described in the facility operational plan:

a. The temperature of each pile shall be measured weekly;

b. Temperature readings shall be taken every 50 feet along the length or around the circumference of a pile, at a depth of three to six feet;

c. Intervals and methods for monitoring temperatures and any alternatives not stated in this regulation must be included in the operational plan and approved in writing by the Department; and

d. A record of all temperature measurements taken shall be maintained and readily available to the Department upon request.

3. All land-clearing debris shall be ground at least once per fiscal year. Stumps or large debris that cannot be ground shall be removed from the facility for disposal or other management at least once per fiscal year.

4. All materials shall be maintained to:

a. Have sufficient space around piles of material to allow access of emergency fire-fighting equipment;

b. Have sufficient space around piles of material to allow loading or other activities described in the approved operational plan;

c. Allow monitoring of internal temperatures; and

d. Provide a safe working environment.

5. Within one (1) year of being ground, mulch and ground material must be bagged, added to a managed compost mass, transferred from the facility, or disposed of in accordance with a Department permit.

6. The working surface of the operational area of all permitted facilities shall be maintained to prevent standing water or uncontrolled releases.

G. Additional Operating Requirements for Type Two and Type Three Facilities.

1. The operation of all composting facilities shall follow acceptable management practices for composting methods that result in the aerobic, thermophilic decomposition of the solid organic constituents of the feedstock. The following composting methods will be allowed:

a. Passive leaf composting, in which composting leaves collected by local government programs are managed with little manipulation after they are mixed and piled; turning shall be performed at least quarterly or as needed to prevent odors;

b. The windrow composting method, in which the following requirements apply: Aerobic conditions at 131 degrees Fahrenheit or 55 degrees Celsius or greater shall be maintained in the composting mass for at least fifteen (15) consecutive days. During the high temperature period, the composting mass shall be turned at least five (5) times. The composting mass shall be turned before the internal temperature exceeds 160 degrees Fahrenheit or 71 degrees Celsius;

c. The aerated static pile composting method, in which the following requirements apply: Aerobic conditions shall be maintained during the composting process. The temperature of the composting mass shall be maintained at 131 degrees Fahrenheit or 55 degrees Celsius for at least three (3) consecutive days;
or

d. The in-vessel composting method, in which the temperature of the composting mass shall be maintained at a minimum temperature of 131 degrees Fahrenheit or 55 degrees Celsius for at least three (3) consecutive days.

e. The use of other composting methods shall require written Department approval.

2. Temperature measurements shall be as follows:

a. The temperature of each composting mass shall be measured daily during the first week of active composting, and not less than weekly thereafter;

b. Temperature readings shall be taken every 50 feet along the length of a composting mass and from within the center of the mass;

c. In-vessel composting systems shall follow the manufacturer's recommendations for monitoring temperatures during active composting;

d. Intervals and methods for monitoring temperatures and any alternatives not stated in this regulation must be included in the operational plan and approved in writing by the Department; and

e. A record of all temperature measurements taken shall be maintained and readily available to the Department upon request.

3. The moisture content in the composting mass shall be monitored regularly and managed to achieve desired results.

4. Pile sizes and spacing. All materials shall be maintained to:

a. Allow the measurement of internal-pile temperatures of the compost mass as required;

b. Enable the compost mass to be turned as needed to result in the aerobic, thermophilic decomposition of the solid organic constituents of the feedstock;

c. Have sufficient space around the composting mass to allow loading and other activities described in the approved operational plan;

d. Have sufficient space around the composting mass to allow access of emergency fire-fighting equipment and procedures as described and approved in the facility operational plan; and,

e. Provide a safe working environment.

5. Material Management shall occur as follows:

a. Grass clippings shall be incorporated into the composting mass within twenty-four (24) hours of arrival at a ratio of no more than one part grass to three parts chipped or ground carbon-rich material by volume;

b. Food residuals and other putrescible, nitrogen-rich feedstocks shall be incorporated into the compost mass the same day of receipt or stored not more than seventy-two (72) hours in closed, air-tight, and leak-proof containers;

c. If manure is stored more than three (3) calendar days, the manure shall be stored on a concrete pad or other impervious surface and covered 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;

d. Category Three feedstocks shall be incorporated into the compost mass upon receipt or stored in a manner that is described in the operational plan and approved by the Department;

e. Source separated feedstocks shall not be combined until incorporated into the compost mass, except as described in the operational plan and approved by the Department;

f. Feedstocks shall be thoroughly mixed into the compost mass in accordance with a formulaic recipe that optimizes Carbon-to-Nitrogen ratios, moisture content, and porosity. Feedstocks with excessive moisture content shall be delivered onto a bed of woodchips or sawdust or otherwise managed to prevent escape of the liquids from the compost mass; and

g. All operations shall be performed to prevent the re-introduction of pathogens into materials that have undergone, or are in the process of, pathogen reduction.

6. Facilities shall identify any chemical changes to a feedstock, or changes to the chemical ratios of a feedstock, significant enough to alter the composting process or the quality of the compost produced, and shall request appropriate permit modifications from the Department for any operational plan changes required as a result of those changes.

7. The following information shall be maintained at all facilities that produce compost for sale or distribution to the public and made available to the Department upon request unless otherwise approved by the Department:

a. Daily and weekly temperature readings and moisture observations of each composting mass that is formulated;

b. Start-up dates for each composting mass that is formulated and the date for each time a composting mass is remixed or turned while composting;

c. Number of days required to produce the end product, by type; and

d. The results of all testing performed in accordance with the quality assurance requirements of this regulation and any corrective action taken to improve product quality to the standards in this regulation.

8. Any compost produced with Category Two or Category Three feedstocks and offered for sale or distribution to the public is required to meet the physical and biological standards listed in this regulation.

9. Compost Program Manager Certification shall be secured and maintained as follows:

a. Unless otherwise approved by the Department, within eighteen (18) months of the effective date of this regulation, all permitted Type Two and Type Three facilities are required to have an operator or one or more employees classified as a manager or supervisor who is duly certified as a compost program manager.

b. Persons who have achieved and maintain compost manager certification by the U.S. Composting Council (USCC), the Solid Waste Association of North America (SWANA), or another Department-approved training program shall be deemed certified by the Department.

c. Documentation of Compost Program Manager Certification shall be maintained at all permitted Type Two and Type Three facilities and made available to the Department upon request unless otherwise approved by the Department.

FH. Quality Assurance and Testing Requirements for Finished Compost.

1. Any compost produced from Category Two or Category Three feedstocks and offered for sale or distribution to the public is required to meet the physical and biological standards listed in this section. Composite samples shall be collected, stored and analyzed in accordance with the procedures found in the U.S. Department of Agriculture publication “Test Methods for the Examination of Composting and Compost:” (TMECC), or equivalent methodology recommended by the U.S. Environmental Protection Agency publication SW-846, “Test Methods for Evaluating Solid Waste, Physical/Chemical Methods.”

—2. Compost from Type One facilities or compost made solely from Category One feedstocks with compliant records of time and temperature monitoring are presumed to meet the standard for biological contaminants and are not required to perform laboratory testing as described in this section.

—3. All compost for sale or distribution to the public and produced from feedstocks other than Category One must be tested and meet the designation of Class A Exceptional Quality Compost or be designated for legal disposal, additional processing, or other use as approved by state or federal agencies having appropriate jurisdiction.

—4. Class A exceptional quality compost:

- a. Contains less than two percent (2%) physical contaminants by dry weight analysis;
- b. Has a stability index rating of stable or very stable;
- c. Meets Class A pollutant limits found in Table 1; and
- d. Meets standards of this regulation for pathogen reduction.

Table 1. Pollutant Standards: Maximum Allowable Concentration
(milligrams per kilogram dry weight)

Pollutant	Class A
Arsenic	41
Cadmium	39
Copper	1500
Lead	300
Mercury	17
Nickel	420
Selenium	100
Zinc	2800

5. The distribution and use of exceptional quality compost is unrestricted and the consumer shall be advised to apply the product at agronomic rates based on product analysis, except that the use and distribution of compost produced from feedstocks generated by facilities permitted pursuant to R.61-67, Standards for Wastewater Facility Construction, shall be subject to all applicable requirements of R.61-9.

6. Compost Testing Frequency. The frequency of laboratory testing for pollutants, biological contaminants, and physical contaminants shall be based on the volume of compost produced annually by the facility as indicated in Table 2:

Table 2. Compost Testing Frequency

Compost Quantity	Frequency
1-2500 tons	1 per quarter (or less as approved)
2501-6250 tons	1 per quarter
6251-17500 tons	1 per 2 months
17501 tons and above	1 per month

7. The composted product shall be analyzed for stability using methods as set forth in the USDA TMECC Section 05.08-A through Section 05.08-F and the Compost Stability Index Table 05.08-1.

8. All compost produced for sale or distribution is required by this regulation to meet the physical and biological contaminant standards in Table 3 by a testing method referenced in ~~Section III.F.1~~ this regulation or an equivalent method allowed by the Department:

Table 3. Physical and Biological Contaminants Limits for Compost

Physical contaminants (man-made inerts)	Less than 2 percent dry weight basis
Biological Contaminants (pathogens)	
Fecal coliform	Less than 1,000 Most Probable Number (MPN) per gram, dry weight basis
Salmonella	Less than 3 MPN per 4 grams, dry weight basis

a. All product quality assurance testing for pollutant standards and biological contaminants required by this regulation or as requested by the Department shall be performed by a South Carolina certified laboratory and reported in a format acceptable to the Department.

b. All products marketed in South Carolina as a soil amendment or fertilizer shall be registered by the product manufacturer with the Clemson University Department of Plant Industry or as otherwise required by law ~~or regulation~~.

GI. Additional Requirements for Permitted Facilities.

1. The Department may impose more stringent requirements than those outlined herein when additional measures are necessary, on a case-by-case basis, to protect public health and the environment from any potentially adverse effects. These requirements include, but are not limited to:

a. Analysis of individual feedstocks to identify any characteristics that may require special management or permit conditions;

b. Feedstock selection; the Department may determine on a case-by-case basis that a material shall not be used as feedstock due to its pollutant content or concentration, the material variability from the source, or its potential for creating adverse environmental effects;

c. Testing frequency and parameters;

d. Location, design, and operating criteria;

e. Monitoring and reporting, including but not limited to, monitoring of groundwater, surface water, soil, plant tissue, feedstocks and/or finished products;

f. Surface or pad requirements; or

g. Other requirements as necessary such as site assessments, groundwater sampling, and corrective action when environmental contamination from a permitted facility is suspected or confirmed.

2. The permittee may request that the Department remove from the permit the additional requirements described in this Part III.G.1 ~~from a permit~~ if, after two (2) years, those processes are proven to the Department to be effective and those mixtures of feedstocks that are proven compatible for composting, as determined by the Department. In all cases, the Department shall retain the authority to determine the effectiveness of the process and/or feedstock mixture ~~to ensure it is protective~~ for the protection of human health, surface water standards, and groundwater standards.

HJ. Financial Assurance.

1. The requirements of this ~~S~~section apply to all permitted facilities except those owned and operated by a local government, by a region comprised of local governments, or by state or federal government entities whose debts and liabilities are the debts and liabilities of the ~~S~~state or the U.S.

~~2.~~ Prior to ~~accepting feedstocks~~ receiving a permit, ~~permitted facilities~~ applicants shall fund a financial ~~responsibility~~ assurance mechanism as described in R.61-107.19, SWM: Solid Waste Landfills and Structural Fill Part I.E, and approved by the Department to ensure the satisfactory closure of the facility as required by this regulation.

~~3.~~ The permittee shall calculate and declare in the permit application the maximum amount in cubic yards of feedstocks, in-process material, and waste material that could be stored at the facility ~~in their application for a permit~~. A final closure cost estimate is required to provide funding for the third party costs to properly dispose of the maximum amount of material that the facility can store at any given time and perform any corrective action for soils and groundwater that the Department may require. The cost estimate shall account for tipping fees, material hauling costs, grading and seeding the site, labor, and the cost for soliciting third party bids to complete closure and restore the site to conditions acceptable to the Department.

a. The maximum capacity of a site shall be calculated in cubic yards assuming compliance with all buffers and spacing requirements. The Department shall use an average cost of disposal per ton of material in Class II landfills, as reported in the most recent Solid Waste Management Annual Report, when calculating the amount of financial assurance necessary for a site. ~~The closure cost estimate shall be three times the cost to dispose the maximum capacity of the site in a Class II landfill.~~

b. ~~During the active life of the facility, the permittee shall annually adjust the closure cost estimate when the disposal cost estimate increases substantially based on information published in the Solid Waste Management Annual Report.~~ Financial assurance shall be required for all material stored on site. Materials stored for further processing, such as the production of lumber or firewood, shall be stored outside of permitted operational areas of the facility, and if not stored in this fashion, shall be included in financial assurance requirements.

c. The permittee shall increase the closure cost estimate and the amount of financial assurance provided if changes to the closure plan disposal costs, or site conditions, or other factors increase the maximum cost of closure at any time during the site's remaining active life.

d. The permittee shall increase the closure cost estimate and the amount of financial assurance provided if a release to the environment occurs to include cost of groundwater monitoring, assessment, and corrective action if the Department determines that these measures are necessary at any time during the active life of the facility. Financial assurance shall be maintained and adjusted annually until the Department agrees that environmental conditions meet applicable standards.

e. ~~At any time during the remaining life of the facility,~~ The permittee may reduce the closure cost estimate and the amount of financial assurance provided for proper closure if the cost estimate exceeds the maximum cost of closure ~~at any time during the remaining life of the facility.~~ The permittee shall submit justification for the reduction of the closure cost estimate and the amount of financial assurance to the Department for review and approval.

~~34. The registrant or permittee shall provide continuous coverage for closure until released from financial assurance requirements, pursuant to this regulation.~~

~~45. The Department may take possession of a financial assurance fund for failure to complete closure in accordance with Part III.I or failure to renew or provide an alternate acceptable financial assurance mechanism.~~

K. Closure.

All facilities ~~will~~shall conduct final closure in accordance with the operational plan submitted to the Department and with the following requirements:

1. Operators of permitted facilities shall provide to the Department written notice of intent to close and their proposed closure date ~~to the Department;~~

2. Upon closing, permitted facilities shall immediately post closure signs at the facility;

3. Unless otherwise approved by the Department, within ninety (90) calendar days after closing ~~date,~~ operators shall:

a. Remove all feedstocks, finished product, and wastes, except that mulch or Class A compost may be spread on the site to a maximum thickness of four inches if tilled into the soil prior to site stabilization;~~;~~

b. As appropriate, grade land to promote positive drainage and stabilize the site to prevent erosion ~~and;~~

c. Appropriately manage all water collected in containment structures or ponds; ~~and~~

d. Submit an annual report for the portion of the year during which the facility was operational, using the annual report form provided by the Department.

4. Permitted facilities with confirmed contamination shall amend ~~their~~its closure plan ~~with~~to include post-closure corrective action requirements for approval by the Department ~~when a facility's remediation activities at the facility continue beyond a facility's closure of the facility.~~

5. Permitted facilities shall request that the Department inspect and approve closure. Upon Department approval of proper closure, the permittee shall be released from financial assurance requirements.

~~J. Permit Violations.~~

~~The Department may take civil or criminal action or issue penalties in accordance with Part I.D of this regulation for a violation of a permit issued pursuant to or in accordance with this regulation.~~

KL. Permit Suspension or Revocation.

1. Whenever the Department finds that material or substantial violations demonstrate a disregard for, or inability to comply with, applicable laws, ~~regulations~~, or requirements, and ~~that~~ these violations would make the continuation of the permit not in the best interest of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit as appropriate and necessary.

a. The Department shall give notice by certified mail to the permittee of facts or conduct that warrant the intended action, and

b. The permittee shall be given an opportunity to show compliance with all lawful requirements for the retention of the permit.

2. If the Department finds that public health, safety, or welfare imperatively requires emergency action, suspension of a permit may be ordered pending proceedings for revocation or other action.

3. If a suspension is issued to a permittee, it shall be issued per an order from the Department, which will direct a facility to cease operating or to cease accepting all types of feedstocks.

a. The suspension order will also include instructions for how the permitted facility can obtain compliance and a deadline by which the facility shall become compliant. Cited violations that may result in a suspension order include, but are not limited to, the following examples:

(1) A Department determination that a facility has exceeded its permitted capacity;

(2) A Department determination that a facility has not submitted to the Department the required amount of financial assurance, or the financial assurance that was submitted is no longer valid, has been cancelled, and not replaced for the facility site;

(3) A Department determination that a facility was issued a written directive or order with a deadline to become compliant but failed to do so by the communicated deadline;

(4) A Department determination that a materially false statement has been made by the facility in the application for a permit; or

(5) A Department determination that the facility has falsified or altered records that are required by this regulation.

b. The suspension shall last until the Department has determined that the facility is in compliance with its permit, applicable statutes or regulations, and/or a prior order, unless the Department designates a time that the facility's suspension will be rescinded.

c. The Department may decline to lift the permit suspension if a facility is cited for any additional violations during the initial suspension period. If a facility is cited for additional violations during the initial suspension period, the Department may only rescind the suspension after the facility achieves compliance with all violations cited by the Department.

d. All rescissions of a suspension shall be communicated to the facility by the Department in writing.

34. If, after a hearing, the Department determines that permit revocation is warranted, an administrative order revoking the permit will be issued.

Part IV. Permit Application.

A. Permit Application Process. The applicant shall submit a permit application to the Department. The permit application shall include one hard copy and one electronic copy of the following ~~in a format approved by the Department~~:

1. A completed and signed application form provided by the Department;
2. Tax map number for the site;
3. Proof of ownership or control of the property;
4. For Type Two or Type Three facilities, a signed statement, on a Department-provided form, from a South Carolina licensed professional engineer, ~~on the form provided by the Department~~, certifying that the site design is compliant with the requirements of this regulation;
5. A vicinity map that shows the location of the facility and the area that is within one mile of the property boundary;
6. A site plan on a scale of not greater than 100 feet per inch that shall, at a minimum, identify the following:
 - a. The facility perimeter, the operational area, and all storage areas with measurements in feet;
 - b. Compliance with required buffers as outlined in ~~Part III.C of~~ this regulation;
 - c. Property lines, access roads, gates, fences, natural barriers, or other Department-approved means of preventing unauthorized access and dumping;
 - d. A topographical survey of the site depicting two-foot contours at a minimum, and six-inch contours for sites evaluated for consistency with the South Carolina Coastal Zone Management Plan;
 - e. A description of any Best Management Practices (BMPs) used for the management of storm water;
 - f. The location of, and distance to, any Waters of the U.S. State on site of the facility or within the buffer areas described in Part III.C;
7. An operational plan that shall contain all items as required under ~~Part III.E.15.~~ this regulation;
8. Any request for a variance as allowed by this regulation; and
9. A final closure cost estimate pursuant to ~~Part III.H.2 of this regulation, and documentation that the applicant has secured appropriate financial assurance.~~

B. Notice.

1. Within fifteen (15) days of submitting an application to the Department, ~~the~~ an applicant for a prospective Type Two and/or Type Three facility shall give notice that he/she has requested a permit to operate of the proposed activity. Notice shall be sent, via certified mail that a permit to operate has been applied for, to the county administrator, the county planning office, and all owners of real property as they appear on the county tax maps, as contiguous landowners of the proposed permit area, including properties that are across a road or any other right-of-way that may separate the parcels. This notice shall contain:

- a. The name and address of the applicant;
 - b. The type of facility and what it will produce, for example, mulch, compost;
 - c. A detailed description of the location of the facility, using road numbers, street names, and landmarks, as appropriate;
 - d. A description of the feedstocks the facility will utilize;
 - e. Department locations (Central Office and appropriate Regional Office) where a copy of the permit application will be available for review during normal working hours; and
 - f. The Department address and contact name for submittal of comments and inquiries.
2. The applicant shall provide evidence of noticing as required in ~~Part IV.B.1~~this regulation to the Department.
3. A comment period of not less than thirty (30) calendar days from the date of Noticing will be provided ~~prior to~~before issuance of a Department Decision.
4. Notice of the Department Decision regarding the permit application will be sent to the applicant, ~~to~~ affected persons or interested persons who have asked to be notified, ~~to~~ all persons who commented in writing to the Department, and ~~to~~ the facility's host county. The use of certified mail to send Notice of the Department's Decision shall be at the discretion of the Department unless specifically requested in writing by an interested person.

C. Application Review and Permit Decision.

~~1. All information submitted to the Department shall be complete and accurate.~~

~~21. Whenever the~~If an applicant submits an incomplete application, the Department shall notify the applicant in writing. If the requested information is not provided within one hundred eighty (180) calendar days of receipt of the notification, the application may be ~~denied~~considered withdrawn. The Department will notify the applicant in writing when an application is considered withdrawn.

~~32.~~ The Department shall deny a permit for a facility that it ~~has determined~~s does not meet the requirements of this regulation.

~~43.~~ The Department may ~~attach~~include additional conditions ~~to~~in a permit when the Department ~~has determined~~s that the operation requires safeguards to protect human health and safety or the environment.

D. Permit Modifications.

Permit modifications must be requested in writing and may not be implemented without prior written consent from the Department. The Department may require Noticing as described in ~~Part IV.B~~of this regulation for modifications that impact the allowable feedstock categories, that impact buffers, or that the Department determines may otherwise impact adjoining properties.

E. Transfer of Ownership.

1. The Department may, upon written request, transfer a permit, as appropriate, to a new permittee where no other change in the permit is necessary.

2. The proposed new owner of a permitted ~~or registered~~ facility shall, prior to the scheduled change in ownership, submit to the Department:

a. ~~A one hard copy and one electronic copy of a completed permit application in a format approved by the Department.~~ A completed and signed application form provided by the Department;

b. A written agreement signed by both parties indicating the intent to change ownership or operating responsibility of the facility;

c. A disclosure statement in accordance with S.C. Code Section 44-96-300, except that local government and regions comprised of local governments are exempt from this requirement; and

~~d. Documentation of financial assurance as required. The previous owner shall maintain financial assurance responsibilities until the new owner can demonstrate satisfactory compliance with Part III.H of this regulation.~~

3. The Department may approve transfer of the permit to the new owner provided:

a. The facility is in compliance with all permit requirements and with this regulation;

b. The new owner has agreed in writing to assume full responsibility in accordance with this regulation, the facility permit, and the approved operational plan; and

c. The new owner has funded an adequate financial assurance mechanism in accordance with the requirements of this regulation.

4. The previous owner shall maintain the existing financial assurance mechanism until the new owner can demonstrate financial responsibility in accordance with this regulation.

5. The new owner shall submit legal documentation of the transfer of ownership of the facility within fifteen (15) days of the actual transfer.

Part V. General Permits.

A. General Permit Issuance. The Department may issue one or more general permits for facilities described as Type One and Type Two facilities.

1. A general permit shall, at a minimum, outline the following:

a. Noticing requirements, including Intent to Operate and public Noticing;

b. Location, siting, and design criteria;

c. Operating, monitoring, and reporting criteria;

d. Financial assurance requirements; and

e. Closure requirements.

2. A general permit pursuant to this Section, may be issued, modified, or terminated in accordance with applicable requirements, terms, and conditions of this regulation.

3. The Department shall publish a notice of any general permit issued, modified, or terminated.

B. Application for Coverage under a General Permit.

1. An operator seeking coverage under a General Permit shall request approval from the Department with a completed Notice of Intent form provided by the Department.

2. A Notice of Intent shall include signatures of the permit applicant and of the landowner, a signed certification that operations will be conducted in accordance with the General Permit, and evidence that the applicant has secured a Financial Assurance mechanism in accordance with ~~Part III.H~~ the requirements of this regulation.

3. The applicant shall also provide a copy of the Notice of Intent to the appropriate local government.

4. A facility may begin operating under a General Permit after a written approval from the Department has been received by the facility operator. Written approval shall not be issued less than thirty (30) days of the date of submission of the Notice of Intent.

C. Corrective Measures and General Permit Revocation.

1. Upon a determination by the Department and written notification that the facility operating under a general permit poses an actual or potential threat to human health or the environment, the Department may require the permittee to implement corrective measures as appropriate.

2. Approval to operate under a General Permit may be revoked for failure to comply with the conditions of the General Permit or this regulation.

a. Whenever the Department finds that material or substantial violations demonstrate a disregard for, or inability to comply with a general permit, and that these violations would make continuation of the approval to operate under a general permit not in the best interest of human health and safety or the environment, the Department may, after a hearing, revoke the approval to operate as appropriate and necessary.

b. For the purposes of ~~Part V.C~~ this regulation, “hearing” means a conference between the Department and a permittee, during which the permittee is given opportunity to respond to a written notice of alleged violation, and may be accompanied by legal and/or technical counsel, at the conference.

c. If, after a hearing, the Department determines that approval to operate under authority of a general permit should be revoked, an administrative order revoking the approval will be issued.

~~Part VI. Prohibitions.~~

~~A. Open dumping of land clearing debris, yard trimmings and other organics is prohibited.~~

~~B. Open burning of land clearing debris, yard trimmings and other organics is prohibited except as approved by the Department for emergency storm debris management or as allowed by Air Pollution Control Regulations and Standards R.61-62.2, Prohibition of Open Burning.~~

61-107.4 Appendix: Feedstock Categories

A. Feedstock Categories.

This Appendix defines categories of common organic feedstocks for composting. The feedstock characteristics of Carbon-to-Nitrogen ratio, moisture, pathogen content, source variability, non-compostable contaminants, trace metals, and toxic metals content are considered when assessing appropriate facility design features and quality assurance monitoring necessary to produce beneficial products in an environmentally protective process. The Department will use these characteristics to assign the category and level of risk posed for any feedstock not listed here. Any mixture of feedstocks for composting shall assume the level of risk for the most problematic feedstock in the mixture.

1. Feedstock Category One.

Category One feedstocks have a high Carbon-to-Nitrogen ratio and pose limited risk of contamination from pathogens, trace metals, hazardous constituents, or physical contaminants that are not compostable. These feedstocks also have low moisture content. Grass clippings have a lower Carbon-to-Nitrogen ratio than other Category One feedstocks, but are included in this category because they are commonly collected with leaf and limb debris. This category includes only:

- a. Yard trimmings, leaves, and grass clippings;
- b. Land-clearing debris;
- c. Wood, ~~W~~woodchips, and sawdust from untreated and unpainted wood that has not been in direct contact with hazardous constituents;
- d. Agricultural crop field residuals;
- e. Compostable bags commonly used for collecting and transporting yard trimmings, leaves, and grass clippings; and
- f. Similar materials as specifically approved in writing by the Department.

2. Feedstock Category Two.

Category Two feedstocks have a lower Carbon-to-Nitrogen ratio than Category One feedstocks, have a high moisture content, and are more likely to contain pathogens, trace metals, or physical contaminants that are not compostable. This category includes only the following source-separated materials:

- a. Non-meat food processing wastes, including marine shells and dairy processing wastes;
- b. Produce and non-meat food preparation residuals generated by wholesale or retail sales establishments or food service establishments;
- c. Plate scrapings including cooked meats generated by food service establishments;
- d. Manufactured compostable products and waste paper products that are
- e. Animal manures and materials incidental to its collection as defined in ~~Part I.B~~ of this regulation;

f. Residual organics from anaerobic digesters or other waste-to-energy conversion processes utilizing only Category One or Category Two feedstocks; and

g. Industrial wastes/sludges that meet the waste characterization requirements found in R.61-107.19, Part IV, Section A for disposal into a Class II Landfill; and

gh. Similar materials as specifically approved in writing by the Department.

3. Feedstock Category Three.

This category includes feedstocks that have the most risk from trace metals, source variability, physical contaminants, pathogens, and other properties that may be detrimental to plants, soils, or living organisms in high concentrations. These feedstocks require more intensive analysis and monitoring prior to being incorporated into the active composting area and require approval for composting by the Department on a case-by-case basis. This category includes:

a. Sewage sludge;

b. Industrial sludges, except as specifically identified in Section A.2 of this Appendix;

c. Drinking water treatment sludge;

d. Fats, oils, and greases (FOG);

e. Animal-derived residuals except as specifically identified in Section A.2 of this Appendix;

f. Residual organics from anaerobic digesters or other waste-to-energy conversion processes utilizing Category Three feedstocks;

g. Other industrially produced non-hazardous organic residuals not previously categorized in this Appendix; and

h. Other organic materials not prohibited below, as approved by the Department.

B. Prohibited Feedstocks. Composting of materials containing the following items is not allowable under this regulation:

1. ~~Mixed-m~~ Municipal solid waste, except those activities under which after a two-year period of operation in compliance with a permit issued under authority of R.61-107.10, SWM: Research, Development, and Demonstration Permit Criteria, have been determined by the Department to have adequately achieved their objectives and satisfactorily protected public health, safety, and the environment;

2. Friable and non-friable asbestos as defined by R.61-86.1, Standards Of Performance For Asbestos Projects;

3. Biomedical or infectious wastes as defined by R.61-105, Infectious Waste Management;

4. Hazardous waste as defined by Resources Conservation and Recovery Act (RCRA), Public Law 94-580, and R.61-79, Hazardous Waste Management Regulations, promulgated pursuant to the South Carolina Hazardous Waste Management Act (SCHWMA), as amended, S.C. Code Ann. Sections 44-56-10 et seq.;

5. Materials for compost or mulch production ~~with~~that contain or are contaminated with Polychlorinated biphenyl (PCB) where concentrations are greater than quantifiable detection limits;

6. Source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended;

7. Radioactive material managed pursuant to R.61-63, Radiological Materials (Title A); and

8. Materials resulting from coal combustion, including but not limited to, fly ash, bottom ash, boiler slag, and flue gas desulfurization materials.

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL CHAPTER 61

Statutory Authority: 1976 Code Sections 44-96-10 et seq.

Notice of Drafting:

The South Carolina Department of Health and Environmental Control (“Department”) proposes amending R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals. Interested persons may submit comments in writing to Juli Blalock at S.C. Department of Health and Environmental Control, Bureau of Land and Waste Management, 2600 Bull Street, Columbia, SC 29201. To be considered, written comments must be received no later than 5:00 p.m. on June 22, 2020, the close of the drafting comment period.

Synopsis:

Pursuant to R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals, the Department oversees the recycling of food waste, yard trash, brush and other organic material to produce compost and wood mulch. The Department proposes amending R.61-107.4, to more effectively regulate composting facilities, and better protect human and environmental health. The proposed amendments will address issues including quality assurance and testing requirements, acceptance of unauthorized wastes, and permitting requirements. Proposed amendments may also include operating requirements, including material management, equipment maintenance, fire preparedness, and prevention of vectors, odors, dust, and litter. The Department also proposes amending the financial assurance requirements for permitted composting facilities to ensure the requirements are adequate for closure, post-closure, and corrective action activities, but do not create an undue burden for composters.

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 Ann., Section 1-23-120(A), requires General Assembly review of this proposed amendment.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals

As of June 22, 2020, the close of the Notice of Drafting comment period:

NAME	SECTION CITATION	PUBLIC COMMENT	DEPARTMENT RESPONSE
<p>Larry Simpson Owner–South Coast Resources, Inc.</p>	<p>None cited.</p>	<p>I hope more restrictive measures are not taken against the wood mulching yards. I would be willing to discuss anytime. I have been in biomass industry for over 30 years</p>	<p>Noted. Proposed revisions are deemed necessary for environmental protection and to ensure funding is available for proper closure of a facility.</p> <p>The Department is determined to it’s mission of protecting human and environmental health without imposing an undue burden on wood mulchers.</p> <p>Mr. Simpson was included in a stakeholder work group and provided a draft regulation for comment.</p>
<p>Lisa Wilson - G.L. Williams & Daughter Trucking, Inc</p>	<p>None cited.</p>	<p>I would like to receive more information on what changes you are proposing for both the compost and C&D recycling facilities. I also request information on who is the driving force behind more changes and regulations. Running a small business is challenging at times and even more with the increased regulations and financial burdens. I do not feel that now is the time for adding to the burdens of the small business.</p>	<p>Noted. Proposed revisions are deemed necessary for environmental protection and to ensure funding is available for closure of a facility.</p> <p>The Department is determined to it’s mission of protecting human and environmental health without imposing an undue burden on small businesses. The changes in these amendments include changes that will relieve some burdens, such as exceptions for small wood grinders and composting on leased properties, and less onerous financial assurance requirements.</p> <p>Staff contacted Ms. Wilson by phone. She was included in the work group meeting and provided a draft regulation for comment.</p>

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

October 8, 2020

(X) ACTION/DECISION
() INFORMATION

I. TITLE: Request for Placement of Crotonyl Fentanyl into Schedule I for Controlled Substances in South Carolina

II. SUBJECT: Placement of Crotonyl Fentanyl in Schedule I for Controlled Substances

II. FACTS:

Controlled substances are governed by the South Carolina Controlled Substances Act (“CSA”), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled “Manner in which changes in schedule of controlled substances shall be made,” controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, 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 Drug Enforcement Administration (“DEA”) issued a final order to place crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, in schedule I of the Controlled Substances Act (“federal CSA”). This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle crotonyl fentanyl. The federal order to schedule crotonyl fentanyl became effective October 2, 2020, *Federal Register*, Volume 85, Number 192, pages 62215-62218; <https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-19305.pdf>.

III. ANALYSIS:

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs (“Single Convention”), March 30, 1961, 18 U.S.T. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (“Commission”) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (“Secretary-General”), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the federal CSA, if control of a substance is required “by United States’ obligations under international treaties, conventions, or protocols, in effect on October 27, 1970,” the Attorney General must issue an order permanently controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b).

1) Background

The DEA issued a temporary scheduling order on February 6, 2018, placing fentanyl-related substances, as defined in the order, in schedule I of the CSA. The order was based on findings by the former Acting Administrator that the temporary scheduling of this class of substances was necessary to avoid an imminent hazard to the public safety. On April 19, 2019, in the *Federal Register*, the DEA provided the chemical name for crotonyl fentanyl, along with four other substances, identifying how these individual substances met the definition for fentanyl-related substances, and, as such, were already covered by the February 2018 temporary order. Regarding crotonyl fentanyl specifically, this substance was not otherwise controlled in any schedule and is structurally related to fentanyl by the replacement of the N-propionyl group by another acyl group. Congress extended the temporary control of fentanyl-related substances on February 6, 2020.

2) Scope and Significance of Abuse

Crotonyl fentanyl has a pharmacological profile similar to morphine, fentanyl, and other synthetic opioids that act as m-opioid receptor agonists. For this reason, crotonyl fentanyl is abused for its opioid-like effects. Law enforcement reports in the United States demonstrate the illicit use and distribution of this substance, which are similar to that of heroin and prescription opioid analgesics. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state, and local forensic laboratories across the country. According to NFLIS, there have been 143 reports containing crotonyl fentanyl since it was first reported in June 2017.

IV. RECOMMENDATION:

In order to meet the United States’ obligations under the Single Convention and because crotonyl fentanyl has no currently accepted medical use in treatment in the United States, the Acting Administrator has determined that crotonyl fentanyl, 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, should remain in schedule I of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers to 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:

() Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide)

Submitted by:



Lisa Thomson
Bureau Director
Bureau of Drug Control



Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:

Federal Register, Volume 85, Number 192, October 2, 2020

and in compliance with requirements of the Office of the Federal Register, the undersigned Department of Commerce Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Commerce. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 29, 2020.

Asha Mathew,

Federal Register Liaison Officer, U.S. Department of Commerce.

[FR Doc. 2020-21897 Filed 9-30-20; 1:00 pm]

BILLING CODE 3510-20-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-633]

Schedules of Controlled Substances: Placement of Crotonyl Fentanyl in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration maintains the placement of crotonyl fentanyl ((*E*)-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbut-2-enamide), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle crotonyl fentanyl.

DATES: Effective October 2, 2020.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs ("Single

Convention"), March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151, as amended. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs ("Commission") adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations ("Secretary-General"), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required "by United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970," the Attorney General must issue an order permanently controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

On February 6, 2018, DEA issued a temporary scheduling order, placing fentanyl-related substances, as defined in the order, in schedule I of the CSA. 83 FR 5188. That order was based on findings by the former Acting Administrator that the temporary scheduling of this class of substances was necessary to avoid an imminent hazard to the public safety; the order was codified at 21 CFR 1308.11(h)(30). On April 19, 2019, in the **Federal Register**, DEA provided the chemical name for crotonyl fentanyl, along with four other substances, identifying how these individual substances met the definition for fentanyl-related substances,¹ and, as such, were already covered by the February 2018 temporary order. 84 FR 16397. Regarding crotonyl fentanyl specifically, this substance was not otherwise controlled in any schedule (*i.e.*, listed under another Administration Substance Controlled Number) and is structurally related to fentanyl by the replacement of the *N*-propionyl group by another acyl group (*i.e.*, meets definition for modification

E). On February 6, 2020, Congress extended the temporary control of fentanyl-related substances, as set forth in 21 CFR 1308.11(h)(30), until May 6, 2021. Public Law 116-114, sec. 2, 134 Stat. 103 (2020).

In November 2019, the Director-General of the World Health Organization recommended to the Secretary-General that crotonyl fentanyl and valeryl fentanyl be placed in Schedule I of the Single Convention, as these two substances have opioid mechanisms of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.*, crotonyl fentanyl is similar to drugs such as oxycodone and fentanyl; valeryl fentanyl is similar to drugs such as fentanyl), and have dependence and abuse potential. On May 7, 2020, the Secretary-General advised the Secretary of State of the United States, by letter, that during its 63rd session in March 2020, the Commission voted to place crotonyl fentanyl and valeryl fentanyl in Schedule I of the Single Convention (CND Mar/63/2 and Mar/63/3). Valeryl fentanyl is temporarily controlled in schedule I of the CSA until February 1, 2021 (85 FR 5321, Jan. 30, 2020), and it will not be discussed in this final order.²

Crotonyl Fentanyl

As discussed in the background section, crotonyl fentanyl is temporarily controlled in schedule I of the CSA, as it meets the definition of fentanyl-related substances, pursuant to 21 CFR 1308.11(h)(30). Accordingly, crotonyl fentanyl is scheduled as part of a class of substances.

Crotonyl fentanyl has a pharmacological profile similar to morphine, fentanyl, and other synthetic opioids that act as μ -opioid receptor agonists. For this reason, crotonyl fentanyl is abused for its opioid-like effects.

Law enforcement reports in the United States demonstrate the illicit use and distribution of this substance, which are similar to that of heroin and prescription opioid analgesics. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state, and local forensic laboratories across the country. According to

¹ These four other substances (2'-fluoro *ortho*-fluorofentanyl, *ortho*-methyl acetylfentanyl, beta'-phenyl fentanyl, and thiofuranyl fentanyl) will not be discussed further in this final order.

² DEA issued a notice of proposed rulemaking to permanently control valeryl fentanyl in schedule I (85 FR 5356, Jan. 30, 2020) and is currently working to finalize that rule.

NFLIS,³ there have been 143 reports containing crotonyl fentanyl since it was first reported in June 2017.

DEA is not aware of any claims or any medical or scientific literature suggesting that crotonyl fentanyl has a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services (HHS) advised DEA, by letter dated November 29, 2017, that there were no investigational new drug applications or approved new drug applications for fentanyl-related substances, a class that, as noted, includes crotonyl fentanyl.

DEA requested that HHS conduct a scientific and medical evaluation and a scheduling recommendation for several fentanyl-related substances, including crotonyl fentanyl, by letter dated April 3, 2019. In response to this request, HHS provided DEA a recommendation, dated July 2, 2020, to place crotonyl fentanyl in schedule I of the CSA. The recommendation from HHS is consistent with the placement of crotonyl fentanyl in Schedule I of the Single Convention in March 2020.

Normally, 21 U.S.C. 811(b) would require DEA to secure such an HHS recommendation as part of the regular scheduling process. As discussed above, however, DEA has authority under 21 U.S.C. 811(d)(1) to control substances that have been added to the Single Convention without making any findings otherwise required by 21 U.S.C. 811(a) or 812(b), and without following the procedures prescribed by 21 U.S.C. 811(a) and (b)—including 811(b)'s requirement that DEA secure an evaluation and recommendation from HHS. Thus, HHS's recommendation supports scheduling crotonyl fentanyl, but its scheduling does not depend on that recommendation.

Therefore, consistent with 21 U.S.C. 811(d)(1), DEA concludes that crotonyl fentanyl has no currently accepted medical use in treatment in the United States⁴ and is most appropriately

³NFLIS was queried on April 14, 2020. Data are still being collected for November 2019 to April 2020 due to the normal lag period for labs reporting to NFLIS.

⁴Although, as discussed above, there is no evidence suggesting that crotonyl fentanyl has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the Food and Drug Administration, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by

placed in schedule I of the CSA, the same schedule in which it currently resides. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to schedule crotonyl fentanyl pursuant to 21 U.S.C. 811(a).

This action establishes a specific listing for crotonyl fentanyl in schedule I of the CSA within 21 CFR 1308.11(b) (the opiates category of schedule I), and assigns an Administration Controlled Substances Number for the substance: As discussed above, crotonyl fentanyl was not previously listed in schedule I individually, but was instead temporarily controlled as part of the class of fentanyl-related substances controlled under 21 CFR 1308.11(h)(30). This action will allow DEA to establish an aggregate production quota for crotonyl fentanyl and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of crotonyl fentanyl who had previously been granted individual quotas for such purposes under the drug code for fentanyl-related substances.

Conclusion

In order to meet the United States' obligations under the Single Convention and because crotonyl fentanyl has no currently accepted medical use in treatment in the United States, the Acting Administrator has determined that crotonyl fentanyl, 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, should remain in schedule I of the CSA.

Requirements for Handling

Crotonyl fentanyl has been controlled as a schedule I controlled substance since February 6, 2018. With publication of the final order contained in this document, crotonyl fentanyl remains subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture of, distribution of, importation of, exportation of, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, crotonyl fentanyl must be registered with DEA to conduct such activities

qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (March 26, 1992).

pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Crotonyl fentanyl must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Crotonyl fentanyl 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 through 1301.93. Non-practitioners handling crotonyl fentanyl must also comply with the employee screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of crotonyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and must be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture crotonyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of crotonyl fentanyl has been required to keep an inventory of all stocks of this substance on hand as of February 6, 2018, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to crotonyl fentanyl pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Order Forms.* All DEA registrants who distribute crotonyl fentanyl must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of crotonyl fentanyl must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving crotonyl fentanyl not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This order is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. The action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties,

conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order (as compared to scheduling by rule pursuant to 21 U.S.C. 811(a)). Therefore, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute "rule making" under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 5 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States because it is being done pursuant to 21 U.S.C. 811(d)(1), which requires that the United States comply with its obligations under the specified international agreements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. An agency

may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This action is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This order will not result in: "an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets." However, pursuant to the CRA, DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

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:
 - a. Redesignate paragraphs (b)(22) through (70) as (b)(23) through (71); and
 - b. Add new paragraph (b)(22).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(22) Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide)

* * * * *

Timothy J. Shea,
Acting Administrator.
 [FR Doc. 2020–19305 Filed 10–1–20; 8:45 am]
BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 1042

[EPA–HQ–OAR–2018–0638; FRL–10013–36–OAR]

RIN 2060–AU30

Amendments Related to Marine Diesel Engine Emission Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the national marine diesel engine program with relief provisions to address concerns associated with finding and installing certified Tier 4 marine diesel engines in certain high-speed commercial vessels. This relief is in the form of additional

lead time for qualifying engines and vessels.

DATES: This final rule is effective on November 2, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0638. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at Air and Radiation Docket and Information Center, EPA Docket Center, EPA/DC, EPA WJC West Building, 1301 Constitution Ave. NW, Room 3334, Washington, DC. Note that the EPA Docket Center and Reading Room were closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID–19. The Docket Center staff will continue to provide remote customer

service via email, phone, and webform. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. For further information on EPA Docket Center services and the current status, go to <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Alan Stout, Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4805; email address: stout.alan@epa.gov.

SUPPLEMENTARY INFORMATION:

Does this action apply to me?

This action relates to marine diesel engines with rated power between 600 and 1,400 kW intended for installation on vessels flagged or registered in the United States, vessels that use those engines, and companies that manufacture, repair, or rebuild those engines and vessels.

Categories and business entities that might be affected by this rule include the following:

Category	NAICS code ^a	Examples of potentially affected entities
Industry	333618	Marine engine manufacturing.
Industry	336611	Shipbuilding and repairing.

^aNorth American Industry Classification System (NAICS).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely covered by these rules. This table lists the types of entities that we are aware may be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your activities are regulated by this action, you should carefully examine the applicability criteria in the referenced regulations. You may direct questions regarding the applicability of this action to the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

I. Summary

EPA’s 2008 Final Rule for Control of Emissions of Air Pollution from Locomotive Engines and Marine Compression-Ignition Engines Less than 30 Liters per Cylinder adopted Tier 4 emission standards for commercial marine diesel engines at or above 600 kilowatts (kW) (73 FR 37096, June 30, 2008). These standards, which were expected to require the use of exhaust aftertreatment technology, phased in

from 2014 to 2017, depending on engine power.¹ After the Tier 4 standards were fully in effect for all engine sizes, some boat builders informed EPA that there were no certified Tier 4 engines available with suitable performance characteristics for the vessels they needed to build, specifically for high-speed commercial vessels that rely on engines with rated power between 600 and 1,400 kW that have high power density.

To address these concerns, EPA proposed, and through this rule is adopting, provisions to provide additional lead time for implementing the Tier 4 standards for engines used in certain high-speed vessels (84 FR 46909, September 6, 2019). We are also finalizing the proposed approaches for streamlining certification requirements to facilitate or accelerate certification of Tier 4 marine engines with high power density. These changes are reflected in amendments to 40 CFR. 1042.145,

¹For engines up to 1,000 kW, compliance could be delayed for up to nine months, but no later than October 1, 2017.

1042.505, and 1042.901 that we are making in this final rule. Each of these elements is discussed in more detail in this final rule.

The September 2019 proposed rule also included provisions related to in-use fuel sulfur standards that apply for global marine fuel. We adopted those regulatory amendments to 40 CFR part 80 in a separate rule (84 FR 69335, December 18, 2019).

The regulatory changes EPA is adopting in this final rule are largely the same as we proposed, with a few adjustments to address concerns raised by commenters. Several commenters also suggested that we broaden the scope of the rule to provide additional relief—either for a longer period or for a wider range of vessels. We are considering further rulemaking action to address these concerns, as described in Section VII.

EPA adopted emission standards for marine diesel engines under Clean Air Act authority (42 U.S.C. 7401–7671q). The amendments in this rule are covered by that same authority.

SUMMARY SHEET

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

October 8, 2020

ACTION/DECISION

INFORMATION

I. TITLE: Request for Placement of Remimazolam into Schedule IV for Controlled Substances in South Carolina

II. SUBJECT: Placement of Remimazolam in Schedule IV 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 United States Food and Drug Administration (“FDA”) approved a new drug application for BYFAVO (remimazolam) for intravenous use on July 2, 2020. Remimazolam is chemically known as 4H-imidazol[1,2-a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4S)-methyl ester, benzenesulfonate (1:1) and also, methyl 3-[(4S)-8-bromo-1-methyl-6-pyridin-2-yl-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid. The Department of Health and Human Services (“HHS”) provided the Drug Enforcement Administration (“DEA”) with a scheduling recommendation to place remimazolam and its salts in schedule IV of the Controlled Substances Act (“federal CSA”). In accordance with the federal CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA is hereby issuing an interim final rule placing remimazolam, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA, effective October 6, 2020. *Federal Register*, Volume 85, Number 194, pages 63014-63019; <https://www.govinfo.gov/content/pkg/FR-2020-10-06/pdf/2020-19313.pdf>.

IV. ANALYSIS:

Remimazolam (4H-imidazol[1,2- a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4S)- methyl ester, benzenesulfonate (1:1) or methyl 3-[(4S)-8-bromo-1-methyl-6-pyridin-2-yl-4H-imidazo[1,2- a][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid), is a new molecular entity with Central Nervous System (“CNS”) depressant properties.

Remimazolam is an agonist at gamma-aminobutyric acid subtype A (“GABA”) receptors. On April 5, 2019, Cosmo Technologies, Ltd. (“Sponsor”) submitted a new drug application (“NDA”) for BYFAVO (remimazolam) to the FDA with a proposed dose of 5.0 mg intravenous (“i.v.”) with supplemental doses of 2.6 mg i.v.. The DEA received notification on July 2, 2020 that FDA, on the same date, approved the NDA for BYFAVO (remimazolam), under section 505(c) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), to be used as an i.v. treatment for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. In January 2020, remimazolam was approved for marketing in Japan for general anesthesia.

On July 10, 2020, DEA received from HHS a scientific and medical evaluation, dated April 15, 2020, entitled “Basis for the Recommendation to Control Remimazolam and its Salts in Schedule IV of the Controlled Substances Act” and a scheduling recommendation. This document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of remimazolam, along with a recommendation from HHS to control remimazolam and its salts under schedule IV of the CSA. DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that remimazolam meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

1) Remimazolam Has a Low Potential for Abuse Relative to the Drugs or Other Substances in Schedule III.

Remimazolam, similar to that of the schedule IV drug midazolam, is an agonist at GABA receptors. Remimazolam produced depressant effects in general behavior assessments, and generalized to midazolam (schedule IV), in a drug discrimination study in animals, demonstrating it has GABA receptor agonist properties. In a human abuse potential study, remimazolam at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking, Overall Drug Liking, Good Drug Effects, and Take Drug Again similar to those of midazolam (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that remimazolam produced abuse-related adverse events, namely euphoria and somnolence. Because remimazolam is similar to midazolam (schedule IV) in its abuse potential, remimazolam has a lower potential for abuse relative to the drugs or other substances in schedule III.

2) Remimazolam Has a Currently Accepted Medical Use in the United States.

FDA recently approved the NDA for BYFAVO (remimazolam) injection for use in the induction and maintenance of procedural sedation in adults undergoing procedures lasting thirty (30) minutes or less. Thus, remimazolam has a currently accepted medical use for treatment in the United States.

3) Remimazolam May Lead to Limited Physical Dependence or Psychological Dependence Relative to the Drugs or Other Substances in Schedule III.

Remimazolam shares a similar pharmacology profile with benzodiazepine drugs. Abrupt discontinuation of benzodiazepines is associated with withdrawal symptoms. Remimazolam produced withdrawal symptoms after abrupt discontinuation in monkeys, indicative of physical dependence, similar to that of benzodiazepines. In addition, remimazolam produced positive subjective responses and euphoria-related adverse events in a human abuse potential study. It is likely that remimazolam can produce psychic dependence similar to midazolam. Thus, abuse of remimazolam may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III of the CSA.

IV. RECOMMENDATION:

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of remimazolam to Schedule IV for controlled substances in South Carolina and the amendment of Section 44-53-250(a) of the South Carolina Code of Laws to include:

() Remimazolam (4H-imidazol[1,2- a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4S)- methyl ester, benzenesulfonate (1:1) or methyl 3-[(4S)-8-bromo-1-methyl-6- pyridin-2-yl-4H-imidazo[1,2- a][1,4]benzodiazepin-4yl]propanoate benzenesulfonic acid).

Submitted by:



Lisa Thomson
Director, Bureau of Drug Control



Gwen Thompson
Director for Healthcare Quality

Attachment:

Federal Register, Volume 85, No. 194, October 6, 2020

a main polymer, currently manufactured on an industrial scale for textile and other purposes, together with the distinguishing attributes that characterize them.

This ISO standard is reasonably available to interested parties. Members of the public can obtain copies of ISO 2076:2013(E) from the International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401-1214 Vernier, Geneva, Switzerland; (+41 22 749 01 11); central@iso.org; <https://www.iso.org/home.html>. They can also obtain copies from the American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036-7417; (212) 642-4900; isot@ansi.org; <https://www.ansi.org>. This ISO standard is also available for inspection at the FTC Library, (202) 326-2395, Federal Trade Commission, Room H-630, 600 Pennsylvania Avenue NW, Washington, DC 20580.

List of Subjects in 16 CFR Part 303

Advertising, Incorporation by reference, Labeling, Recordkeeping, Textile fiber products.

For the reasons discussed in the preamble, the Commission amends part 303 of title 16, Code of Federal Regulations, as follows:

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

■ 1. The authority citation for part 303 continues to read as follows:

Authority: 15 U.S.C. 70 *et seq.*

■ 2. Amend § 303.7:

■ a. By revising the introductory text; and

■ b. In paragraph (v), by removing the words “16 CFR 303.7(c)” and adding, their place, the words “paragraph (c) of this section”.

The revision reads as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

Pursuant to the provisions of section 7(c) of the Act, the Commission hereby establishes the generic names for manufactured fibers, together with their respective definitions, set forth in this section, and the generic names for manufactured fibers, together with their respective definitions, set forth in International Organization for Standardization (ISO) 2076:2013(E). ISO 2076:2013(E), “Textiles—Man-made fibres—Generic names,” Sixth edition, November 15, 2013, is incorporated by reference into this section with the approval of the Director of the Federal

Register under 5 U.S.C. 552(a) and 1 CFR part 51.

To enforce any edition other than that specified in this section, the Federal Trade Commission must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the Federal Trade Commission, 600 Pennsylvania Avenue NW, Room H-630, Washington, DC 20580, (202) 326-2222, and is available from: (a) The International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401-1214 Vernier, Geneva, Switzerland; (+41 22 749 01 11); central@iso.org; <https://www.iso.org/home.html>; and (b) the American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036-7417; (212) 642-4900; isot@ansi.org; <https://www.ansi.org>. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

* * * * *

By direction of the Commission, Commissioner Slaughter not participating.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020-19515 Filed 10-5-20; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-658]

Schedules of Controlled Substances: Placement of Remimazolam in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Interim final rule with request for comments.

SUMMARY: On July 2, 2020, the U.S. Food and Drug Administration approved a new drug application for BYFAVO (remimazolam) for intravenous use. Remimazolam is chemically known as 4*H*-imidazo[1,2-*a*][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4*S*)-methyl ester, benzenesulfonate (1:1) and also, methyl 3-[(4*S*)-8-bromo-1-methyl-6-pyridin-2-yl-4*H*-imidazo[1,2-*a*][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid.

The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place remimazolam and its salts in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing remimazolam, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA.

DATES: The effective date of this rulemaking is October 6, 2020. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before November 5, 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.

Interested persons may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before November 5, 2020.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-658” on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) 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 [Regulations.gov](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, 8701 Morrisette Drive, Springfield, VA 22152.

• *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

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

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 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 supplemental information, including the complete Department of Health and Human Services (HHS) and DEA eight-factor analyses, to this interim final rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551-559. 21 CFR 1308.41-1308.45; 21 CFR part 1316, subpart D. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the person's interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

Background and Legal Authority

Under the CSA, as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114-89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of HHS has advised DEA that a New Drug

Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an interim final rule controlling the drug within 90 days.

Subsection (j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS' scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection (j)(3) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause therefore. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.¹

Subsection (j)(3) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b).

Remimazolam (4*H*-imidazol[1,2-*a*][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4*S*)-methyl ester, benzenesulfonate (1:1) or methyl 3-[(4*S*)-8-bromo-1-methyl-6-pyridin-2-yl-4*H*-imidazo[1,2-*a*][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid), is a new molecular entity with CNS depressant properties. Remimazolam is an agonist at gamma-aminobutyric acid subtype A (GABA_A) receptors. On April 5, 2019, Cosmo Technologies, Ltd. (Sponsor) submitted an NDA for BYFAVO (remimazolam) to FDA with a proposed dose of 5.0 mg (intravenous; i.v.) with supplemental doses of 2.6 mg (i.v.). On July 2, 2020, DEA received notification that FDA, on the same date, approved the NDA for BYFAVO (remimazolam), under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), to be used as an i.v. treatment for the induction and maintenance of

¹ Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

procedural sedation in adults undergoing procedures lasting 30 minutes or less. In January 2020, remimazolam was approved for marketing in Japan for general anesthesia.²

Determination To Schedule Remimazolam

On July 10, 2020, DEA received from HHS a scientific and medical evaluation (dated April 15, 2020) entitled “Basis for the Recommendation to Control Remimazolam and its Salts in Schedule IV of the Controlled Substances Act” and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of remimazolam, along with HHS’s recommendation to control remimazolam and its salts under schedule IV of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that remimazolam meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on HHS’ recommendation, NDA approval by HHS/FDA, and DEA’s determination, DEA is issuing this interim final rule to schedule remimazolam as a schedule IV controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both DEA and HHS analyses are available in their entirety under “Supporting Documents” in the public docket for this interim final rule at <http://www.regulations.gov>, under Docket Number “DEA-658.” Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. Its Actual or Relative Potential for Abuse

Remimazolam is a new molecular entity that has not been marketed in the United States, and was approved in Japan for general anesthesia in January 2020. Evidence regarding its diversion, illicit manufacturing, or deliberate ingestions is lacking. DEA notes that there are no reports for remimazolam in the National Forensic Laboratory

Information System (NFLIS),³ which collects drug cases submitted to and analyzed by state and local forensic laboratories. There were also no reports in STARLiMS,⁴ DEA’s laboratory drug evidence data system of record.

As stated by HHS, remimazolam is so related in action to depressant drugs such as benzodiazepines in schedule IV that it is reasonable to assume that there may be comparable diversions from legitimate channels, use contrary to or without medical advice, and capability of creating hazards to the users and to the safety of the community. Preclinical and clinical studies show that remimazolam has similar pharmacological mechanism of action as an agonist at the GABA_A receptors as midazolam. Data gathered from general behavior studies indicate remimazolam produces a sedative effect, and similar abuse-related effects in humans and in animal studies to those of midazolam, a schedule IV depressant. It is likely that remimazolam has similar abuse potential and is likely to be abused for its depressant effects, contrary to medical advice.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Remimazolam shares similar pharmacological mechanism of action via GABA_A receptor agonism as schedule IV benzodiazepines, such as midazolam. The GABA_A receptor is a ligand-gated chloride ion channel consisting of five subunits and a central chloride channel. Benzodiazepines enhance the opening of the ligand-gated chloride channel and the influx of chloride.

Remimazolam, similar to schedule IV benzodiazepines, has sedative activity in animals. Acute administration of remimazolam in rats elicited dose-dependent behaviors indicative of sedative and muscle relaxation properties of the drug. In a drug

³ NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1.0 million distinct annual State and local drug analysis cases. 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 were queried April 23, 2020.

⁴ On October 1, 2014, DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposted in STARLiMS. STARLiMS data were queried May 5, 2020.

discrimination study using male rats previously trained to discriminate midazolam, remimazolam produced interoceptive cues that are similar to those of midazolam. Remimazolam was self-administered variably based on session duration. In the shorter-access paradigm (two-hour sessions), only two of four monkeys tested self-administered remimazolam, whereas for the longer-access paradigm (24-hour sessions), all four monkeys self-administered remimazolam at a rate higher than placebo and pentobarbital, the reference drug (a schedule II or III depressant).⁵

In human abuse potential studies, remimazolam, in agreement with its mechanism of action as a GABA_A receptor agonist, produced subjective responses and abuse-related neuropharmacology profile similar to that of midazolam, a schedule IV depressant.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Remimazolam is a new molecular entity. It is chemically known as 4*H*-imidazol[1,2-*a*][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4*S*)-methyl ester, benzenesulfonate (1:1) and also as methyl 3-[(4*S*)-8-bromo-1-methyl-6-pyridin-2-yl-4*H*-imidazo[1,2-*a*][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid. It is a white to off-white powder that is freely soluble in water. In preclinical studies, remimazolam, an ester based drug, is rapidly hydrolyzed by tissue esterases, primarily in the liver by carboxylesterase-1, and results in one inactive metabolite. In humans, acute administration of the proposed therapeutic dose (5 mg, i.v.) of remimazolam resulted in rapid onset sedative effects (one to three minutes), fast time to maximal plasma concentration (T_{max} , nine minutes), and a short half-life (twenty minutes).

4. Its History and Current Pattern of Abuse

There is no information on the history and current pattern of abuse for

⁵ The HHS review of remimazolam incorrectly stated that pentobarbital was a schedule IV substance. FDA/Controlled Substance Staff through an email correspondence confirmed that it was an inadvertent error in the HHS review. Pentobarbital is currently controlled as schedule II (21 CFR 1308.12(e)), or as schedule III if any material, compound, mixture, or preparation containing any quantity of pentobarbital having a depressant effect on the central nervous system (21 CFR 1308.13(c)(1)), or any suppository dosage form and its salts that are approved by FDA for marketing only as a suppository (21 CFR 1308.13(c)(2)).

² Keam SJ (2020). Remimazolam: First Approval. *Drugs*; 80(6):625–633.

remimazolam, since it has not been marketed, legally or illegally, in the United States, and only recently in Japan. HHS notes that the abuse potential of remimazolam is similar to that of schedule IV benzodiazepines. Therefore, if remimazolam were available for marketing, it is likely to be abused in a manner similar to schedule IV benzodiazepines, such as midazolam.

DEA conducted a search of NFLIS and STARLiMS databases for remimazolam encounters. No records of encounters by law enforcement were identified in these databases, which is consistent with the fact that remimazolam is a new molecular entity.

The pharmacological mechanism of action of remimazolam through GABA_A receptor agonism suggests that its pattern of abuse would be similar to schedule IV depressants with a similar mechanism of action, such as midazolam.

5. The Scope, Duration, and Significance of Abuse

Remimazolam is not marketed in the United States, legally or illegally, and marketed only recently in Japan. However, because of remimazolam's pharmacological similarities to schedule IV benzodiazepines, remimazolam, similar to these schedule IV substances, is likely to be abused when available in the market.

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

According to HHS, the public health risk associated with remimazolam is due to its abuse potential and is largely borne by the individual. Data from preclinical and clinical studies showed that remimazolam has abuse potential similar to that of the schedule IV depressant midazolam. In clinical studies when remimazolam was given to healthy individuals, adverse events such as euphoric mood and somnolence occurred; thus, remimazolam produced rewarding and depressant effects, as would be expected from a benzodiazepine. Therefore, upon availability for marketing, it is likely to pose a public health risk to a degree similar to schedule IV benzodiazepines, such as midazolam.

7. Its Psychic or Physiological Dependence Liability

As described in the HHS review, the Sponsor conducted a study related to physical dependence liability produced by remimazolam in six cynomolgus monkeys (0.5, 0.75, and 1.0 mg/kg/h, continuous i.v. infusion for 28 days) and psychic dependence liability in 39 humans (doses tested 5 and 10 mg, i.v.).

During extended daily dosing administrations lasting a period of 28 days, all monkeys showed depressant signs, such as ataxia, slowed motion, and hyporeactivity. During the discontinuation phase, all monkeys showed withdrawal signs including: Facial apprehension, hyperirritability, piloerection, muscle rigidity, retching and vomiting, tremors, restlessness, and impaired motor activity. Decreases in food consumption and body weights were also observed. Severe withdrawal symptoms such as dissociation from the environment, systemic convulsions, and continuously prone position for 25 hours were observed in one monkey, and remimazolam administration lessened this withdrawal syndrome in this monkey. HHS concluded that remimazolam produces physical dependence, as evidenced by the withdrawal syndrome observed after its chronic administration was discontinued.

Remimazolam produced positive subjective responses to ratings of Drug Liking, Overall Drug Liking, Good Drug Effects, and Take Drug Again in a human abuse potential study. The responses were significantly higher than the placebo and similar to midazolam, a schedule IV depressant. HHS concluded that remimazolam can produce psychic dependence to a similar extent as midazolam.

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA

Remimazolam is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's recommendation, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of remimazolam. As such, DEA hereby schedules remimazolam as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

1. Remimazolam Has a Low Potential for Abuse Relative to the Drugs or Other Substances in Schedule III.

Remimazolam, similar to that of the schedule IV drug midazolam, is an agonist at GABA_A receptors. Remimazolam produced depressant effects in general behavior assessments, and generalized to midazolam (schedule IV) in a drug discrimination study in animals, demonstrating it has GABA_A receptor agonist properties. In a human abuse potential study, remimazolam at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking, Overall Drug Liking, Good Drug Effects, and Take Drug Again similar to those of midazolam (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that remimazolam produced abuse-related adverse events, namely euphoria and somnolence. Because remimazolam is similar to midazolam (schedule IV) in its abuse potential, remimazolam has a lower potential for abuse relative to the drugs or other substances in schedule III.

2. Remimazolam Has a Currently Accepted Medical Use in the United States.

FDA recently approved the NDA for BYFAVO (remimazolam) injection for use in the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. Thus, remimazolam has a currently accepted medical use for treatment in the United States.

3. Remimazolam May Lead To Limited Physical Dependence or Psychological Dependence Relative to the Drugs or Other Substances in Schedule III.

Remimazolam shares a similar pharmacology profile with benzodiazepine drugs. Abrupt discontinuation of benzodiazepines is associated with withdrawal symptoms. Remimazolam produced withdrawal symptoms after abrupt discontinuation in monkeys, indicative of physical dependence, similar to that of benzodiazepines. In addition, remimazolam produced positive subjective responses and euphoria-related adverse events in a human abuse potential study. It is likely that remimazolam can produce psychic dependence similar to midazolam. Thus, abuse of remimazolam may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III of the CSA.

Based on these findings, the Acting Administrator of DEA concludes that remimazolam warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Remimazolam

Remimazolam is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including the following:

1. *Registration.* Any person who intends to handle (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) remimazolam, or who desires to handle remimazolam, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles or intends to handle remimazolam and is not registered with DEA must submit an application for registration and may not continue to handle remimazolam 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.

2. *Disposal of stocks.* Any person who does not desire or is not able to maintain a schedule IV registration must surrender all quantities of currently held remimazolam or may transfer all quantities of remimazolam to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Remimazolam is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling remimazolam 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 remimazolam must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of remimazolam must take an inventory of remimazolam on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance

with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with DEA to handle remimazolam must take an initial inventory of all stocks of controlled substances (including remimazolam) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including remimazolam) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for remimazolam, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for remimazolam, or products containing remimazolam, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of remimazolam may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the FDCA and CSA.

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

10. *Liability.* Any activity involving remimazolam not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in

CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) the date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause.

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

This interim final rule is not an E.O. 13771 regulatory action pursuant to E.O. 12866 and OMB guidance.⁶

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have

⁶ Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled “Reducing Regulation and Controlling Regulatory Costs” (Feb. 2, 2017).

substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

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 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.14:

■ a. Redesignate paragraphs (c)(51) through (c)(57) as (c)(52) through (c)(58); and

■ b. Add new paragraph (c)(51).

The addition reads as follows:

§ 1308.14 Schedule IV.

* * * * *
(c) * * *

(51) Remimazolam	2846
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Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–19313 Filed 10–5–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 9924]

RIN 1545–B032

Income Tax Withholding From Wages

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document sets forth final regulations that provide guidance for employers concerning income tax withholding from employees’ wages. These final regulations concern the amount of Federal income tax employers withhold from employees’ wages, implement changes in the Internal Revenue Code made by the Tax Cuts and Jobs Act, and reflect the redesigned withholding allowance certificate (Form W–4) and related IRS publications. These final regulations affect employers that pay wages subject to Federal income tax withholding and employees who receive wages subject to Federal income tax withholding.

DATES:

Effective date: These final regulations are effective on October 6, 2020.

Applicability dates: For dates of applicability see §§ 31.3402(a)–1(h), 31.3402(b)–1(b), 31.3402(c)–1(f), 31.3402(f)(1)–1(c), 31.3402(f)(2)–1(h), 31.3402(f)(3)–1(d), 31.3402(f)(4)–1(e), 31.3402(f)(5)–1(d), 31.3402(f)(6)–1(c), 31.3402(g)–1(d), 31.3402(h)(4)–1(c), 31.3402(i)–1(b), 31.3402(l)–1(e), 31.3402(m)–1(f), and 31.3402(n)–1(f).

FOR FURTHER INFORMATION CONTACT:

Concerning these final regulations, Mikhail Zhidkov of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), (202) 317–4774 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 3402(a)(1) provides that, except as otherwise provided in section 3402, every employer making a payment of wages shall deduct and withhold from such wages a tax determined in accordance with tables or computational procedures prescribed by the Secretary of the Treasury. Section 3402(a)(1) further provides that any tables or procedures prescribed under section 3402(a)(1) shall be in such form, and provide for such amounts to be deducted and withheld, as the Secretary determines to be most appropriate to carry out the purposes of chapter 1 (imposition of individual income tax). Section 3402 sets forth certain methods of withholding but also gives the Secretary broad regulatory authority in providing for tables or computational procedures for income tax withholding.

Generally, employers apply the withholding tables or computational procedures based on the entries on the Form W–4 the employee furnishes the employer. An employee who receives wages subject to withholding under section 3402 is required to furnish his or her employer a Form W–4 on commencement of employment or, generally, within 10 days after the employee experiences a “change of status” that reduces the “withholding allowance” to which the employee is entitled. See section 3402(f)(2).

An employee completes Form W–4 based on the employee’s personal tax situation by applying the factors listed in section 3402(f)(1). Section 3402(f)(1) describes the combination of these factors as the employee’s “withholding allowance.” Once an employee completes a valid Form W–4, the employee must furnish the Form W–4 to the employer. The employer puts the Form W–4 into effect in accordance with the timing rules in section