

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

January 7, 2021

- () ACTION/DECISION
(X) INFORMATION

I. TITLE: Healthcare Quality Administrative and Consent Orders.

II. SUBJECT: Healthcare Quality Administrative Orders and Consent Orders for the period of November 1, 2020 through November 30, 2020.

III. FACTS: For the period of November 1, 2020 through November 30, 2020, Healthcare Quality reports three (3) Consent Orders totaling \$3,400 in assessed monetary penalties and one hundred and twenty (120) Notices of Violation and Civil Penalty totaling \$34,000 in assessed monetary penalties. No Administrative Orders were executed during the reporting period.

Name of Bureau	Facility, Service, Provider, or Equipment Type	Notices of Violation and Civil Penalty	Administrative Orders	Consent Orders	Assessed Penalties
Bureau of Facilities Oversight	Community Residential Care Facility	103	0	0	\$28,550
	Nursing Home	17	0	0	\$5,450
Bureau of EMS and Healthcare Professionals	Paramedic	0	0	1	\$0
Bureau of Radiological Health	Dental X-Ray Facility	0	0	2	\$3,400
TOTAL		120	0	3	\$37,400

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Director of Healthcare Quality

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

January 7, 2021

Bureau of Facilities Oversight

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

Violations: The Department found that the one hundred and three (103) community residential care facilities (CRCFs) and seventeen (17) nursing homes listed below failed to submit a weekly visitation report to the Department by the mandatory deadline. Failure to submit the report by the deadline is in violation of the Department’s October 7, 2020, Public Health Order that requires all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report on their visitation status.

Enforcement Action: In November 2020, the Department issued Notices of Violation and Civil Penalty imposing a civil monetary penalty of two hundred and fifty dollars (\$250) against ninety-three (93) community residential care facilities (CRCFs) and twelve (12) nursing homes. An additional three hundred and fifty dollars (\$350) civil monetary penalty per week was imposed on ten (10) community residential care facilities (CRCFs) and five (5) nursing homes, who received Repeat Notices of Violation and Civil Penalty in November. All of the facilities listed below were required to pay the full amount of their accumulated penalties within twenty (20) days of the dated notices. The facilities listed as having a Civil Penalty greater than two hundred and fifty dollars (\$250) were repeat offenders during the month of November.

Facility Name	Facility Type	Civil Penalty	Payment Received
A’LELIA RESIDENTIAL CARE	CRCF	\$250.00	Yes
AMARA PLACE AT COLUMBIA	CRCF	\$250.00	Yes
ARBOR LANDING AT PAWLEYS	CRCF	\$250.00	Yes
ASHLEY LANDING ASSISTED LIVING	CRCF	\$250.00	Yes
BLOOM AT BLUFFTON	CRCF	\$250.00	Yes
BOWLES COMMUNITY CARE HOME	CRCF	\$250.00	Yes
BOWLES COMMUNITY CARE HOME 2	CRCF	\$250.00	Yes
BRIAN’S RESIDENTIAL CARE	CRCF	\$250.00	Yes
BROOKDALE CONWAY	CRCF	\$250.00	Yes
BROOKDALE HARBISON	CRCF	\$250.00	Yes
BROOKDALE NORTH AUGUSTA	CRCF	\$250.00	Yes
BROOKSTONE TERRACE OF WOODRUFF LLC	CRCF	\$250.00	Yes
BURGESS RESIDENTIAL CARE #3	CRCF	\$250.00	Yes
BURGESS RESIDENTIAL CARE FACILITY #4	CRCF	\$250.00	Yes
BURGESS RESIDENTIAL CARE FACILITY	CRCF	\$250.00	Yes
CABADING HOMES #1	CRCF	\$250.00	Yes
CABADING HOMES #2	CRCF	\$250.00	Yes
CABADING HOMES #3	CRCF	\$250.00	Yes
CAMP COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
CANTRELL’S RESIDENTIAL CARE FACILITY	CRCF	\$250.00	Yes

Facility Name	Facility Type	Civil Penalty	Payment Received
CAROLINA GARDENS AT CONWAY	CRCF	\$250.00	Yes
CAROLINA GARDENS AT ROCK HILL	CRCF	\$250.00	Yes
CATHERINE'S MANOR II	CRCF	\$600.00	Yes
CLS CARE HOME	CRCF	\$350.00	Yes
COUNTRY COMFORT COMMUNITY HOME	CRCF	\$250.00	Yes
CUMMINGS COMMUNITY RESIDENTIAL CARE HOME	CRCF	\$600.00	Yes
DIXON'S COMMUNITY CARE HOME	CRCF	\$250.00	Yes
EDEN TERRACE OF SPARTANBURG	CRCF	\$250.00	Yes
EMERALD RCF I	CRCF	\$250.00	Yes
EMERALD RCF II	CRCF	\$250.00	Yes
FAMILY RESIDENTIAL CARE HOME I	CRCF	\$250.00	Yes
FAMILY RESIDENTIAL CARE HOME II	CRCF	\$250.00	Yes
FAMILY RESIDENTIAL CARE HOME III	CRCF	\$250.00	Yes
FARMINGTON COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
FOREST VIEW MANOR RETIREMENT CENTER	CRCF	\$250.00	Yes
GOOD SAMARITAN RESIDENTIAL CARE	CRCF	\$250.00	Yes
GREENVILLE COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
GREER COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
HAMPTON STREET COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
HANNAH RESIDENTIAL MANOR	CRCF	\$250.00	Yes
HARMONY AT WESCOTT PLANTATION	CRCF	\$250.00	Yes
HELMS-GORDON RESIDENTIAL CARE HOME	CRCF	\$450.00	Yes
INDIGO HALL	CRCF	\$250.00	Yes
INVERNESS AT SPARTANBURG	CRCF	\$250.00	Yes
IVORYS LOVING CARE II	CRCF	\$600.00	Yes
IVORY'S LOVING CARE RESIDENTIAL FACILITY	CRCF	\$250.00	Yes
IVY GROVE RESIDENTIAL CARE CENTER	CRCF	\$250.00	Yes
J J RESIDENTIAL CARE	CRCF	\$250.00	Yes
JENNI-LYNN ASSISTED LIVING COMMUNITY	CRCF	\$250.00	Yes
JOHNSONVILLE ADULT CARE SERVICES	CRCF	\$250.00	Yes
JOSHUAS FOUNDATION	CRCF	\$250.00	No
JOY COMMUNITY CARE HOME	CRCF	\$250.00	Yes
LAMBS ROAD COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
LAURENS ESTATES	CRCF	\$250.00	Yes
LENEVAR COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
M & M RESIDENTIAL CARE HOME	CRCF	\$250.00	Yes
MAGNOLIAS OF WALTERBORO	CRCF	\$250.00	Yes
MASTER CARE	CRCF	\$250.00	Yes
MCKINNEY HOUSE	CRCF	\$250.00	Yes
MEMORY CARE OF SIMPSONVILLE	CRCF	\$250.00	Yes
MIDWAY RESIDENTIAL CARE FACILITY #1	CRCF	\$250.00	Yes
MIDWAY RESIDENTIAL CARE FACILITY #1A	CRCF	\$250.00	Yes
MIDWAY RESIDENTIAL CARE FACILITY #2	CRCF	\$250.00	Yes
MIDWAY RESIDENTIAL CARE FACILITY #3	CRCF	\$250.00	Yes
MIDWAY RESIDENTIAL CARE FACILITY #4	CRCF	\$250.00	Yes
MIDWAY RESIDENTIAL CARE FACILITY #5	CRCF	\$250.00	Yes
MORNINGSIDE OF BEAUFORT	CRCF	\$250.00	No
MORNINGSIDE OF ROCK HILL	CRCF	\$250.00	Yes
OAKRIDGE COMMUNITY CARE HOME #1	CRCF	\$600.00	No

Facility Name	Facility Type	Civil Penalty	Payment Received
PALMETTOS OF BLUFFTON	CRCF	\$250.00	Yes
PALMETTOS OF CHARLESTON	CRCF	\$250.00	Yes
PALMS ON MAIN ASSISTED LIVING FACILITY	CRCF	\$250.00	Yes
PARKER	CRCF	\$800.00	Yes
PASSIONATE CARE COMMUNITY CENTER	CRCF	\$250.00	Yes
PEARL AT PORT ROYAL	CRCF	\$250.00	No
PHOENIX AT GREER	CRCF	\$250.00	Yes
PINEDALE RESIDENTIAL CENTER	CRCF	\$250.00	Yes
PRESIDENTIAL COMMUNITY CARE HOME FACILITY	CRCF	\$250.00	Yes
REID'S RESIDENTIAL CARE FACILITY	CRCF	\$250.00	Yes
RETREAT AT CAROLINA BAY	CRCF	\$250.00	Yes
RETREAT AT GAFFNEY	CRCF	\$250.00	Yes
ROSEWOOD ASSISTED LIVING	CRCF	\$250.00	Yes
ROUSE COMMUNITY CARE HOME #2	CRCF	\$250.00	No
S&S BOARDING HOME LLC	CRCF	\$250.00	Yes
SC EPISCOPAL HOME AT STILL HOPES	CRCF	\$250.00	Yes
SECESSIONVILLE COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
SHEPHERD'S CARE CENTER	CRCF	\$250.00	Yes
SOUTH ISLAND ASSISTED LIVING	CRCF	\$250.00	Yes
SOUTHERN HERITAGE	CRCF	\$250.00	Yes
SPRINGS AT SIMPSONVILLE	CRCF	\$250.00	Yes
THORNE RETIREMENT HOME	CRCF	\$250.00	Yes
WARE SHOALS MANOR	CRCF	\$250.00	Yes
WELLMORE OF LEXINGTON	CRCF	\$350.00	Yes
WESLEY COURT ASSISTED LIVING COMMUNITY	CRCF	\$600.00	Yes
WESLEYAN SUITES	CRCF	\$250.00	Yes
WEST END RETIREMENT CENTER INC	CRCF	\$350.00	Yes
WILDEWOOD DOWNS ASSISTED LIVING COMMUNITY	CRCF	\$250.00	Yes
WILLIAMSBURG RESIDENTIAL CARE FACILITY	CRCF	\$250.00	Yes
WOODBRIIDGE SENIOR LIVING	CRCF	\$250.00	Yes
WOODLAND PLACE	CRCF	\$250.00	Yes
WRIGHT'S RESIDENTIAL CARE #2 A & B	CRCF	\$250.00	Yes
WRIGHT'S RESIDENTIAL CARE FACILITY 1	CRCF	\$250.00	Yes
ZEIGLER STREET COMMUNITY RESIDENCE	CRCF	\$250.00	Yes
BLACKVILLE HEALTHCARE AND REHAB	Nursing Home	\$350.00	Yes
BLUE RIDGE IN BROOKVIEW HOUSE	Nursing Home	\$250.00	Yes
DR RONALD E MCNAIR NURSING AND REHABILITATION CENTER	Nursing Home	\$600.00	Yes
DUNDEE MANOR	Nursing Home	\$350.00	Yes
LAKE MARION NURSING FACILITY	Nursing Home	\$250.00	Yes
LAKE MOULTRIE NURSING HOME	Nursing Home	\$250.00	Yes
MAGNOLIA MANOR-GREENVILLE	Nursing Home	\$250.00	Yes
METHODIST MANOR HEALTHCARE CENTER	Nursing Home	\$250.00	Yes
NHC HEALTHCARE GARDEN CITY	Nursing Home	\$250.00	Yes
PLACE AT PEPPER HILL	Nursing Home	\$250.00	Yes
RETREAT AT WELLMORE OF LEXINGTON	Nursing Home	\$800.00	Yes
SALUDA NURSING CENTER	Nursing Home	\$250.00	Yes
SANDPIPER REHAB & NURSING	Nursing Home	\$350.00	Yes
SOUTH CAROLINA EPISCOPAL HOME AT STILL HOPE	Nursing Home	\$250.00	Yes

Facility Name	Facility Type	Civil Penalty	Payment Received
SPRENGER HEALTHCARE OF PORT ROYAL	Nursing Home	\$250.00	No
SUMTER EAST HEALTH AND REHABILITATION CENTER	Nursing Home	\$250.00	Yes
WILDEWOOD DOWNS NURSING AND REHABILITATION CENTER	Nursing Home	\$250.00	Yes

Bureau of EMS and Healthcare Professionals

Level of Certification	Total # of Certified Paramedics
Paramedic	4,014

2. Raymond Lee Petit – Paramedic

Inspections and Investigations: The Department conducted an investigation in March 2020 and found that the Paramedic was in violation of regulatory requirements.

Violations: The Department determined that the Paramedic was in violation of the EMS Act and Regulation 61-7, *Emergency Medical Services*, for abandoning a patient at the scene after the patient was treated for a suspected overdose. The Paramedic and their Emergency Medical Technician (EMT) partner left the patient at the scene in the custody of law enforcement rather than transporting the patient to the hospital.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In November 2020, the parties executed a consent order suspending Mr. Petit’s Paramedic certification for twenty-four (24) months with the terms as follows. As a term of the suspension of his Paramedic certification, Mr. Petit has been issued an Advanced Emergency Medical Technician (AEMT) certification and may request reinstatement of the Paramedic certification from the Department after seven (7) months with the remaining seventeen (17) months of the twenty-four (24) month suspension held in abeyance. Mr. Petit also agreed to take the National Association of Emergency Medical Technicians’ (NAEMT) Professional Ethics and Personal Leadership (PEPL) course within twelve (12) months of the consent order being executed and provide evidence of its completion to the Department.

Remedial Action: Mr. Petit’s Paramedic certification remains suspended and he has not taken the PEPL course yet.

Prior Enforcement Actions: None in the past five (5) years.

Bureau of Radiological Health

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

3. Mark LaRue, DMD – Charleston, SC

Inspections and Investigations: The Department conducted a routine inspection in September 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 November 2020, the parties executed a consent order imposing a civil monetary penalty of one thousand and seven hundred dollars (\$1,700) against the registrant. The registrant was required to pay two hundred and fifty-five dollars (\$255) of the assessed penalty within thirty (30) days of executing the Consent Order. The remaining one thousand and four hundred and forty-five dollars (\$1,445) of the penalty will be stayed.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five (5) years.

4. I'On Family Dentistry – Mount Pleasant, SC

Inspections and Investigations: The Department conducted a routine inspection in September 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 November 2020, the parties executed a consent order imposing a civil monetary penalty of one thousand and seven hundred dollars (\$1,700) against the registrant. The registrant was required to pay two hundred and fifty-five dollars (\$255) of the assessed penalty within thirty (30) days of executing the Consent Order. The remaining one thousand and four hundred and forty-five dollars (\$1,445) of the penalty will be stayed.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five (5) years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
January 7, 2021

_____ ACTION/DECISION

 X INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.
2. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period November 1, 2020, through November 30, 2020.
3. **FACTS:** For the reporting period of November 1, 2020, through November 30, 2020, the Office of Environmental Affairs issued twenty-eight (28) Consent Orders with total assessed civil penalties in the amount of thirty thousand, six hundred thirty dollars (\$30,630.00). Seven (7) Administrative Orders with total assessed civil penalties in the amount of three hundred eighty-two thousand, two hundred thirty-six dollars (\$382,236.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	3	\$16,750.00	1	\$1,450.00
Aboveground Tanks	0	0	0	0
Solid Waste	0	0	1	\$500.00
Hazardous Waste	1	\$353,486.00	0	0
Infectious Waste	0	0	0	0
Mining	0	0	1	0
SUBTOTAL	4	\$370,236.00	3	\$1,950.00
Water				
Recreational Water	0	0	14	\$12,800.00
Drinking Water	0	0	1	\$680.00
Water Pollution	1	\$12,000.00	4	\$10,400.00
Dam Safety	0	0	0	0
SUBTOTAL	1	\$12,000.00	19	\$23,880.00
Air Quality				
SUBTOTAL	0	0	0	0
Environmental Health Services				
Food Safety	0	0	6	\$4,800.00
Onsite Wastewater	2	0	0	0
SUBTOTAL	2	0	6	\$4,800.00
OCRM				
SUBTOTAL	0	0	0	0
TOTAL	7	\$382,236.00	28	\$30,630.00

Submitted by:

Myra C. Reece

Myra C. Reece
Director of Environmental Affairs

**ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
January 7, 2021**

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

- 1) Order Type and Number: Administrative Order 19-0208-UST
 Order Date: November 20, 2020
 Individual/Entity: **Hafida E. Osborn**
 Facility: Johnson's Old Rail Road Express
 Location: 4580 Highway 501 West
 Conway, SC 29526

 Mailing Address: Same
 County: Horry
 Previous Orders: 18-0272-UST (\$120.00)
 Permit/ID Number: 19028
 Violations Cited: The State Underground Petroleum
 Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq.
 (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control
 Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.93(a) and 280.110(c) (2012 and
 Supp. 2019).

Summary: Hafida E. Osborn (Individual/Entity) is the owner of underground storage tanks located in Horry County, South Carolina. The Department issued a Notice of Alleged Violation on May 7, 2019. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for an UST system and failed to provide evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility form and provide evidence of financial assurance by January 8, 2021. The Department has assessed a total civil penalty in the amount of three thousand, eight hundred fifty dollars (\$3,850.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, eight hundred fifty dollars (**\$3,850.00**) by January 8, 2021.

Updates: No updates.

- 2) Order Type and Number: Administrative Order 20-0064-UST
 Order Date: November 20, 2020
 Individual/Entity: **Joe Kelly**
 Facility: Joe Kelly's Trophy Shop
 Location: Highway 72
 Mountville, SC 29370

 Mailing Address: 4445 Highway 39
 Mountville, SC 29370

 County: Laurens

Previous Orders: None
Permit/ID Number: 10292
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann., § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92.280.65(a) and (b). (2012 and Supp. 2019).

Summary: Joe Kelly (Individual/Entity) is responsible for a petroleum release from an underground storage tank (UST) previously removed from the property located in Laurens County, South Carolina. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to conduct a groundwater sampling event to investigate a petroleum release as soon as practicable or in accordance with a schedule established by the Department.

Action: The Individual/Entity is required to submit the groundwater sampling report to the Department by March 1, 2021. The Department assessed a civil penalty in the amount of nine thousand, nine hundred dollars (\$9,900). The Individual/Entity shall pay the civil penalty in the amount of nine thousand, nine hundred dollars (**\$9,900.00**) by March 1, 2021.

Updates: No updates.

3) Order Type and Number: Administrative Order 20-0079-UST
Order Date: November 20, 2020
Individual/Entity: **Mohammad Basem**
Facility: B&M of South Carolina, LLC
Location: 4650 Board Street Ext.
Sumter, SC 29154
Mailing Address: 4756 Broad Street
Sumter, SC 29150
County: Sumter
Previous Orders: None
Permit/ID Number: 09825
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.34(c) and 280.40(a) (2012 and Supp. 2019).

Summary: Mohammad Basem (Individual/Entity) is the owner of underground storage tanks located in Sumter County, South Carolina. The Department conducted an inspection on March 9, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide records to the Department upon request and failed to provide an adequate release detection method for an Underground Storage Tank (UST) system.

Action: The Individual/Entity is required to submit the most current, passing automatic tank gauge record for the 8,000-gallon regular UST as proof that a valid release detection method is in place. The Department has assessed a total civil penalty in the

amount of three thousand dollars (\$3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars (**\$3,000.00**) by January 8, 2021.

Updates: No updates.

- 4) Order Type and Number: Consent Order 19-0500-UST
Order Date: November 3, 2020
Individual/Entity: **Kareem Harding**
Facility: Yahuah People Unite
Location: 650 Center Street
Chester, SC 29706
Mailing Address: 656 Center Road
Chester, SC 29706
County: Chester
Previous Orders: 19-0412-UST (\$3,200.00, stipulated)
Permit/ID Number: 18376
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.93(a) and 280.110(c) (2012 & Supp 2019).

Summary: Kareem Harding (Individual/Entity) owns and operates underground storage tanks in Chester County, South Carolina. The Department issued a Notice of Alleged Violation on October 17, 2019. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for underground storage tank systems and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to submit a completed Certificate of Financial Responsibility Form and evidence of financial assurance by December 18, 2020. The Department has assessed a total civil penalty in the amount of one thousand, four hundred fifty dollars (\$1,450.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, four hundred fifty dollars (**\$1,450.00**) by December 18, 2020.

Updates: No updates.

Solid Waste Enforcement

- 5) Order Type and Number: Consent Order 20-23-SW
Order Date: November 23, 2020
Individual/Entity: **Kenan Aydin**
Facility: Lot 35 Catawba Crest Lane
Location: 269 Catawba Crest Lane
Clover, SC 29710
Mailing Address: 6211 Whitewater Drive
Charlotte, NC, 28214
County: York
Previous Orders: None

Permit/ID Number: N/A
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, Part I.A.8., Part I.B.20., Part I.B.53., and Part II.B.1. (2018)

Summary: Kenan Aydin (Individual/Entity) owns a property in York County, South Carolina. The Department conducted a complaint investigation on April 10, 2020, and June 5, 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 obtain a permit to engage in a structural fill activity from the Department.

Action: The Individual/Entity is required to: apply a two (2) foot thick final earth cover to the fill area with at least 1%, but not greater than 4% surface slope, grated to promote positive drainage; remove and properly dispose of any remaining concrete that was not being pushed in the ditch; use appropriate best management practices to control stormwater runoff; seed the finished surface of the filled area with native grasses or other suitable ground cover to establish and maintain into the second growing season a 75% or greater permanent vegetative cover with no substantial bare spots by March 24, 2021; 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 by January 2, 2021. The Department has assessed a total civil penalty in the amount of one thousand, one hundred dollars (\$1,100.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**) by January 7, 2021 and pay a suspended penalty in the amount of five thousand, four hundred dollars (\$5,400.00) should any requirement in the Order not be met.

Update: No updates.

Hazardous Waste Enforcement

6) Order Type and Number: Administrative Order 19-21-HW
Order Date: November 5, 2020
Individual/Entity: **Carolina Plating Works, Inc.**
Facility: Carolina Plating Works, Inc.
Location: 1101 West Blue Ridge Drive
Greenville, SC 29609
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: SCR 003 351 996
Violations Cited: The South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 et seq. (2019), the South Carolina Hazardous Waste Management Regulations, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp 2019), and the Hazardous Waste Post-Closure Care Permit Conditions.

Summary: Carolina Plating Works, Inc. (Individual/Entity), holds a Hazardous Waste Post-Closure Care Permit for a closed surface impoundment and for the

identification and corrective action of solid waste management units at the Site. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act, the South Carolina Hazardous Waste Management Regulations, and the Hazardous Waste Post-Closure Care Permit Conditions, as follows: failed to conduct groundwater monitoring and submit results on a semi-annual basis; failed to provide a detailed annual report describing the effectiveness of the corrective action program; failed to update post-closure cost estimates; failed to fully fund existing financial assurance; failed to update financial assurance for inflation or operational changes; and failed to make a hazardous waste determination on the recovered groundwater.

Action: The Individual/Entity is required to: comply with all requirements of the Regulation, the Permit, and the Order; submit a Class 3 permit modification by December 5, 2020; and at least ninety (90) days before the sale of the property, notify the Department of the pending sale and provide new owner information. The Department has assessed a total civil penalty in the amount of three hundred fifty-three thousand, four hundred eighty-six dollars (\$353,486.00). The Individual/Entity shall pay a civil penalty in the amount of three hundred fifty-three thousand, four hundred eighty-six dollars (**\$353,486.00**).

Update: A Request for Review was filed on December 4, 2020.

Mining Enforcement

7) Order Type and Number: Consent Order 20-09-MSWM
Order Date: November 12, 2020
Individual/Entity: **Buddy Clawson Construction, Inc.**
Facility: Clawson Mine
Location: East of Highway 165 (Brattonsville Road) approximately 0.75 miles southeast of the junction of Highways 322 (McConnells Highway) and 165 (Brattonsville Road). TMS # 4100000010
Mailing Address: 425 Brattonsville Road
McConnells, SC 29726
County: York
Previous Orders: 19-08-MSWM (\$2,000.00)
Permit/ID Number: GP1-001965
Violations Cited: The South Carolina Mining Act, S.C. code Ann. § 48-20-10 et seq. (2008 & Supp. 2018); South Carolina Mining Regulation (2012) R.89-280; and the Permit GP1-001965 Section IV., Part B.2 and Section IV., Part B.8.

Summary: Buddy Clawson Construction, Inc. (Individual/Entity) owns and operates Clawson Mine in York County, South Carolina. The Department conducted an inspection on August 10, 2017. The Individual/Entity has violated the South Carolina Mining Act, the South Carolina Mining Regulations, and the Permit, as follows: failed to limit mining operation disturbance to five (5) acres and failed to maintain a pit slope not steeper than 3:1 (horizontal: vertical).

Action: The Individual/Entity is required to: immediately cease and desist all mining activities outside of the original GP1 Permit footprint; notify the Department of

York County Zoning Board approval of the proposed mining activity and complete the Individual Mining Permit application by May 12, 2021 or begin grading, stabilizing and seeding all of the mined area outside of the original GP1 Permit footprint with reclamation to be completed according to the South Carolina Mining Regulations by November 12, 2022. The Individual Mining Permit application on file with the Department will be automatically withdrawn from submission, with said withdrawal acknowledged in writing by the Department, unless the York County Zoning Board grants approval for the proposed mining activity and a completed Individual Mining Permit application is on file with the Department by May 12, 2021.

Updates: No updates.

BUREAU OF WATER

Recreational Waters Enforcement

8)	<u>Order Type and Number:</u>	Consent Order 20-122-RW
	<u>Order Date:</u>	November 2, 2020
	<u>Individual/Entity:</u>	The Breakers Horizontal Property Regime
	<u>Facility:</u>	The Breakers
	<u>Location:</u>	1074 North Forest Beach Drive Hilton Head, SC 29928
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Beaufort
	<u>Previous Orders:</u>	None
	<u>Permit/ID Number:</u>	07-126-1
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: The Breakers Horizontal Property Regime (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on July 22, 2020, and September 4, 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 cracked; the deck was cracked with sharp edges; the chlorine level was not within the acceptable range of water quality standards; and, the cyanuric acid level was above the water quality standards acceptable limit.

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

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

9)	<u>Order Type and Number:</u>	Consent Order 20-123-RW
	<u>Order Date:</u>	November 2, 2020

<u>Individual/Entity:</u>	Canlen Walk Limited Partnership
<u>Facility:</u>	Grove at Oakbrook
<u>Location:</u>	325 Midland Parkway Summerville, SC 29485
<u>Mailing Address:</u>	Same
<u>County:</u>	Dorchester
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	18-1001B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Canlen Walk Limited Partnership (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. The Department conducted inspections on July 13, 2020, and August 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: the deck depth marker tiles were broken; a ladder was missing bumpers; the bathrooms were not accessible; there was no drinking water fountain; the pool equipment room was not locked; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; the facility address posted at the emergency notification device was not permanent or weather resistant; the “No Lifeguard On Duty – Swim At Your Own Risk” signs posted did not have the correct wording; 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 Individual/Entity has paid the civil penalty. This Order has been closed.

10) <u>Order Type and Number:</u>	Consent Order 20-124-RW
<u>Order Date:</u>	November 2, 2020
<u>Individual/Entity:</u>	The Mark at Dorchester, LP
<u>Facility:</u>	Arbor Village Apartments
<u>Location:</u>	10825 Dorchester Road Summerville, SC 29485
<u>Mailing Address:</u>	Same
<u>County:</u>	Dorchester
<u>Previous Orders:</u>	19-098-RW (\$680.00)
<u>Permit/ID Number:</u>	18-1054B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: The Mark at Dorchester, LP (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Dorchester County, South Carolina. The Department conducted inspections on June 5, 2020, and July 22, 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 furniture was not at least four feet from the edge of the pool; the deck was uneven with sharp edges; there was debris in the skimmer baskets; chemicals were hand-fed into the pool while the pool was open to the public; the chlorine and pH levels

were not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; the life ring was not in its designated location; the current pool operator of record information was not posted to the public; the facility could not produce current valid documentation of pool operator certification; the bound and numbered log book was not maintained on a daily basis; and, there were chlorine sticks 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, 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 paid the civil penalty. This Order has been closed.

11)	<u>Order Type and Number:</u>	Consent Order 20-125-RW
	<u>Order Date:</u>	November 4, 2020
	<u>Individual/Entity:</u>	Shelly Woods Homeowners' Association, Inc.
	<u>Facility:</u>	Shelly Woods
	<u>Location:</u>	1015 Shelly Woods Drive Fort Mill, SC 29708
	<u>Mailing Address:</u>	P.O. Box 11906 Charlotte, NC 28220
	<u>County:</u>	Lancaster
	<u>Previous Orders:</u>	None
	<u>Permit/ID Number:</u>	29-1022C
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Shelly Woods Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Lancaster County, South Carolina. The Department conducted inspections on June 18, 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: 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 water level was too high.

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

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

12)	<u>Order Type and Number:</u>	Consent Order 20-126-RW
	<u>Order Date:</u>	November 2, 2020
	<u>Individual/Entity:</u>	Hudson Capital Investments, LLC
	<u>Facility:</u>	Forest Pointe

Location: 504 Forest Pointe
Walterboro, SC 29488
Mailing Address: 1221 Main Street, Suite 1100
Columbia, SC 29201
County: Colleton
Previous Orders: None
Permit/ID Number: 15-1003B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Hudson Capital Investments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Colleton County, South Carolina. The Department conducted inspections on June 29, 2020, and July 31, 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 non-slip treads; skimmers were missing weirs; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the pool rules sign did not have all of the required rules; there were no "Shallow Water – No Diving Allowed" signs posted; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; and, there were chlorine pucks in the skimmer baskets.

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

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

13) Order Type and Number: Consent Order 20-127-RW
Order Date: November 4, 2020
Individual/Entity: **North Charleston Hotel Group, LLC**
Facility: Comfort Suites
Location: 2450 Prospect Drive
North Charleston, SC 29406
Mailing Address: 3479 Lawrenceville-Suwanee Road
Suwanee, GA 30024
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1285B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: North Charleston Hotel Group, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 5, 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: a ladder was missing bumpers; a skimmer was missing a weir; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring rope was tangled and not in operable use; 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 Individual/Entity has paid the civil penalty. This Order has been closed.

14) Order Type and Number: Consent Order 20-128-RW
Order Date: November 6, 2020
Individual/Entity: **BRG Cedar Grove, LLC**
Facility: Cedar Grove Apartments
Location: 8708 Evangeline Drive
North Charleston, SC 29420
Mailing Address: 104 Hume Avenue
Alexandria, VA 22301
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1029B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: BRG Cedar Grove, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 12, 2020, and July 28, 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 foot rinse shower was not operating properly; the pool equipment room was not locked; the fill spout was not stainless steel or equivalent; the chlorine level was not within the acceptable range of water quality standards; the life ring was not United States Coast Guard approved; the emergency notification device was not operational; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review; and, a skimmer was missing a weir.

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

15) Order Type and Number: Consent Order 20-129-RW
Order Date: November 10, 2020
Individual/Entity: **GCA Passage, LLC**
Facility: The Passage
Location: 100 Underwood Lane
Summerville, SC 29486
Mailing Address: Same
County: Berkeley

Previous Orders: None
Permit/ID Number: 08-1085B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: GCA Passage, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on July 1, 2020, and August 5, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the equipment room was not locked; the pH level was not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the pool rules sign was not properly filled out; the emergency notification device was not operating; 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 Individual/Entity has paid the civil penalty. This Order has been closed.

16) Order Type and Number: Consent Order 20-130-RW
Order Date: November 10, 2020
Individual/Entity: **Sweetgrass at Bees Ferry JV, LLC**
Facility: Harper Place Apartments
Location: 3202 Coastal Grass Way
Charleston, SC 29414
Mailing Address: 710 Peachtree Street NE, Suite 100
Atlanta, GA 30308
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1376B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sweetgrass at Bees Ferry JV, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 3, 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 bathrooms did not have paper towels or a hand dryer; there was no drinking water fountain; the trash cans were full of trash and were attracting insects; the pool equipment room was not accessible; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; there were no “No Lifeguard On Duty – Swim At Your Own Risk” signs posted; the “Shallow Water – No Diving Allowed” signs posted were obstructed; and, the bound and numbered log book was not available for review.

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

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

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

17) Order Type and Number: Consent Order 20-131-RW
Order Date: November 12, 2020
Individual/Entity: **The Ocean Point Property Owners' Association, Inc.**
Facility: Ocean Point
Location: Ocean Point Drive
Isle of Palms, SC 29451
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-412-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Ocean Point Property Owners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 17, 2020, and July 20, 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 deck was uneven with sharp edges; the skimmer lids were cracked; the drinking water fountain was not accessible on the first inspection, and was not operating properly on the second inspection; the fill spout was not co-located with a ladder or diving board; the gate did not self-close and latch; and, the life ring rope 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 Individual/Entity has paid the civil penalty. This Order has been closed.

18) Order Type and Number: Consent Order 20-132-RW
Order Date: November 12, 2020
Individual/Entity: **Ocean Crest Inn and Suites, LLC**
Facility: Ocean Crest Inn and Suites
Location: 601 South Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: 19-286-RW (\$1,360.00)
Permit/ID Number: 26-263-1 & 26-299-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Ocean Crest Inn and Suites, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of an indoor pool and an outdoor pool located in Horry County, South Carolina. The Department conducted inspections of the indoor pool on July 22, 2020, and August 12, 2020, and violations were issued for failure to properly operate and maintain. The Department conducted inspections of the outdoor pool on June 19, 2020, June 22, 2020, and August 12, 2020, and violations were issued for failure to properly operate and maintain; and on June 22, 2020, a violation was issued for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers at both pools; the chlorine level was not within the acceptable range of water quality standards at both pools; the pH level was not within the acceptable range of water quality standards at the indoor pool; the lifeline floats were not properly spaced at the indoor pool; there was a hose on the deck of the indoor pool that presented a trip hazard; there were pipes above the indoor pool that were leaking; there was a hole in the pool wall at the outdoor pool; a skimmer was missing a weir at the outdoor pool; the drinking water fountain was not operating properly at the outdoor pool; a gate did not self-close and latch at the outdoor pool; the life ring was deteriorated at the outdoor pool; the emergency notification device was not operational at the outdoor pool; there was no pool rules sign at the outdoor pool; the bound and numbered log book for the outdoor pool was not maintained on a daily basis; the current pool operator of record information was not posted to the public at the outdoor pool; and, the outdoor 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 four thousand, four hundred dollars (\$4,400.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, four hundred dollars (**\$4,400.00**) in installments. Payments are due February 15, 2021, March 15, 2021, and April 15, 2021.

Update: No updates.

19) <u>Order Type and Number:</u>	Consent Order 20-133-RW
<u>Order Date:</u>	November 16, 2020
<u>Individual/Entity:</u>	South Hampton Ventures, LLC
<u>Facility:</u>	Courtyard by Marriott
<u>Location:</u>	1251 Woodland Avenue Mount Pleasant, SC 29404
<u>Mailing Address:</u>	17 Lockwood Drive, Suite 400 Charleston, SC 29401
<u>County:</u>	Charleston
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	10-1146B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: South Hampton Ventures, 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 28, 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: the foot rinse shower was not operating properly; the chlorine level was not within the acceptable

range of water quality standards; and, the bound and numbered logbook 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 Individual/Entity has paid the civil penalty. This Order has been closed.

20) Order Type and Number: Consent Order 20-134-RW
Order Date: November 16, 2020
Individual/Entity: **173 Meeting Street Inn Limited Partnership**
Facility: Meeting Street Inn
Location: 173 Meeting Street
Charleston, SC 29401
Mailing Address: 8 Cumberland Street
Charleston, SC 29401
County: Charleston
Previous Orders: 19-080-RW (\$680.00)
Permit/ID Number: 10-209-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: 173 Meeting Street Inn Limited Partnership (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Charleston County, South Carolina. The Department conducted inspections on June 17, 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 chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was too high; there were no “No Lifeguard On Duty – Swim At Your Own Risk” signs posted; there was no foot rinse shower; there was no drinking water fountain; and, there was no spa rules sign.

Action: The Individual/Entity is required to: by November 30, 2020, submit to the Department a standard operating procedure to ensure that the spa is properly operated and maintained, and maintains compliance with Regulation 61-51. 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 **stipulated penalty** in the amount of one thousand, six hundred dollars (**\$1,600.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has submitted a standard operating procedure to follow to ensure compliance. This Order has been closed.

21) Order Type and Number: Consent Order 20-135-RW
Order Date: November 23, 2020
Individual/Entity: **The Grove at Ebenezer, LLC**
Facility: The Grove
Location: 1037 Grove Boulevard

	Florence, SC 29501
<u>Mailing Address:</u>	Same
<u>County:</u>	Florence
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	21-1035B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: The Grove at Ebenezer, 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 June 5, 2020, June 10, 2020, June 19, 2020, July 7, 2020, July 22, 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: there was debris in the skimmer baskets; the water level was too low; there was no drinking water fountain; there was no foot rinse shower; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operational; there were no “Shallow Water – No Diving Allowed” signs posted; there were no “No Lifeguard On Duty – Swim At Your Own Risk” signs posted; the current pool operator of record information was not posted to the public; and, the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of at least three times per week by a pool operator of record.

Action: The Individual/Entity is required to: by December 13, 2020, submit to the Department a standard operating procedure to ensure that the pool is properly operated and maintained, and maintains compliance with Regulation 61-51. 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 **stipulated** penalty in the amount of two thousand, forty dollars (**\$2,040.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has submitted a standard operating procedure to follow to ensure compliance. This Order has been closed.

Drinking Water Enforcement

22)	<u>Order Type and Number:</u>	Consent Order 20-028-DW
	<u>Order Date:</u>	November 12, 2020
	<u>Individual/Entity:</u>	Daniel Baxley Farms, LLC
	<u>Facility:</u>	Baxley & Baxley Farms
	<u>Location:</u>	1524 Minturn Road Minturn, SC 29573
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Dillon
	<u>Previous Orders:</u>	None
	<u>Permit/ID Number:</u>	17IR023
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-113.H.2

Summary: Daniel Baxley Farms, LLC (Individual/Entity) owns and is responsible for obtaining the proper permit for a groundwater withdrawal system located in Dillon County, South Carolina. On August 14, 2020, a violation was issued as a result of Department review of groundwater withdrawal permitting records. The Individual/Entity

has violated the Groundwater Use and Reporting Regulation as follows: failed to submit a completed application to the Department to renew its groundwater withdrawal permit at least ninety (90) days prior to the expiration date.

Action: The Individual/Entity has submitted a completed application and renewed its groundwater withdrawal permit. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars (\$680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **(\$680.00)** by December 12, 2020.

Update: No updates.

Water Pollution Enforcement

23) Order Type and Number: Administrative Order 20-041-W
Order Date: November 3, 2020
Individual/Entity: **Franklin W. Howey, Jr. Individually and d.b.a. Howey Family Farms, LLC and Chesterfield County Farms, LLC**
Facility: Howey Family Farms, LLC and Chesterfield County Farms, LLC
Location: Off Hornsboro Road in Chesterfield County, South Carolina
Mailing Address: 912 Fletcher Broome Road
Monroe, NC 28110
County: Chesterfield
Previous Orders: 18-027-W (\$3,750.00)
Permit/ID Number: None
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-90(a) (2008 & Supp. 2019), S.C. Standards for the Permitting of Agricultural Animal Facilities, S.C. Code Ann Regs. 61-43 Part 400.60(C)(20) and Part 400.60(D)(3).

Summary: Franklin W. Howey, Jr. Individually and d.b.a. Howey Family Farms, LLC and Chesterfield County Farms, LLC (Individual/Entity) was issued a Notice of Alleged Violation on February 6, 2020, for improperly stockpiled and applied animal manure and animal by-products to certain properties in Chesterfield County, South Carolina. The Individual/Entity has violated the Pollution Control Act and S.C. Standards for the Permitting of Agricultural Animal Facilities as follows: stockpiled uncovered manure, not on a concrete or other approved pad, for more than three days; and land applied manure within fifty feet of a ditch leading directly to waters of the State.

Action: The Individual/Entity is required to: immediately ensure that any stockpiled manure is properly covered or properly land applied; immediately register with the South Carolina Secretary of State if continuing to conduct business as incorporated entity; by December 3, 2020, submit notification of manure being covered or land applied and an application for a land application permit if continuing to perform manure handling activities. The Department has assessed a total civil penalty in the amount of twelve thousand dollars (\$12,000.00). The Individual/Entity shall pay a civil penalty in the amount of twelve thousand dollars **(\$12,000.00)** by December 3, 2020.

Update: No updates.

- 24) Order Type and Number: Consent Order 20-042-W
Order Date: November 5, 2020
Individual/Entity: **Belton-Honea Path Water Authority**
Facility: Belton-Honea Path Water Treatment Plant
Location: 525 Filter Plant Road
Honea Path, SC 29654
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit/ID Number: SCG646063
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), Water Pollution Control Permits, 3 S.C. Code Ann Regs. 61-9.122.21(d) (2011), and NPDES Permit SCG646063

Summary: Belton-Honea Path Water Authority (Individual/Entity) owns and is responsible for the proper operation and maintenance of a water treatment plant (WTP) in Anderson County, South Carolina. On August 19, 2020, a Notice of Violation was issued as a result of its failure to reapply for permit coverage within one hundred eighty (180) days prior to the existing NPDES permit's expiration date. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits 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 continue operating the WTP in accordance with the most recent NPDES permit until a new permit becomes effective. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**).

Updates: The Individual/Entity submitted an administratively complete application for renewal of their NPDES permit and has paid the penalty.

- 25) Order Type and Number: Consent Order 20-043-W
Order Date: November 5, 2020
Individual/Entity: **Town of Batesburg-Leesville**
Facility: Town of Batesburg-Leesville WWTF
Location: 100 Commissioner Street
Lexington, SC 29006
Mailing Address: P.O. Box 2329
Calhoun Falls, SC 29070
County: Lexington
Previous Orders: 20-004-W (\$5,000.00)
Permit/ID Number: NPDES Permit SC0024465
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. 61-9.122.41(a) and (e) (2011), and Part III. A of NPDES Permit SC0024465

Summary: Town of Batesburg-Leesville (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Lexington County, South Carolina. The Individual/Entity reported violations of the permitted discharge limits for chronic effluent toxicity (CTOX) as reported on discharge monitoring reports submitted to the Department for the quarterly monitoring periods ending August 30, 2019, and February 29, 2020; failed to properly operate and maintain its facility as determined by a collection system inspection performed by the Department on March 5, 2020. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent limits of its National Pollutant Discharge Elimination System permit for CTOX, and properly operate and maintain in good working order all facilities and systems of treatment and control.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by December 5, 2020; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of four thousand, two hundred dollars (\$4,200.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, two hundred dollars (**\$4,200.00**).

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

26) <u>Order Type and Number:</u>	Consent Order 20-044-W
<u>Order Date:</u>	November 12, 2020
<u>Individual/Entity:</u>	Pioneer Rural Water District
<u>Facility:</u>	Lake Hartwell WTP
<u>Location:</u>	1142 Highway 59 Fair Play, SC 29643
<u>Mailing Address:</u>	Same
<u>County:</u>	Oconee County
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	SCG646068
<u>Violations Cited:</u>	Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), Water Pollution Control Permits, 3 S.C. Code Ann Regs. 61-9.122.21(d) (2011), and NPDES Permit SCG646068

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

Action: The Individual/Entity is required to continue operating the WTP in accordance with the most recent NPDES permit until a new permit becomes effective. The Department has assessed a total civil penalty in the amount of one thousand dollars

(\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**).

Updates: The Individual/Entity has paid the penalty.

27) Order Type and Number: Consent Order 20-045-W
Order Date: November 17, 2020
Individual/Entity: **Isle of Palms Water & Sewer Commission**
Facility: Isle of Palms WWTF
Location: 1300 Palm Boulevard
Isle of Palms, SC 29451
Mailing Address: P.O. Box 528
Isle of Palms, SC 29451
County: Charleston
Previous Orders: None
Permit/ID Number: NPDES Permit SC0043583
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: Isle of Palms Water & Sewer Commission (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Hampton County, South Carolina. On February 3, 2020, a Notice of Violation was issued as a result of violations of the permitted discharge limits for total copper (copper) as reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for copper.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by December 17, 2020; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of four thousand, two hundred dollars (\$4,200.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, two hundred dollars (**\$4,200.00**) by December 17, 2020.

Updates: No updates.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

28) Order Type and Number: Consent Order 2020-206-06-019
Order Date: November 2, 2020
Individual/Entity: **Little Caesars Georgetown**
Facility: Little Caesars Georgetown

Location: 1177 North Fraser Street
Georgetown, SC 29440
Mailing Address: P.O. Box 39
Elizabethtown, NC 28337
County: Georgetown
Previous Orders: 2019-206-06-129 (\$800.00)
Permit Number: 22-206-06366
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Little Caesars Georgetown (Individual/Entity) is a restaurant located in Georgetown County, South Carolina. The Department conducted an inspection on February 20, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. 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 complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

29) Order Type and Number: Consent Order 2020-206-07-006
Order Date: November 2, 2020
Individual/Entity: **Peno Mediterranean Grill**
Facility: Peno Mediterranean Grill
Location: 7620 Rivers Avenue, Suite 375
North Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit Number: 10-206-11696
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Peno Mediterranean Grill (Individual/Entity) is a restaurant located in Charleston County, South Carolina. The Department conducted inspections on January 16, 2019, January 9, 2020, January 17, 2020, and February 27, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that a person in charge is certified by a food protection manager certification program that is recognized by the Conference for Food Protection.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **(\$400.00)**.

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

30) Order Type and Number: Consent Order 2020-206-07-007
Order Date: November 3, 2020
Individual/Entity: **Wal-Mart Stores East, LP DBA Wal-Mart #1359 Deli/Bakery**
Facility: Wal-Mart #1359 Deli/Bakery
Location: 7400 Rivers Avenue
North Charleston, SC 29406
Mailing Address: 702 SW 8th Street, Department 8916
Bentonville, AR 72716
County: Charleston
Previous Orders: None
Permit Number: 10-206-04309
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Wal-Mart #1359 (Individual/Entity) operates a deli/bakery located in Charleston County, South Carolina. The Department conducted inspections on September 11, 2019, February 11, 2020, February 21, 2020, and March 2, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that after cleaning and sanitizing, equipment and utensils were properly air-dried before contact with food (and may not be cloth dried) and failed to provide an irreversible registering temperature indicator for measuring the utensil surface temperature in hot water mechanical warewashing operations.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**\$400.00**) by December 3, 2020.

Update: No updates.

31) Order Type and Number: Consent Order 2020-206-04-023
Order Date: November 6, 2020
Individual/Entity: **Hooks BBQ**
Facility: Hooks BBQ
Location: 3566 Highway 9
Cheraw, SC 29520
Mailing Address: Same
County: Chesterfield
Previous Orders: None
Permit Number: 13-206-01495
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Hooks BBQ (Individual/Entity) is a restaurant located in Chesterfield County, South Carolina. The Department conducted inspections on February 15, 2018, February 14, 2019, and February 13, 2020. The Individual/Entity has violated the South

Carolina Retail Food Establishment Regulation as follows: failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**\$400.00**) by December 6, 2020.

Update: On December 18, 2020, the Department initiated a payment plan offer to the Individual/Entity per their request.

32)	<u>Order Type and Number:</u>	Consent Order 2020-206-04-027
	<u>Order Date:</u>	November 6, 2020
	<u>Individual/Entity:</u>	Lynn's Café
	<u>Facility:</u>	Lynn's Café
	<u>Location:</u>	101 West McGregor Street Pageland, SC 29728
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Chesterfield
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	13-206-01408
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Lynn's Café (Individual/Entity) is a restaurant located in Chesterfield County, South Carolina. The Department conducted inspections on February 21, 2018, April 19, 2018, March 18, 2019, and January 22, 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 and failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars (\$1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars (**\$1,600.00**) by December 6, 2020.

Update: On December 18, 2020, the Department initiated a payment plan offer to the Individual/Entity per their request.

33)	<u>Order Type and Number:</u>	Consent Order 2020-206-010
	<u>Order Date:</u>	November 16, 2020
	<u>Individual/Entity:</u>	Domino's Pizza
	<u>Facility:</u>	Domino's Pizza
	<u>Location:</u>	4420 Highway 24 Anderson, SC 29621

Mailing Address: Same
County: Anderson
Previous Orders: 2018-206-01-024 (\$200.00);
2019-206-01-027 (\$500.00)
Permit Number: 04-206-03307
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Domino's Pizza (Individual/Entity) is a restaurant located in Anderson County, South Carolina. The Department conducted an inspection on March 9, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Individual/Entity corrected all violations prior to the issuance of the Order. 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 complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

On Site Wastewater Enforcement

34) Order Type and Number: Administrative Order 20-109-OSWW
Order Date: November 5, 2020
Individual/Entity: **Johnny Strobles**
Facility: Johnny Strobles
Location: 1145 Valentine Lane
Greer, SC 29651
Mailing Address: 719 Sunnyglen Court
Greer, SC 29651
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Johnny Strobles (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on September 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 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 all requirements of the Order. This Order has been closed.

35) <u>Order Type and Number:</u>	Administrative Order 20-112-OSWW
<u>Order Date:</u>	November 17, 2020
<u>Individual/Entity:</u>	Retire 2, LLC and Alvaro and Brenda Laureano
<u>Facility:</u>	Retire 2, LLC and Alvaro and Brenda Laureano
<u>Location:</u>	8211 North Highway 11 Tamassee, SC 29686
<u>Mailing Address:</u>	203 High Point Court Seneca, SC 29672 208 Ashley Road Clemson, SC 29631
<u>County:</u>	Oconee
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Retire 2, LLC and Alvaro and Brenda Laureano (Individual/Entity) own property located in Oconee County, South Carolina. The Department conducted an investigation on August 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 business 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: Upon further evaluation by a Department licensed OSWW contractor, the system needed increased maintenance frequency instead of a one-time repair. The Department licensed OSWW contractor has provided a specific schedule that has been agreed upon between the Individual/Entity and the OSWW contractor.

* 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: January 7, 2021

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

From: Bureau of Environmental Health Services

Re: Notice of Proposed Regulation Amending R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products

I. Introduction

The Bureau of Environmental Health Services (“Bureau”) proposes the attached Notice of Proposed Regulation amending R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products, for publication in the January 22, 2021, *South Carolina State Register* (“*State Register*”). Legal authority resides in S.C. Code Sections 44-1-140 and 44-1-150, which allow the Department of Health and Environmental Control (“Department”) to promulgate regulations for the production, storing, labeling, transportation, and selling of milk and milk products, filled milk and filled milk products, imitation milk and imitation milk products, synthetic milk and synthetic milk products, milk derivatives, and any other products made in semblance of milk or milk products. Furthermore, S.C. Code Section 44-1-150 allows for the enforcement of these regulations. 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 R.61-34, Raw Milk for Human Consumption, the Department provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Bureau proposes amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream and buttermilk, and any additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing (if allowed). The proposed revisions would also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance (“PMO”).

2. Pursuant to R.61-34.1, Pasteurized Milk and Milk Products, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Bureau proposes adopting requirements of the 2019 PMO through amendment of R.61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO would enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Bureau further proposes clarification of requirements for potable water sources.

3. The Bureau also proposes changes for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvements. Proposed amendments to both regulations also include updates to administrative and enforcement provisions.

2. The Department had a Notice of Drafting published in the March 27, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from forty-eight parties by the April 27, 2020, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

forty-eight parties by the April 27, 2020, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

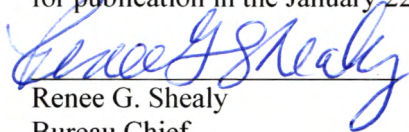
3. Appropriate Department staff conducted an internal review of the proposed amendments on December 3, 2020.

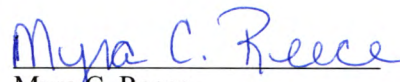
4. The Bureau conducted two separate stakeholder meetings on December 7, 2020. The first meeting for R.61-34.1 had five stakeholders in attendance, and the second meeting for R.61-34 had twenty-one stakeholders in attendance. Comments made in these meetings included support for the amendments, suggestions for terminology, and discussion of the scope of raw milk products addressed in R.61-34. The Bureau considered these comments and, where appropriate, incorporated them into these proposed regulations.

5. The Bureau will hold additional stakeholder meetings during the public comment period for the Notice of Proposed Regulation to ensure that all concerns have been addressed. Stakeholders have expressed appreciation for the Department's industry engagement.

III. Request for Approval

The Bureau respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the January 22, 2021, *State Register*.


Renee G. Shealy
Bureau Chief


Myra C. Reece
Director

Attachments:

- A. Notice of Proposed Regulation
- B. Notice of Drafting published in the March 27, 2020, *State Register*
- C. Summary of Public Comments Received and Department Responses

ATTACHMENT A

**STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk
Products**

January 7, 2021

Document No. _____

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

Statutory Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

61-34. Raw Milk for Human Consumption.
61-34.1. Pasteurized Milk and Milk Products.

Preamble:

Pursuant to R.61-34, Raw Milk for Human Consumption, the Department of Health and Environmental Control (“Department”) provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Department proposes amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream and buttermilk, and to add additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing. The proposed revisions would also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance (“PMO”).

Pursuant to R.61-34.1, Pasteurized Milk and Milk Products, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Department proposes adopting requirements of the 2019 PMO through amendment of R.61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO would enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Department further proposes clarification of requirements for potable water sources.

The Department also proposes changes for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvements. Proposed amendments to both regulations also include updates to administrative and enforcement provisions.

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 March 27, 2020, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

In all sections of the proposed amendments to R.61-34 and R.61-34.1, capitalization, punctuation, spelling, and grammatical errors have been corrected. The addition of the word “raw” and “raw milk product” have been added to all relevant citations of R.61-34 for clarity and comprehensiveness. In R.61-34.1, all references to the 2013 version of the Grade “A” Pasteurized Milk Ordinance (PMO or Ordinance) have been changed to the 2019 version. For brevity and space, these modifications are not listed.

R.61-34, Raw Milk for Human Consumption

Statutory Authority

Added: Statutory authority under Sections 44-1-140(3) and 44-1-150.

Table of Contents

Modified: Replaced “bottling” with “and Plants Producing and Packaging” in Section IV title (formerly Section V title) for clarity.

Modified: Moved “Labeling” section to after “The Examination of Raw Milk and Raw Milk Products for Human Consumption” section to improve the readability and flow of the regulation.

Added: New section VIII “Standards for Further Processing of Raw Milk Products”; renumbered the remaining sections.

Added: New section XIII “Delayed Implementation”; renumbered the remaining section.

In Section I, Definitions and Standards.

Amended: All definition titles were changed from all capitalization to capitalizing the first letter of each word for consistency.

Added: Definition of “Adulterated” to provide guidance and clarity for the regulated community as to what conditions will constitute adulteration of raw milk and raw milk products.

Added: Definition of “Buttermilk” as a raw milk product allowed in accordance with this regulation.

Deleted: “Cooling Pond” as a term no longer referenced in the regulation. Cooling ponds are not a commonly used facility at SC dairy farms.

Added: Definition of “Craft Usage” to clarify raw milk may not be sold without a permit.

Added: Definition of “Cream” as a raw milk product allowed in accordance with this regulation.

Modified: Definition of “Drug” for simplicity and clarity, removed the term “articles” and changed to “a substance”.

Modified: Definition of “Milk or Milk Products Distributor” to clarify that the term includes all entities distributing products produced and packaged at a permitted raw milk facility.

Added: Definition of “Milk or Milk Products Plant” for clarity in regard to further processing.

Modified: Definition of “Officially Designated Laboratory” to add “SC” designation before “Grade A” for clarity and precision.

Modified: Definition of “Person” to include producers, distributors, and plant operators.

Added: Definition of “Raw Milk” for clarity.

Added: Definition of “Raw Milk Products” for clarity and to specify that raw milk products that may be permitted and sold under this regulation are limited to unpasteurized buttermilk and cream.

Added: Definition of “Risk” to provide guidance and clarity for the regulated community as to what constitutes a risk.

Modified: Item B to strike the term “Grade ‘A’” to clarify that all raw milk and raw milk products shall meet the requirements stated. Item B is also modified to incorporate raw milk products and expand the location where a raw milk product can be produced, provided that the location is still under the control of the producer. This provision will allow the use of “Shared Use Kitchens” permitted under R.61-25, Retail Food Establishments, for further processing of raw milk products.

In Section II, Adulterated or Misbranded Raw Milk or Raw Milk Products.

Modified: Item A to add “barter” for clarity and comprehensiveness.

Modified: Item C to clarify when raw milk or raw milk products can be examined.

Modified: Item D to clarify that raw milk may not contain more than 3% water and to incorporate former Item E to indicate that a cryoscope and the freezing point test will be used to determine whether water has been added. Amended to clarify Department process for observation and collection of samples and enforcement after a dairy farm’s violation of its individual freezing point standard within a two-year period. Renumbered the remaining item. Corrected math error in Celsius to Fahrenheit conversion.

Modified: Item E (former Item F) to update administrative provisions regarding actions taken when raw milk or raw milk products are found to be adulterated. The reference to a “Grade ‘A’” permit is also modified to specify “SC Grade ‘A’” for clarity and precision.

In Section III, Permits.

Modified: Item A to add “barter” and to specify that all raw milk or raw milk products in commerce used for craft purposes must be from a permitted dairy.

Added: Item B to clarify that the distribution of legally permitted and properly labeled raw milk and raw milk products by distributors and retailers does not require a permit so long as the product has not been repackaged or relabeled.

Added: A new Item C to make clear Department authority to investigate complaints of improperly distributed raw milk and raw milk products distributed by non-permitted persons. Renumbered remaining items.

Modified: Item D to clarify that permits may not be used by anyone other than the permit holder.

Modified: Item E to clarify that every producer of raw milk or raw milk products shall hold a valid Department permit prior to beginning operation.

Added: Item F to clarify that, except for raw milk cheese produced in accordance with R.61-36, Manufactured Grade Dairy Products, the production, distribution, storage, and sale of unpasteurized milk products other than Department-permitted unpasteurized buttermilk and cream are prohibited.

Added: Item G to clarify that the addition of flavorings or other ingredients other than cultures, citric acid, or salt needed to produce buttermilk are prohibited. Renumbered remaining section.

Modified: Item H to replace “difficulty in complying” with “noncompliance” for clarity.

In Section IV, Inspection of Dairy Farms and Plants Producing and Packaging Raw Milk and Raw Milk Products for Human Consumption.

Modified: Item A to add a reference to dairy plants for comprehensiveness, and to remove the “one size fits all” requirement for inspections and instead have the inspection frequency to be based on the risk level associated with the operation, or as otherwise deemed necessary by the Department. This will align the frequency for inspections for this regulation with other Departmental food safety regulations.

Modified: Items B- F to update administrative procedures, to reorganize for better flow and clarity of the inspection process, and to remove unnecessary requirement for posting of the inspection report at the farm.

In Section V, The Examination of Raw Milk and Raw Milk Products for Human Consumption.

Modified: Item A to correct terminology.

Modified: Item B to correct section reference.

Modified: Item D to remove specific sampling schedule and instead to base sampling on the level of risk of the product.

Deleted: Items E and F as unnecessary for regulatory purposes. These sampling processes conducted by the Department will be included in internal Department standard operating procedures.

Modified: E. to clarify the language and section referenced regarding permit suspensions related to sampling.

Deleted: H. as unnecessary for regulatory purposes, these sampling processes that are conducted by the Department will be included in internal Department standard operating procedures (SOP’s)

Modified: F. to clarify that samples that are positive for pathogenic organisms shall be considered to be an imminent health hazard and shall not be offered for sale.

Deleted: L-N. as unnecessary for regulatory purposes, these sampling processes that are conducted by the Department will be included in internal Department standard operating procedures (SOP’s).

In Section VI, Labeling.

Added: B. to prevent the use of misleading statements on the label of products.

Modified: C.3. to add additional consumer advisory label requirement “Consuming raw milk products may increase your risk of foodborne illness.”. This will align R.61-34’s consumer advisory with the requirements of R.61-25 Retail Food Establishments (Ch. 3-603 Consumer Advisory) and may facilitate the sale of raw milk and raw milk products at retail stores by eliminating the current requirement for a placard at the point of sale in these facilities.

Added: D. to require that raw milk that has had the cream skimmed off it be labeled as such so that the consumer knows that they are purchasing a product that is not “straight from the cow or goat’s teat”.

Added: E. to clarify that if the term Grade A is used, it must be in conjunction with “SC” on the label.

Added: Item F to clarify that descriptive labeling terms such as “wholesome” and “healthy” shall not be used and that the label shall not be false or misleading.

Added: Item G to clarify that the permit holder’s label and permit number are not transferable and may not be used by anyone other than the permit holder.

In Section VII, Standards for Raw Milk and Raw Milk Products for Human Consumption.

Modified: The entire section to replace “milkhouse” with current industry terminology of “milkroom or processing room”.

Added: Language in Table 1 to address temperature standards for raw milk products, to remove outdated internal citation, and to clarify that all pathogenic organisms may not exceed zero organisms.

Added: Language in first note after Table 1 to specify when additional tests may be conducted.

Added: Second note after Table 1 to specify when pathogenic testing is to be conducted.

Modified: Subitem B.1.a to clarify that the Department will direct how to discard milk.

Modified: Subitem B.1.b to remove unnecessary information.

Modified: Subitem B.1.i.(2) to replace “deleterious” with “harmful” for clarity and simplicity.

Modified: Subitem B.2.a to remove unnecessary requirements.

Modified: Subitem B.2.f to remove unnecessary language.

Added: Subitem B.2.h to allow for the granting of construction variances and waivers when, in the opinion of the Department, they will not create a hazard or nuisance.

Deleted: Subitem B.3.d as this is redundant and covered under B.3.a. Renumbered following subitem.

Deleted: Subitem B.3.f as this is no longer applicable to modern dairies. Renumbered following subitem.

Deleted: Subitem B.4.e as this is no longer applicable to SC dairies. Renumbered following subitems.

Modified: Subitem B.5.a to address further processing of raw milk products.

Modified: Subitem B.7.a to remove reference to pit privies and to allow limited use of portable chemical toilets for consistency with onsite wastewater requirements.

Modified: Subitem B.7.b to remove reference to screening of earth pit vents as these are no longer used on dairy farms.

Deleted: Subitem B.7.c as privies are no longer used on dairy farms; renumbered remaining subitems.

Modified: Subitem B.8.g to update requirement for samples for bacteriological examination from every three years to every year.

Deleted: Subitems B.8.g.1-2 as unnecessary.

Deleted: Subitem B.8.i as unnecessary for regulatory purposes. These sampling processes conducted by the Department will be included in internal Department standard operating procedures. Renumbered the remaining subitem.

Modified: Subitem B.9.e to update internal citation to Section IX.

Deleted: The note in B.9.n as unnecessary, as it was only informational.

Modified: Subitem B.11.b.(3) to clarify that the sanitization method must be approved by the FDA, EPA, or the Department.

Modified: Subitem B.12.a to add reference to AMI milking equipment for comprehensiveness.

Added: Subitem B.15.b by renumbering of “Note” to (7) and removed “Note” for clarity and improved codification.

Modified: Subitem B.17.c by deleting unnecessary duplicate language.

Modified: Subitem B.17.d to replace “concerned” with “associated” for clarity.

Added: Subitem B.18.b to establish temperature requirements for all finished, processed, and packaged raw milk and raw milk products after processing, during storage, and during transportation; renumbered remaining subitem.

Deleted: Former Subitem B.18.c as unnecessary, as this type of system is not in use at raw milk dairies.

In Section VIII, Standards for Further Processing of Raw Milk Products.

Added: New section in its entirety to establish standards for the further processing of raw milk into raw buttermilk and raw cream.

In Section IX, Bottling, Packaging, Container Filling and Container Closure/Sealing.

Modified: Subitem A.1 replaced “milkhouse” with “milkroom and processing rooms.”

In Section X, Animal Health.

Modified: Item B to remove specific brucellosis and tuberculosis testing requirements from the regulation and update reporting requirement to include the State Veterinarian office in accordance with applicable law. The provision is also modified to clarify that all animals producing raw milk and raw milk products must be free of brucellosis and tuberculosis.

Deleted: Subitems B.1-4 as unnecessary and duplicative as this is under the jurisdiction of the office of the State Veterinarian.

In Section XI, Recall.

Modified: to add references to “distributor” for clarity and comprehensiveness.

In Section XII, Enforcement.

Added: Item B to include language that clarifies that civil monetary penalties may be used along with suspensions and revocations of permits. Renumbered remaining items.

Deleted: Subitem C.1 (former subitem B.1) and moved its language, amended as appropriate, to section to subitem C.2 for better flow of the section. The language is amended to clarify and update enforcement procedures for immediate suspension of a permit.

Added: New subitem C.1.c. to clarify that permits may be suspended for the violation of a permit or an order. Renumbered remaining subitems.

Modified: Item D to clarify and update enforcement procedures for revocation of a permit and to align language with other Departmental food safety regulations.

Modified: Subitem E.1 to replace “make” with “submit a” for clarity.

Modified: Subitem E.2 to clarify timeframe and conditions for reinstatement of a permit.

Modified: Subitem E.3 to update internal citation.

Modified: Subitem E.4 to replace “make” with “submit a” for clarity and also to clarify that past history may include previous enforcement, suspension, or revocation history.

Added: Subitem E.5 to specify a timeframe and conditions for requesting a new permit after a permit revocation.

Deleted: Former Item E as duplicative of other regulatory and statutory language.

In Section XIII, Delayed Implementation.

Added: New section in its entirety to allow for delayed implementation of labeling changes. This will allow existing permit holders to use the supplies of labels they have on hand and eliminate any economic impact of the labeling changes.

In Section XIV, Severability Clause.

No Changes

61-34.1, Pasteurized Milk and Milk Products

Modified: The entire regulation to replace “Regulatory Agency” with “Department”. Added “or milk products” where applicable for clarity.

In Section I, Applicability of the Grade “A” Pasteurized Milk Ordinance, 2019 Revision

Modified: Item A to clarify that references to the Pasteurized Milk Ordinance may appear as PMO “or Ordinance,” for clarity.

Modified: Subitem A.3 to specify that Section 7 includes specific items for clarity.

Modified: Subitem C.1.a to correct reference.

Added: Subitem C.1.c to specify language in the PMO referring to South Carolina for clarity.

Added: Subitem C.1.d to clarify that specified references to Section 3 of the PMO will include Section C.3 of R.61-34.1 and applicable portions of Section 3 of the PMO.

Modified: Subitem C.2 to remove “exceptions” and reword for clarity.

Modified: Subitem C.2.a, second paragraph, to clarify that milk may not contain more than 3% water; to indicate that a cryoscope and freezing point test will be used to determine whether water has been added; and to clarify Department process for observation and collection of samples and enforcement after a dairy farm’s violation of its individual freezing point standard within a two-year period. The third paragraph is amended to reference use of hold orders, reference “sales or distribution,” and to clarify that a recall would be initiated when a drug residue test is positive. Corrected math error in Celsius to Fahrenheit conversion.

Modified: Subitem C.3.a to clarify section of the PMO that is not included in this regulation.

Modified: Subitem C.3.b, Issuance of Permits, first paragraph, to clarify that: a permit must be obtained prior to the beginning of operation; all parts of the operation must be in compliance with the regulation to receive a permit; and permits are not transferable. Amended subitem C.3.b, Issuance of Permits, second and fourth paragraphs, to update relevant references to the “Ordinance” to specifically reference R.61-34.1 for clarity and comprehensiveness.

Modified: Subitem C.3.b, Suspension of Permit, to update and align the language with other Departmental food safety regulations and clarify and update enforcement procedures.

Added: Subitem C.3.b, Revocation of Permit, to codify enforcement procedures related to revocation of a permit.

Modified: Subitem C.3.b, Reinstatement of Permits, to add that an application for reinstatement for a suspended permit must be in writing and address all the correction of violations. Also added paragraph addressing the timeframe and conditions for reapplying for a new permit after a permit revocation.

Modified: Subitem C.4 to delete requirement to post the inspection report at the facility as unnecessary.

Added: Subitem C.4.a to clarify that non-IMS plants do not have to comply with Paragraph 3.c on page 22 in the PMO, 2019 Revision.

Added: Subitem C.4.b to replace the deleted section of C.4 and to provide for the use of electronically transmitted reports.

Added: Subitem C.4.c to clarify the process for requesting an extension of time to correct a violation.

Added: Subitem C.5 to address the requirement of the water system to meet at a minimum the standard of a state category 3 small water system.

Modified: Subitem C.6 to replace the language of Section 15 of the PMO in its entirety to include South Carolina specific authorities administrative provisions. This section also clarifies that the appendices of the PMO are also adopted and clarifies the range of enforcement procedures that may apply in response to a violation of the regulation, the PMO, a permit, or order.

Added: Subitem C.9 to clarify that Appendix T of the PMO is adopted except that it does not apply to non-IMS listed plants.

Added: Subitem C.10 to clarify that the Department regulates cottage cheese, dry curd cottage cheese, and reduced fat or low-fat cottage cheese under the terms of the PMO.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Sandra D. Craig of the Bureau of Environmental Health Services; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; craigsd@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on February 22, 2021, 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 March 11, 2021, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. Because of ongoing COVID-19 concerns, interested persons who do not wish to appear in person may participate in the public hearing by calling in through an assigned conference line. These participants may register in advance by visiting the DHEC Events webpage (www.scdhec.gov/events) and selecting the appropriate Board meeting date. A link to register will be provided on the accompanying meeting information page. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: <http://www.scdhec.gov/Agenda>.

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

Preliminary Fiscal Impact Statement

There are no anticipated new costs associated with the implementation of these regulations to the state or its political subdivisions.

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 REGULATIONS:

61-34, Raw Milk for Human Consumption.

Purpose: The Department provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Department proposes amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream and buttermilk, and any additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing. The proposed revisions would also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance (“PMO”).

61-34.1, Pasteurized Milk and Milk Products.

Purpose: The Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Department proposes adopting requirements of the 2019 PMO through amendment of R.61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO would enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Department further proposes clarification of requirements for potable water sources.

The Department also proposes changes for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvement. Proposed amendments to both regulations also include updates to administrative and enforcement provisions.

Legal Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

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

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

The purpose of R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products, is to safeguard public health and provide consumers safe, unadulterated milk and milk products manufactured in South Carolina for sale and distribution in state, and pasteurized milk and milk products sold and distributed both in and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of milk and milk products.

The Department last amended R.61-34 in 2009 and R.61-34.1 in 2015. Since those amendments there have been changes in the milk and milk products industry and numerous revisions to the PMO. The Department’s regulations are based on the PMO and, in the case of R.61-34.1, the procedures of the National Conference on Interstate Milk Shippers (NCIMS), specifically Sections VI and VII of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the NCIMS* and the *FDA PMO, 2019 Revision*, which provide that a state’s dairy regulation must be at least as stringent as the PMO to meet requirements for interstate commerce of pasteurized milk and milk products. Updating R.61-34 and R.61-34.1 to the most current amendments of the PMO ensures the regulations reflect current standards and sanitation practices. Furthermore, South Carolina milk producers and processors will be able to continue shipment of milk and milk products in interstate commerce and market their milk products as Grade “A.” Updating R.61-34.1 to reflect the current federal standards also serves to reduce administrative

burdens on the regulated community by facilitating streamlined inspections and compliance under both state and federal requirements.

The Department proposes amending the provisions of R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products, to incorporate relevant standards of the updated federal ordinance. In addition, the Department proposes amending the provisions of R.61-34 to incorporate sanitation standards to address the further processing of raw milk for human consumption. These changes serve to make clear those raw milk products that may be produced and sold pursuant to a Department permit and to specify standards for these products to promote clarity and protection of public health.

The proposed amendments to these regulations also include updates to state-specific administrative and enforcement provisions that serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated new costs associated with the implementation of these regulations. The proposed amendments will benefit public health by ensuring safe, unadulterated dairy food and dairy food products on the farm, at manufacturing plants, and throughout the distribution chain. The proposed amendments to these regulations also serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. The amendment of R.61-34 and R.61-34.1 will allow the regulations to be in compliance with the most current food safety science regarding milk and milk products. Furthermore, for R.61-34.1 to be in compliance with the FDA Grade “A” Interstate Milk Shippers (IMS) procedures that govern the shipment of milk and milk products across state boundaries, the regulation may not be more than six (6) years behind the current NCIMS procedures and the PMO. By updating selected sections of R.61-34.1 to the 2019 PMO by reference, the regulation will meet this criteria and South Carolina milk producers will be able to continue to ship milk and milk products outside the limits of the state.

UNCERTAINTIES OF ESTIMATES:

None

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of these regulations will not compromise the protection of the environment or the public health. The proposed regulations will help to ensure that consumers are receiving safe, unadulterated dairy products. The amendment of R.61-34 and R.61-34.1 also provides effective means of reducing the risks of foodborne illnesses at dairy farms and dairy manufacturing plants, thus protecting consumers and industry from potentially devastating public health consequences and financial loss.

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

There will be no adverse effect on the environment if the regulations are not implemented.

Failure to adopt these amendments would prevent implementation of the latest sanitary standards and a comprehensive approach to food safety management needed in addressing food protection in the dairy industry. This could have a detrimental effect on the health of South Carolina’s citizens and visitors.

Statement of Rationale:

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

The Department proposes these amendments to meet the latest sanitation requirements for providing safe, unadulterated pasteurized and unpasteurized dairy products to consumers and to ensure a comprehensive approach to food safety management in the dairy industry. Furthermore, the amendments to R.61-34.1 will satisfy requirements for the shipment of milk and milk products produced under this regulation to be shipped outside the limits of South Carolina.

Text:

~~Indicates Matter Stricken~~

Indicates New Matter

61-34. Raw Milk for Human Consumption.

Statutory Authority:

S.C. Code Sections: 1976 Code Section(s) 44-1-140(3) and 44-1-150

Table of Contents

SECTION I.	Definitions and Standards
SECTION II.	Adulterated or Misbranded <u>Raw Milk or Raw Milk Products</u>
SECTION III.	Permits
SECTION IV.	Labeling <u>Inspection of Dairy Farms and Plants Producing and Packaging Raw Milk and Raw Milk Products for Human Consumption</u>
SECTION V.	Inspection of Dairy Farms bottling Raw Milk for Human Consumption <u>The Examination of Raw Milk and Raw Milk Products for Human Consumption</u>
SECTION VI.	The Examination of Raw Milk for Human Consumption <u>Labeling</u>
SECTION VII.	Standards for Raw Milk <u>and Raw Milk Products for Human Consumption</u>
SECTION VIII.	<u>Standards for Further Processing of Raw Milk Products</u>
SECTION VIII <u>IX.</u>	Bottling, Packaging, Container Filling, and Container Closure/Sealing
SECTION IX <u>X.</u>	Animal Health
SECTION X <u>XI.</u>	Recall
SECTION XI <u>XII.</u>	Enforcement
<u>SECTION XIII.</u>	<u>Delayed Implementation</u>
SECTION XII <u>XIV.</u>	Severability Clause

SECTION I. Definitions and Standards.

A. The following definitions shall apply in the interpretation and the enforcement of this Regulation:

1. ~~ABNORMALITIES OF MILK~~Abnormalities of Milk means

a. Abnormal Milk: Milk that is visibly changed in color, odor, and/or texture.

b. Undesirable Milk: Milk that, prior to the milking of the animal, is known to be unsuitable for sale, such as colostrum.

c. Contaminated Milk: Milk that is not sellable or is unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements or

treatment with medicines or insecticides not approved for use on dairy animals by the United States Food and Drug Administration (FDA) or the United States Environmental Protection Agency (EPA).

2. Adulterated: means raw milk or raw milk products are deemed to be adulterated if the product:
- a. Bears or contains any poisonous or deleterious substance in a quantity that may render it injurious to health;
 - b. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by state or federal regulation, or is in excess of such tolerance if one has been established;
 - c. Consists, in whole or in part, of any substance unfit for human consumption;
 - d. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;
 - e. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
 - f. Has any substance added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;
 - g. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342); or
 - h. Contains any animal drug residues.

~~23. AUTOMATIC MILKING INSTALLATION~~ Automatic Milking Installation (AMI) means the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning, and sanitation.

4. Buttermilk means a dairy product that is produced by culturing milk or cream with characterizing microbial organisms and which contains at least 3.25% milkfat and at least 8.25% milk solids not fat.

~~35. CLEAN~~ Clean means ~~direct product contact surfaces that have had~~ the effective and thorough removal of product and/or contaminants from direct product contact surfaces.

~~46. CODE OF FEDERAL REGULATIONS~~ Code of Federal Regulations (CFR) means the current Code of Federal Regulations.

~~57. COMMON NAME~~ Common Name means the generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc.

~~6. COOLING POND~~ a man-made structure designed for the specific purpose of cooling cows.

8. Craft Usage means the use of raw milk to create products such as soap, candles, or other non-edible products.

9. Cream means a dairy product that is composed of the higher-fat layer separated from the top of milk and which contains at least 18% milkfat.

~~7~~10. ~~DAIRY FARM~~Dairy Farm means any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hooved mammals) are kept for milking purposes and from which a part or all of the milk or milk products ~~is~~are provided, sold, or offered for sale.

~~8~~11. ~~DEPARTMENT~~Department means the South Carolina Department of Health and Environmental Control and its representatives.

~~9~~12. ~~DRUG~~Drug means:

a. ~~articles~~A substance recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them;

b. ~~articles intended for use~~A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease ~~in man or other animals~~;

c. ~~articles~~A substance (other than food) intended to affect the structure or any function of the body ~~of man or other animals~~; and

d. ~~articles~~A substance intended for use as a component of ~~any articles~~ a substance specified in clause a, b, or c but does not include devices or their components, parts, or accessories.

~~10~~13. ~~GOAT MILK~~Goat Milk means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this Regulation.

~~11~~14. ~~MILK~~Milk means the normal lacteal secretion of hooved mammals, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Regulation. Hooved mammals milk shall include bovine milk, goat milk, sheep milk, ~~and~~ water buffalo milk, etc.

~~12~~15. ~~MILK DISTRIBUTOR~~Milk or Milk Products Distributor means any person who offers for sale milk or milk products that ~~has~~have been packaged at ~~the same~~ a permitted location ~~that it was produced~~.

16. Milk or Milk Products Plant means any place, premises, or establishment where milk or milk products are collected, handled, processed, and stored or prepared for distribution.

~~13~~17. ~~MILK PRODUCER~~Milk or Milk Products Producer means any person who operates a dairy farm and provides, sells, or offers milk or milk products for sale that ~~was~~were produced at the farm.

~~14~~18. ~~MISBRANDED MILK~~Misbranded Milk or Milk Product means any milk or milk product ~~deemed to be misbranded~~ when:

a. ~~¶~~The product's container bears or accompanies any false or misleading written, printed, or graphic matter;

b. ~~¶~~The milk or milk product does not conform to the definitions as contained in this Regulation; and/or

c. ~~¶~~The product is not labeled in accordance with this Regulation.

~~1519. OFFICIALLY DESIGNATED LABORATORY~~Officially Designated Laboratory means a commercial laboratory authorized to do official work by the Department or a milk industry laboratory officially designated by the Department for the examination of producer samples of SC Grade A raw milk and raw milk products for human consumption and commingled milk tank truck samples of raw milk and raw milk products for drug residues and bacterial limits.

~~1620. PERSON~~Person means any individual, producer, distributor, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

21. Raw Milk means milk that has not received any heat treatment such as pasteurization or any other further processing.

22. Raw Milk Products means unpasteurized buttermilk or cream.

23. Risk means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

~~1724. SANITIZATION~~Sanitization means the application of any effective method or substance to a clean surface for the destruction of pathogens and of other organisms as far as is practical. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers and shall be acceptable to the Department.

~~1825. SHEEP MILK~~Sheep Milk means the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this Regulation.

~~1926. WATER BUFFALO MILK~~Water Buffalo Milk means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Regulation.

B. Standards.

All ~~Grade "A"~~raw milk and raw milk products for human consumption shall be bottled, packaged, and sealed at the same location where ~~it was~~they were produced, or, in the case of raw milk products, at a location under the direct control of the raw milk producer that has been approved by the Department, and ~~¶~~ all raw milk and raw milk products shall conform to the chemical, physical, bacteriological, and temperature standards ~~and~~ as well as the sanitation requirements of this Regulation.

SECTION II. Adulterated or Misbranded Raw Milk or Raw Milk Products.

A. No person shall, within ~~the State of~~South Carolina or its jurisdiction, produce, provide, sell, offer, barter, or expose for sale, or have in possession with intent to sell any raw milk or raw milk product that is adulterated or misbranded.

B. Any adulterated or misbranded raw milk or raw milk product may be impounded by the Department and disposed of in accordance with applicable laws or regulations.

C. ~~Milk~~ Raw milk and raw milk products shall will be examined by the Department ~~as often as necessary~~ in the course of routine or complaint inspections, outbreak investigations, or as otherwise deemed appropriate by the Department to determine that ~~it is~~ they are not adulterated or misbranded. The Department may, upon written notice to the owner or person in charge, place a hold order on any raw milk or raw milk product that it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, raw milk and raw milk products shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on raw milk or raw milk products by the Department, and neither such raw milk or raw milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department ~~except~~ if ordered by a court of competent jurisdiction.

D. Adding water to raw milk will be considered a violation of this Regulation if the raw milk contains in excess of three percent (3%) water. A cryoscope shall be used to determine percentage of water by measuring the freezing point of the raw milk. When the freezing point of raw milk is greater than 34.32.945°F: (-0.525°C-), the farm shall be notified that apparently the raw milk apparently contains added water. If a second violation of this freezing point standard occurs within two (2) years, an observed milking or operation of processing operations shall may be observed, conducted and samples will be collected and analyzed. The freezing point obtained from raw milk collected during the observation shall be used to determine a definite freezing point standard from the individual farm. A violation of the determined freezing point standard for a specific operation by over three (3%) percent within two (2) years of setting the standard for the individual farm shall call for a two (2) calendar day permit suspension or equivalent.

~~E. A cryoscope shall be used to determine adulteration by water.~~

~~FE.~~ When raw milk or raw milk products is are found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, it they shall be impounded placed under a hold order and additional samples analyzed. Milk-Raw milk or raw milk products found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals raw milk or raw milk products are positive for drug residues, the raw milk or raw milk products shall be disposed of in a manner that removes it from the human or animal food chain. The Department shall immediately suspend the producer's SC Grade "A" permit, or equally effective measures shall be taken, to prevent the sale or distribution of raw milk or raw milk products containing drug residues, and a penalty shall be imposed. Future sales or distribution are prohibited until subsequent testing reveals the raw milk or raw milk products is are free of drug residue. The SC Grade "A" producer's permit may be reinstated to allow the sale or distribution of raw milk or raw milk products for human food when a representative sample taken by the Department from the producer's raw milk or raw milk products is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated, and an investigation shall be made to determine the cause. The farm inspection must be completed by the Department to determine the cause of the residue and actions that need to be taken to prevent future violations, including on-farm changes in procedures necessary to prevent future occurrences as recommended by the Department.

SECTION III. Permits.

A. It shall be unlawful for any person who does not possess a permit from the Department to manufacture, bring into, send into, or receive into South Carolina or its jurisdiction, have in storage, sell, barter, or offer for sale therein, or offer to give away any raw milk or raw milk products defined in this Regulation, including but not limited to raw milk for craft usage.

B. Raw milk and raw milk products that have been manufactured under the provisions of this Regulation may be further distributed or sold at retail locations in South Carolina by distributors and retailers.

Distributors and retailers are not required to have a permit, provided that the product has not been repackaged or relabeled.

C. Although distributors and retailers listed in Section III.B do not require a permit, the Department retains the authority to conduct an investigation in response to a complaint. The Department may require corrective action and issue orders as deemed necessary in response to food safety or health risks identified during the investigation.

BD. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Permits shall not be transferable to other persons and/or locations or used by a person other than the permit holder.

CE. Every milk producer and distributor of raw milk or raw milk products for human consumption shall hold a valid permit issued by the Department prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this Regulation.

F. The production, distribution, storage, and sale of unpasteurized milk products other than the raw milk products defined in this Regulation (unpasteurized buttermilk and cream) are prohibited in South Carolina and will be considered to be violations of this Regulation, except that aged raw milk cheese may be produced in accordance with the provisions of R.61-36, Manufactured Grade Dairy Products.

G. The addition of flavoring or other ingredients to raw milk or raw milk products other than cultures, citric acid, or salt needed for the processing of buttermilk is prohibited.

DH. The Department may deny a permit to produce, distribute or sell raw milk or raw milk products for human consumption when the applicant or facility has a history of difficulty in complying noncompliance with other standards, regulations, or statutes governing milk and milk products.

SECTION IV. Labeling.

~~— A. All bottles, containers, and packages enclosing raw milk for human consumption shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, the Code of Federal Regulations, and in addition shall comply with the applicable requirements of this section.~~

~~B. All bottles, containers, and packages enclosing raw milk for human consumption shall be conspicuously marked with:~~

~~— 1. the words “Grade A Raw” on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.~~

~~— 2. the identity of the farm where packaged. This identity shall include the name, address, and the Department Permit Number.~~

~~— 3. the following information statement, in print no smaller than six (6) point font, shall be included on the package: This is a raw milk product that is not pasteurized.~~

~~4. the common name of the hooved mammal producing the milk shall precede the name of the milk when the product is made from other than cattle’s milk. As an example, “Goat,” “Sheep,” “Water Buffalo,” or “Other Hooved Mammal” milk respectively.~~

~~C. The Department shall not permit the use of any misleading marks, words, or endorsements upon the label. The Department may permit the use of registered trade designs or similar terms on the bottle cap or label, when, in its opinion, they are not misleading and are not used to obscure the labeling required by the Regulation. Descriptive labeling terms such as must not be used in conjunction with the Grade "A" designation or name of the raw milk and must not be false or misleading.~~

SECTION IV. Inspection of Dairy Farms and Plants Bottling Producing and Packaging Raw Milk and Raw Milk Products for Human Consumption.

A. Each dairy farm or plant manufacturing raw milk or raw milk products for human consumption shall be inspected by the Department prior to the issuance of a permit. Following the issuance of a permit, the Department shall inspect each dairy farm or plant at least once every three (3) months. ~~For the purposes of determining the inspection frequency for dairy farms producing raw milk for human consumption, the interval shall include the designated three (3) month period in addition to the remaining days of the month in which the inspection is due a frequency determined by the risk level assigned to the product(s) being manufactured or distributed, or as otherwise deemed necessary by the Department.~~ Inspections of dairy farms ~~shall~~ will be made at milking time ~~as often as~~ when possible.

B. ~~Should a violation of any requirement set forth in Section VII be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection shall be used to determine compliance with the requirements of Section VII. Any violation of the same requirement of Section VII on such second inspection shall call for enforcement action pursuant to Section XI of this Regulation provided that when the Department finds that a critical processing element violation involving conditions whereby direct contamination of raw milk is occurring, the Department shall take immediate action to prevent further movement of such milk until such violations of critical processing element(s) have been corrected. The Department shall conduct inspections and investigations as are necessary for the enforcement of this Regulation.~~

C. ~~One copy of the inspection report shall be handed producer, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department. The inspector will notify the owner or other responsible person of the intent to inspect upon arrival at the premises.~~

D. ~~The Department shall also make such other inspections and investigations as are necessary for the enforcement of this Regulation. A copy of the inspection report will be provided, either electronically or in paper form, to the permit holder, manager, or other duly authorized representative.~~

E. ~~Inspection Notification— The inspector should advise the owner or other responsible person of the intent to inspect upon arrival at the premises. Every raw milk producer shall, upon request of a Department representative, permit the Department access to all parts of the establishment or facilities to determine compliance with the provisions of this Regulation. A permit holder, manager, or other duly authorized representative shall furnish the Department, upon request and for official use only, a true statement of the actual quantities of raw milk or raw milk product purchased and sold, and a list of all sources of ingredients, records of inspections, records of tests, and cooling time and temperature records.~~

F. ~~Every permit holder shall, upon request of the Department, allow access of officially designated persons to all parts of the permitted establishment or facilities to determine compliance with the provisions of this Regulation. Should a violation of any requirement set forth in Section VII or Section VIII be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three (3) calendar days. Any violation of a requirement of Section VII or~~

Section VIII may result in enforcement action pursuant to Section XII of this Regulation. When the Department at any time finds that a critical processing element violation involving conditions whereby direct contamination of raw milk or raw milk products is occurring, the Department shall take immediate action to prevent transfer from the vessel or location of such raw milk or raw milk products until such violations of critical processing element(s) have been corrected.

G. It shall be unlawful for any person who, in an official capacity, under the provisions of this Regulation obtains any information of disposition of milk, or results of inspections or tests thereof to use such information to his/her own advantage or to reveal it to any unauthorized person.

SECTION ~~VIV~~. The Examination of Raw Milk and Raw Milk Products for Human Consumption.

A. Samples of raw milk or raw milk products for human consumption may be taken for ~~scientific examination~~analysis for public health purposes, at any reasonable time or place, and examined ~~bacteriologically~~ or for any other public health reason by ~~agents~~ of the Department.

B. Samples of raw milk and raw milk products for human consumption shall be collected and tested prior to a permit being issued. No permit shall be issued until the milk and milk products ~~meets~~meet the requirements of Section VII-A and Section VIII.

C. The producer shall provide to the Department satisfactory pathogenic testing results prior to:

1. receiving a permit and beginning production and/or distribution; or
2. reinstatement of a permit that has been suspended because of positive results of testing for pathogenic organisms in association with a suspected outbreak of disease. In testing associated with a suspected outbreak of disease, the Department shall provide up to two (2) tests at no cost to the producer; pathogen testing required beyond these two (2) tests shall be the responsibility of the producer.

~~D. During any consecutive six (6) months, at least four (4) samples of raw milk for human consumption shall be collected from each producer in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Department or shall be taken from each producer under the direction of the Department and delivered in accordance with this section. Samples of raw milk and raw milk products shall be collected by the producer or the Department, as directed, at a frequency that is deemed appropriate by the Department based on the level of risk of the product. The Department will require sampling for bacterial counts, somatic cell counts, coliform, cooling temperatures, pesticide residue, drugs, and/or pathogenic organisms as deemed appropriate by the Department. Sampling will be conducted in accordance with Department standard operating procedures for sampling of raw milk and raw milk products.~~

~~E. Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on raw milk for human consumption. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.~~

~~F. When multiple samples of the same milk are collected from the same producer from multiple tanks on the same day, the laboratory results shall be averaged arithmetically by the Department and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.~~

~~GE. Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the raw milk or~~

~~raw milk products~~ as defined in this Regulation, the Department shall send ~~a certified or hand-delivered~~ written notice thereof to the person concerned. This notice shall be in effect so long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) calendar days of the sending of such notice, but not before the lapse of three (3) calendar days. ~~Immediate suspension of permit shall be implemented.~~The Department shall suspend the permit in accordance with Section XII whenever the standard is violated by three (3) of the last five (5) bacterial counts, coliform determinations, cooling temperatures, or somatic cell counts.

~~H. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues, and no milk shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.~~

~~I.~~ F. When sampling for pathogenic organisms is conducted in association with a suspected outbreak of disease, and the samples test positive for pathogenic organisms, such positive finding of pathogenic organisms shall be considered an imminent health hazard, and the product involved shall be disposed of and not be offered for sale. ~~the~~The Department shall immediately suspend the permit. The permit shall remain suspended until a representative sample containing a minimum of two (2) consecutive milkings are found to be free of pathogenic organisms.

~~J.~~ G. Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the latest edition of Standard Methods for the Examination of Dairy Products (SMEDP) of the American Public Health Association, and the latest edition of Official Methods of Analysis (OMA) of the Association of Official Agricultural Chemists (AOAC) International. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories.

~~K.~~ H. All violations of bacteria, coliform, somatic cell counts, and cooling temperature standards shall be followed ~~promptly~~ promptly by inspection, if needed, to determine and correct the cause.

~~L. Laboratory Techniques—Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with FDA 2400 Series forms, SMEDP and OMA.~~

~~1. The procedures shall be those specified therein for:~~

~~a. Standard plate count at 32°C (Agar or Petrifilm Method).~~

~~b. Alternate methods, including Plate Loop Count and the Bacto Scan FC and the Spiral Plate Count Method for viable counts for raw milk.~~

~~c. Coliform test with solid media or Petrifilm method at 32°C, and the Petrifilm High Sensitivity Coliform Count Method for all milk.~~

~~d. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk shall be used for each drug of concern. Regulatory action shall be taken on all confirmed positive results. A result shall be considered positive if it has been obtained by using a method that has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA.~~

~~e. Screening and confirmatory methods for the detection of abnormal milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.~~

~~(1) Milk (Non Goat): Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting.~~

~~(2) Goat Milk: In addition to the above mentioned tests, the California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one (1), respectively. Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Pyronine Y Methyl green stain or "New York modification" shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.~~

~~f. Any other tests that have been approved by the Food and Drug Administration or the Centers for Disease Control and Prevention to be equally accurate, precise, and practical.~~

~~g. All standards used in the development and use of drug residue detection methods designed for Grade "A" PMO monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method shall define the standard to be used.~~

~~M. Sampling Procedures—SMEDP guidance for sampling of milk shall be used:~~

~~1. When bacterial counts and temperature determinations are made of several samples of the same milk collected from the same producer on the same day, these values are averaged arithmetically, and the results recorded as the count or temperature determinations of the milk for that day. All counts and temperatures should be recorded on a milk ledger form for dairy farms as soon as reported by the laboratory.~~

~~2. A computer or other information retrieval system may be used.~~

~~N. Sampling Raw Milk—When samples of raw milk are taken, they shall be randomly drawn following adequate agitation. Sampling procedures shall not contaminate the sample of remaining milk, temperature when collected, and date and hour collected. The sample shall be immediately placed under refrigeration. Samples shall not be submerged in a coolant or handled in any manner which may cause contamination. All samples shall be maintained at 40°F (4°C) or below until analyzed. At no time shall the period of time between collection and analysis exceed forty eight (48) hours. Samples shall be collected by personnel who have been certified as sample collectors by Certified State Milk Sanitation Rating Officers.~~

SECTION VI. Labeling.

A. All bottles, containers, and packages enclosing raw milk or raw milk products for human consumption shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, and the Code of Federal Regulations, and shall comply with the applicable requirements of this section.

B. No person shall use any misleading marks, words, or endorsements upon the label. The Department may permit the use of registered trade designs or similar terms on the bottle cap or label when, in its opinion, they are not misleading and are not used to obscure the labeling required by the Regulation.

C. All bottles, containers, and packages enclosing raw milk or raw milk products for human consumption shall be conspicuously marked with:

1. The word “Raw” on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

2. The identity of the farm where packaged. This identity shall include the name and the Department Permit Number.

3. The following consumer advisory, in print no smaller than six (6) point font, shall be included on the package: “This is a raw milk product that is not pasteurized. Consuming raw milk products may increase your risk of foodborne illness.”

4. The common name of the hooved mammal producing the milk shall precede the name of the milk or raw milk product when the product is made from other than cattle’s milk. As an example, “Goat,” “Sheep,” “Water Buffalo,” or “Other Hooved Mammal” milk, respectively.

D. Raw milk that has had cream separated from it must also be labeled as per Section VIII.B.3.

E. The term Grade “A” Raw may only be used with the designation of SC to read “SC Grade ‘A’ Raw”. Other grade designations may not be used.

F. Descriptive labeling terms such as “wholesome” or “healthy” must not be used. The label must not be false or misleading.

G. A permit holder’s label and Department permit number are not transferable and may only be used by that permit holder.

SECTION VII. Standards for Raw Milk and Raw Milk Products for Human Consumption.

A. General

1. All Grade “A” raw milk and raw milk products for human consumption shall be produced to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this section.

2. No process or manipulation other than appropriate refrigeration shall be applied to raw milk or raw milk products for the purpose of removing or deactivating microorganisms.

SC GRADE “A” RAW MILK AND RAW MILK PRODUCTS FOR HUMAN CONSUMPTION	Temperature	<u>Raw milk:</u> Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after milking, provided, that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F).
--	-------------	---

		<u>Raw milk and raw milk products: All finished, processed, and packaged raw milk and raw milk products shall be maintained at 7°C (45° F) or less after processing, during storage, and during transportation. Production of buttermilk shall also meet the requirements of Section VIII.A.3.</u>
	Bacterial Limits	Individual producer <u>raw milk and raw milk products</u> not to exceed 10,000 per mL
	Drugs	No positive results on drug residue detection methods as referenced in Section VI – Laboratory Techniques.
	Somatic Cell Count*	Individual producer <u>raw milk</u> not to exceed 500,000 per mL.
	Coliform	Not to exceed 10 per gram.
	Pathogenic Organisms: **Escherichia Coli	Individual producer: <u>raw milk and raw milk products</u> not to exceed zero (0) organisms
	**0157:H7	<u>Individual producer: raw milk and raw milk products not to exceed zero (0) organisms</u>
	**Salmonella	<u>Individual producer: raw milk and raw milk products not to exceed zero (0) organisms</u>
	**Listeria Monocytogenes	<u>Individual producer: raw milk and raw milk products not to exceed zero (0) organisms</u>
	**Campylobacter	<u>Individual producer: raw milk and raw milk products not to exceed zero (0) organisms</u>

*Goat Milk 1,000,000 per mL: when greater than 1,000,000, additional confirmatory or screening tests will be used.

** Pathogenic testing required before permitting and in association with a foodborne disease outbreak. See Section V.C.1, V.C.2, and V.F.

B. Sanitation Requirements for SC Grade “A” Raw Milk and Raw Milk Products ~~F~~for Human Consumption.

1. Milk with Abnormalities

a. Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded as the Department may direct.

b. Lactating animals that have been treated with, or have ~~consummed~~consumed, chemical, medicinal, or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Department may direct. ~~(For applicability to automatic milking installations (AMI’s), refer to Appendix Q of the PMO.)~~

c. ~~Milk~~Raw milk or raw milk products from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, shall not be offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

d. ~~Milk~~Raw milk or raw milk products from lactating animals treated with or exposed to insecticides not approved for use on dairy animals by the United States Environmental Protection Agency shall not be offered for sale.

e. The Department may require additional tests for the detection of milk with abnormalities as it deems necessary.

f. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, shall be handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

g. Lactating animals secreting milk with abnormalities shall be milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk shall be maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

h. Equipment, utensils, and containers used for the handling of milk with abnormalities shall not be used for the handling of raw milk or raw milk products to be offered for sale, unless they are first cleaned and effectively sanitized.

i. Processed animal waste derivatives used as a feed ingredient for any portion of the total ration of the lactating dairy animal shall:

(1) ~~be~~ properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

(2) ~~not~~ contain levels of deleterious substances, harmful pathogenic organisms, or other toxic substances which are secreted in the milk at any level that may be ~~deleterious~~harmful to human health.

j. Unprocessed poultry litter and unprocessed recycled animal body discharges shall not be fed to lactating dairy animals.

2. Milking Barn, or Parlor Construction

A milking barn or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations.

a. All floors must be constructed of concrete or equally impervious material; ~~convalescent (maternity) pens located in milking areas of stanchion type barns may be used when they comply with the guidelines specified in Appendix C. III. of the PMO.~~ Floors shall be easily cleaned and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools.

b. Walls and ceilings shall be smooth, painted, or finished in an approved manner, and ~~are~~be in good repair. Ceilings shall be dust-tight; approved materials include wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable, or parlor. If a hay opening is provided from the loft into the milking portion of the barn, such opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

c. Separate stalls or pens for horses, calves, and bulls shall be provided. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

d. Natural and/or artificial light well distributed for day and/or night milking must be provided to ~~insure~~ensure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles (110 lux) of light in all working areas shall be provided.

e. Sufficient air space and air circulation to prevent condensation and excessive odors ~~will~~must be provided.

f. There ~~will~~must be no overcrowding ~~which will be evidenced~~ by the presence of calves, cows, or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn. ~~It is recommended that pit areas in parlors should be at least six (6) feet in width from overhang when cows are milked on two (2) sides, and six (6) feet working areas when single row of stalls. Ceiling height shall be at least seven (7) feet in areas where cows stand;~~

g. There must be dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed. A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. When conditions warrant, the Department may approve a barn without four (4) walls extending from floor to roof, or a shed-type barn provided the requirement of Section VII.B.3., ~~which prohibiting~~prohibits animals and fowl from entering the barn, is satisfied. Lactating animal-housing areas (stables without stanchions, such as loose housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, and wandering sheds) may be of shed-type construction, provided no milking is conducted therein. (These structures are classified as part of the cowyard under Section VII.B.4.)

h. The Department may grant a variance or waiver from one or more of the requirements of paragraphs VII.B.2.a through VII.B.2.g when, in the opinion of the Department, a health hazard or nuisance will not result from the variance or waiver.

3. Milking Barn, Stable, or Parlor Cleanliness

a. The interior of the milking barn, stable, or parlor shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Outside surfaces of pipeline systems located in the milking barn, stable, or parlor must be kept reasonably clean.

b. Gutter cleaners must be kept reasonably clean.

c. Swine and fowl shall be kept out of the milking barn.

~~d. All pens, calf stalls, and bull pens, if not separated from the milking barn, stable, or parlor, must be kept clean.~~

~~e.~~ Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor (as in covered, dust-tight boxes or bins). Open feed dollies or carts may be used for distributing the feed, but not storing food, in the milking area.

~~f. Milk stools, sureingles, and antikickers shall be kept clean and stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse, when not in use.~~

~~g.e.~~ Food mangers shall be kept clean so as not to attract flies; leftover feed in feed mangers must appear fresh and not be wet or soggy.

4. Cowyard

a. The cowyard, which is interpreted to be the enclosed or unenclosed area approximately adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes.

b. Wastes from the barn, ~~or milkhouse~~milkroom, or processing room shall not be allowed to pool in the cowyard. Depressions and soggy areas shall be filled, and lactating animal lanes kept reasonably dry. Cowyards which are muddy due to recent rains should not be considered as violating this item.

c. Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate in such a manner as to permit the soiling of lactating animals' udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered part of the cowyard. Manure packs shall be solid to the footing of the animal.

d. In loafing or lactating animal housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks.

~~e. Cooling ponds shall be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies, and tails of lactating animals exiting the pond.~~

~~f.e.~~ Waste feed shall not be allowed to accumulate.

~~g.f.~~ Swine shall be kept out of the cowyard.

~~h.g.~~ Cowyards shall be kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

5. ~~Milkhouse~~Milkroom or Processing Room—Construction and Facilities

a. A separate ~~milkhouse~~milkroom and/or processing room of sufficient size shall be provided, in which the cooling, handling, further processing, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted, except as provided for in Section VII.B.12 of this Regulation.

b. ~~The milkhouse~~Every milkroom and processing room shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Floors shall be sloped to drains so that there are no pools of standing water. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

c. The joints between floors and walls shall be watertight.

d. The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner. Surfaces and joints shall be tight and smooth. Acceptable materials include sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color. Surfaces up to splash height shall be non-absorbent and easily cleanable.

e. ~~The milkhouse~~Every milkroom and processing room shall have adequate natural and/or artificial light and be well ventilated. A minimum of twenty (20) foot-candles (220 lux) of light shall be provided at all working areas from natural and/or artificial light for ~~milkhouse~~milkroom and processing room operations.

f. The ~~milkhouse~~milkroom and processing room shall be used for no other purpose than ~~milkhouse~~milkroom and processing room operations; there shall be no direct opening into any barn, stable, parlor or into a room used for domestic purposes. A direct opening between the ~~milkhouse~~milkroom or processing room and milking barn, stable or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided and opens outward from the milk room. A vestibule, if used, must comply with the applicable ~~milkhouse~~milkroom and processing room construction requirements. Screened vents in the wall between the ~~milkhouse~~milkroom or processing room and a breezeway, which separates the ~~milkhouse~~milkroom or processing room from the milking parlor, are permitted, provided animals are not housed within the milking facility.

g. Water under pressure shall be piped into the ~~milkhouse~~milkroom and/or processing room.

h. ~~The milkhouse~~Every milkroom and processing room shall be adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

i. Vents, if installed, and lighting fixtures shall be located to preclude the contamination of bulk milk tanks or clean utensil storage area.

j. The ~~milkhouse~~milkroom and/or processing room shall be equipped with a wash-and-rinse vat having at least two (2) compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one (1) part of the two (2)-compartment vat; provided that the cleaning-in-place station rack in or on the vat and milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional if so determined by the Department on an individual farm basis.

k. Each ~~milkhouse~~milkroom and/or processing room shall be provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

6. ~~Milkhouse or Room~~Milkroom and Processing Room – Cleanliness

a. The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and equipment, and other ~~milkhouse~~milkroom or processing room equipment shall be kept clean. Vestibules, if provided, shall be kept clean.

b. Only articles directly related to ~~milkhouse~~milkroom or processing room activities shall be permitted in the ~~milkhouse~~milkroom or processing room.

c. The ~~milkhouse~~milkroom and processing room shall be kept free of trash, animals, and fowl.

d. Incidental articles such as desks, refrigerators, and storage cabinets may be in the ~~milkhouse~~milkroom or processing room provided they are kept clean, ample space is available to conduct the normal operations in the ~~milkhouse~~milkroom or processing room, and they will not cause contamination of the milk.

7. Toilet

a. Every dairy farm shall be provided with one (1) or more toilets, conveniently located and properly constructed, operated, maintained and utilized in a sanitary manner. There shall be at least one (1) flush toilet connected to a public sewer system or to an individual sewage-disposal system, ~~or if occupied for less than two (2) hours per day, a portable chemical toilet may be used, earth pit privy or other type of privy.~~ Such ~~sewerage~~sewage systems shall be constructed and operated in accordance with applicable Department regulations and statutes.

b. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply. ~~Vents of earth pits shall be screened.~~

~~e. No privy shall open directly into the milkhouse.~~

~~e.c.~~ The toilet room, including all fixtures and facilities, shall be kept clean and free of insects and odors.

~~ed.~~ Where flush toilets are used, doors to toilet rooms shall be tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects.

8. Water Supply

a. Water for ~~milkhouse~~milkroom or processing room and milking operations shall be from an approved supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

b. No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

c. There shall be no submerged inlets through which a safe water supply may be contaminated.

d. The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply.

e. New individual water supplies and water supply systems that have been repaired or otherwise become contaminated shall be thoroughly disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

f. All containers and tanks used in the transportation of water shall be sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump, hose, and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure to prevent their contamination. The storage tank at the dairy farm shall be constructed of

impervious material provided with a dust and rainproof cover, ~~and provided with~~ as well as with an approved-type vent and roof hatch. All new reservoirs, or reservoirs which have been cleaned, shall be disinfected prior to placing them into service.

g. Samples for bacteriological examination shall be taken upon the initial approval of the physical structure based upon the requirements of this Regulation, when any repair or alteration of the water supply system has been made, and at least every ~~three (3)-years, provided that:~~

~~(1) water supplies with buried well casing seals installed prior to the adoption of this section shall be tested at intervals no greater than six (6) months apart. Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal needs replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section.~~

~~(2) when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) months.~~

h. Bacteriological examinations shall be conducted in a laboratory acceptable to the Department.

~~i. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated period plus the remaining days of the month in which the sample is due.~~

~~ji. Current records of water test results shall be retained on file with the Department or as the Department directs.~~

9. Utensils and Equipment – Construction

a. All multiuse containers, equipment, and utensils that are exposed to raw milk or raw milk products, or from which liquids may drip, drain or be drawn into raw milk or raw milk products, and used in the handling, storage, or transportation of milk shall be made of smooth, non-absorbent, corrosion-resistant, nontoxic materials, and shall be constructed to be easily cleaned. Acceptable materials include:

(1) ~~s~~SStainless steel of the AISI (American Iron and Steel Institute) 300 series, or equally corrosion-resistant, nontoxic metal;

(2) ~~h~~HHeat-resistant glass; or

(3) ~~p~~Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion; under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, and relatively insoluble; ~~;~~ do not release component chemicals or impart flavor or odor to the product; ~~;~~ and which maintain their original properties under repeated use conditions.

b. All containers, utensils, and equipment shall be in good repair and shall be free of breaks, corrosion, pits, cracks, ~~;~~ or inclusions.

c. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size shall be used for hand milking and hand stripping.

d. Strainers, if used, shall be constructed of perforated metal design, or single-service strainer media should be utilized. Multiple-use woven material shall not be used for straining milk.

e. All single-service articles shall be manufactured, packaged, transported, stored, and handled in a sanitary manner and shall comply with the applicable requirements of Section ~~VIII~~VIII. Articles intended for single-service use shall not be reused.

f. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Section VII.B.9.a, g₂ and h.

g. Mechanically cleaned milk pipelines and return-solution lines shall be self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in Section VII.B.9.a.(3), and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

h. Mechanically cleaned milk pipelines and return solution lines installed after the effective date of this Regulation shall have welded ferrule/flange fittings; rolled fittings shall not be used.

i. Detailed plans for cleaned-in-place pipeline systems shall be submitted to the Department for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Department.

j. All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces shall be constructed to be easily cleaned and inspected. Pipelines, milking equipment, and appurtenances that require a ~~screw driver~~screwdriver or special tool shall be considered easily accessible for inspection, provided the necessary tools are available at the ~~milkhouse~~milkroom or processing room. Milking systems shall not have components incorporated in the return solution lines, that by design do not comply with the criteria for product-contact surfaces, such as:

(1) ~~Ball~~Ball type plastic valves;

(2) ~~Plastic~~Plastic tees with barbed ridges to better grip the plastic or rubber hoses; and

(3) PVC water type piping.

k. Milk cans shall have umbrella-type lids.

l. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of this Regulation.

m. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free joint between the hose and the fitting and can be cleaned by mechanical means. The hoses shall be included as part of a mechanical cleaning system.

n. Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the “3-A Sanitary Standards for Multiple-Use Plastic

Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20” and if it remains sufficiently clear that the interior surfaces can be properly inspected. Short lengths of flexible plastic tubing (eight [8] feet or less) may be inspected for cleanliness by sight or by use of a “rod.” The transparency or opacity of such tubing under this condition is not a factor in determining cleanliness.

~~NOTE: 3 A Sanitary Standards for Dairy Equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection, and the Milk Safety Branch, Food and Drug Administration, Public Health Service, Center for Food Safety and Applied Nutrition, Department of Health and Human Services. Equipment manufactured in conformity with 3 A Sanitary Standards complies with the sanitary design and construction standards of this Regulation.~~

o. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials, and odor.

10. Utensils and Equipment—Cleaning

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of raw milk and raw milk products shall be cleaned after each milking or once every twenty-four (24) hours for continuous operations.

b. There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

11. Utensils and Equipment – Sanitization

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of raw milk and raw milk products shall be sanitized before each usage.

b. Sanitization shall be achieved by use of the following methods:

(1) Complete immersion in hot water at a temperature of at least 77°C (170°F), for at least five (5) minutes, or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by the use of a suitable accurate thermometer (at the outlet) for at least five (5) minutes;

(2) Complete immersion for at least one (1) minute in or exposure for at least one (1) minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes; or

(3) By any method which has been demonstrated to be equally effective and approved by the FDA, EPA, or the Department.

12. Utensils and Equipment – Storage

a. All containers, utensils, and equipment used in the handling, storage, or transportation of raw milk and raw milk products, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use, except that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers, and milk pumps, and AMI milking equipment which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria, may be stored in the milking barn or parlor, provided this

equipment is designed, installed, and operated to protect the product and solution-contact surfaces from contamination at all times.

b. Strainer pads, parchment papers, gaskets, and similar single-service articles shall be stored in a suitable container or cabinet and protected against contamination.

13. Utensils and Equipment—Handling

After sanitization, all containers, utensils, and equipment shall be handled in a manner that prevents contamination of any product-contact surface.

a. Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.

b. Any sanitized product-contact surface which has been otherwise exposed to contamination shall be cleaned and sanitized before being used.

14. Milking—Flanks, Udders, and Teats

a. Milking shall be done in the milking barn or parlor.

b. The flanks, udders, bellies, and tails of all milking cows shall be free from ~~visable~~visible dirt. All brushing shall be completed prior to milking.

c. The udders and teats shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be relatively dry before milking. Sanitizing solutions shall be used in accordance with manufacturer specifications and recommendations.

d. Wet hand milking is prohibited.

e. Flanks, bellies, tails, and udders shall be clipped as often as necessary to facilitate cleaning of these areas.

15. Drug and Chemical Control

a. Cleaners and Sanitizers

(1) Cleaners and sanitizers shall be stored in dedicated end-use containers which properly identify the contents.

(2) Bulk cleaners and sanitizers that are transferred from the manufacturer's or distributor's container shall be stored only in an end-use container that is properly labeled with the container's contents.

(3) The manufacturer's or distributor's label for each cleaner and sanitizer, including the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor, shall be maintained on the premises and be readily accessible for reference or inspection.

b. Drugs

(1) Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for over-the-counter (OTC) drugs or veterinary practitioner dispensing the product for prescription and extra label use drugs. Drug labels shall also include:

- (a) ~~d~~Directions for use and prescribed withholding times;
- (b) ~~e~~Cautionary statements, if needed; and
- (c) ~~a~~Active ingredient(s) in the drug product.

(2) Drugs dispensed by a pharmacy on the order of a veterinarian shall have labeling that includes the name of the prescribing veterinarian and the name and address of the dispensing pharmacy; the address of the prescribing veterinarian may be included on the labeling.

(3) Drugs intended for treatment of non-lactating dairy animals shall be segregated from those drugs used for lactating animals in separate shelves in cabinets, refrigerators, or other storage facilities.

(4) Unapproved drugs shall not be used and shall not be stored in the ~~milkhouse~~milkroom, processing room, milking barn, stable, or parlor.

(5) Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats, and hand sinks are not subject to contamination by the drugs.

(6) Equipment used to administer drugs shall not be cleaned in the wash vats.

~~NOTE:~~(7) Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the raw milk or raw milk product-contact surfaces of containers, utensils, or equipment.

16. Milking—Transfer and Protection of Milk

a. Each pail or container of milk shall be taken immediately from the milking barn or parlor to the ~~milkhouse~~milkroom or processing room. No milk shall be strained, poured, transferred, or stored outside the ~~milkhouse~~milkroom or processing room.

b. The milk receiving receptacle shall be raised above the floor.

17. Personnel

a. Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent, and individual sanitary towels, or other approved hand drying devices, convenient to the ~~milkhouse~~milkroom, processing room, milking barn, stable, parlor and flush toilet, and shall be used for no other purpose. Utensil wash and rinse vats shall not be considered as handwashing facilities.

b. Hands shall be washed clean and dried with an individual sanitary towel or other approved hand drying device immediately before milking, before performing any ~~milkhouse~~milkroom or processing room function, and immediately after the interruption of any of these activities. Milkers shall wear clean outer garments while milking or handling raw milk, raw milk products, milk containers, utensils, or equipment.

c. No person who by medical examination or supervisory observation is shown to have or appears to have an illness, open lesion (including boils, sores, or infected wounds) or any other abnormal source of microbial contamination shall work at any dairy farm in any capacity that brings them into contact with the production, handling, storage, or transportation of raw milk, raw milk products, containers, equipment, and/or utensils. ~~Any producer or distributor of milk who suspects that any employee has contracted any disease in a communicable form or has become a carrier of such disease shall notify the Department immediately.~~

d. When reasonable cause exists to suspect the possibility of transmission of infection or disease from any person ~~concerned~~ associated with the handling of raw milk or raw milk products, the Department may:

(1) ~~Order~~ Order the immediate exclusion of that person from raw milk handling or handling of raw milk products;

(2) ~~Order~~ Order the immediate exclusion of the raw milk or raw milk products supply concerned from distribution and consumption;

(3) ~~Order~~ Order adequate medical and bacteriological examination of the person to determine if ~~the~~ an infection or disease is present; or

(4) ~~Order~~ Order any combination of the previous measures.

18. Cooling

a. Raw milk shall be cooled to 10°C (50°F) or less within four (4) hours or less of the commencement of the first milking, and to 7°C (45° F-) or less within two (2) hours after the completion of milking, and shall be maintained at that temperature, including during packaging and transportation; except that, the blend temperature after the first milking and subsequent milking shall not exceed 10°C (50°F).

b. All finished, processed, and packaged raw milk and raw milk products shall be maintained at 7°C (45° F) or less after processing, during storage, and during transportation.

~~b~~c. Recirculated cold water that is used in plate or tubular coolers or heat exchangers shall be from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards set by the Department.

~~e. All farm bulk milk tanks manufactured after January 1, 2000, shall be equipped with an approved temperature recording device.~~

~~(1) The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap.~~

~~(2) The recording device shall be verified every six (6) months and documented in a manner acceptable to the Department using an accurate (+/- 1°C (2°F)) thermometer that has been calibrated by a traceable standard thermometer, within the past six (6) months, with the results and date recorded and the thermometer being properly identified, or by using a traceable standard thermometer that has been calibrated within the last year.~~

~~—————(3) Recording thermometer charts shall be maintained on the premises for a period of a minimum of six (6) months and available to the Department.~~

~~—————(4) The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to the Department.~~

~~—————(5) The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than ten (10) percent of its calibrated capacity.~~

~~—————(6) The recording thermometer shall comply with the current technical specifications for tank recording thermometers.~~

~~—————(7) A recording thermometer and/or any other device that meets the intent of this Regulation and technical specifications, and is acceptable to the Department, can be used to monitor/record the bulk tank temperature.~~

~~—————(8) The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.~~

19. Vehicles.

Vehicles used to transport raw milk and raw milk products shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; ~~and no~~ substance capable of contaminating raw milk or raw milk products shall be transported with raw milk or raw milk products.

20. Insect and Rodent Control.

a. Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents, and by chemicals used to control such vermin.

b. Milkrooms and processing rooms shall be free of insects and rodents.

c. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

d. Feed shall be stored in such a manner that it will not attract birds, rodents, or insects.

e. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing shall be properly bedded and managed to prevent fly breeding.

f. Milkrooms and processing rooms shall be effectively screened or otherwise protected against the entrance of vermin, including hose ports and floor drains through walls.

g. Outer ~~milkhouse~~milkroom and processing rooms doors shall be tight and self-closing. Screen doors shall open outward.

h. Only pesticides approved for use by the Department and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

i. Pesticides shall be used only in accordance with manufacturer's directions.

SECTION VIII. Standards for Further Processing of Raw Milk Products.

A. Buttermilk

1. All equipment used for the production and processing of buttermilk must be smooth, non-absorbent, and easily cleanable.

2. All ingredients must come from an approved source.

3. The pH of the buttermilk must be maintained at 4.6 or below following production and at the time of packaging, or the product must be maintained at 7°C (45° F) or below. All finished, processed, and packaged buttermilk must meet the requirements of VII.B.18.b.

B. Cream

1. All equipment used for the production and processing of cream must be smooth, non-absorbent, and easily cleanable.

2. Cream must be removed from the raw milk vat by the use of a separator or other method approved by the Department. The hand skimming of cream is prohibited.

3. Raw milk that has had the cream removed shall be labeled as “Raw Milk with Cream Removed.”

4. All finished, processed, and packaged cream must meet the requirements of VII.B.18.b.

SECTION VIII IX. Bottling, Packaging, Container Filling, and Container Closure/Sealing.

A. Bottling, Packaging, and Container Filling.

1. Bottling, packaging, and container filling of raw milk and raw milk products shall be done at the place of production in a sanitary manner by approved mechanical equipment. Bottling, packaging, and container filling of raw milk or raw milk products may be conducted in the milkhouse, milkroom, and processing rooms or room.

2. Bottling or packaging machine supply tanks and bowls shall have covers which are smooth and easily cleanable and shall be constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

3. A drip deflector shall be installed on each filler valve. The drip deflector shall be designed and adjusted to divert condensation away from the open container.

4. All containers, seals, and caps shall be from an approved Interstate Milk Shippers listed facility.

5. All containers, seals, and caps shall be handled in a sanitary manner and protected against undue exposure during the operation.

6. When any lubricant is applied to the filler equipment or other milk contact surfaces, the lubricant shall be food grade and applied in a sanitary manner.

7. Containers shall be closed immediately after being filled.

B. Container Closure/Sealing.

1. All container caps, sealers, and closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination.
2. Only new containers, container caps, sealers, and closures shall be used. Reusable glass containers must be approved by the Department prior to use.
3. All container closure/sealing shall be done at the place of production in a sanitary manner by approved mechanical equipment.
4. Hand capping or sealing of containers is prohibited.
5. If suitable mechanical equipment for the capping or closing of specific container(s) of 12.8 liters (three [3] gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Department. Approval of such methods shall be obtained prior to beginning operation.
6. Bottles and packages which have been imperfectly capped, sealed, or closed shall have the contents emptied immediately into approved sanitary containers that are protected from contamination and maintained at 7°C (45°F) or less; when handled and stored properly, the contents may be repackaged in new containers at a later time.
7. All caps, seals, and closures shall be designed and applied so that the sealed container is tamper-evident (removal cannot be made without detection), and the pouring lip shall be protected to at least its largest diameter.
8. Caps, sealers, and closures shall not be left in the equipment at the end of an operating period. Caps, sealers, and closures remaining in the chute between the hopper and the capping device shall be discarded.
9. Loose caps, sealers, and closures may be returned to storage by enclosing them in a clean, protective wrap, plastic bag, or container approved by the Department.

SECTION ~~IX~~ X. Animal Health.

A. All raw milk and raw milk products for human consumption within ~~the State of~~ South Carolina shall be from healthy animals. ~~Milk~~ Raw milk and raw milk products from unhealthy animals shall not be offered for sale, barter, or be given away, or combined with other raw milk, or raw milk products for human consumption.

B. All animals producing raw milk or raw milk products for human consumption shall be ~~tested~~ free of ~~for~~ brucellosis and tuberculosis ~~every twelve (12) months~~. Animals showing positive by lesions or a positive test shall be reported to the Department; and shall also be reported to the State Veterinarian office in accordance with applicable law.

~~— 1. Shall be separated, and kept separate, from the remainder of the herd;~~

~~— 2. A certificate, identifying each animal, signed by a licensed veterinarian and the director of the laboratory making the test, shall be filed with the Department;~~

~~— 3. Shall be retested by a licensed veterinarian at a frequency specified by the United States Department of Agriculture (USDA), and test results shall be filed with the Department; and~~

~~— 4. Disposition of diseased animals shall be conducted in accordance with guidelines published by the USDA and shall be reported to the Department.~~

C. For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical, or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.

D. Animals shipped into South Carolina for additions to herds shall have been tested for tuberculosis and brucellosis within thirty (30) calendar days prior to being brought into the state, except that this shall not apply, with regard to brucellosis, to those cattle that have been vaccinated for brucellosis and are under thirty (30) months of age.

E. Records supporting the tests required in this section shall be made available to the Department and be validated with the signature of a licensed veterinarian.

~~SECTION X~~ XI. Recall.

Each producer and distributor of raw milk and raw milk products for human consumption shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any of these procedures as necessary with respect to any product for which the producer, distributor, or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the producer or distributor, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the producer or distributor to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The producer or distributor shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

~~SECTION XI~~ XII. Enforcement.

A. General.

This Regulation is issued under the authority of Sections 44-1-140(3) and 44-1-150, S.C. Code of Laws, 1976, as amended. It shall be enforced in accordance with interpretations and public health reasons approved by the Department.

B. Penalties.

Any person found to be in violation of this Regulation, in noncompliance with the issued permit, or in violation of an order issued by the Department shall be subject to civil monetary penalties, permit suspension, and/or permit revocation. Each day of continued violation shall be a separate offense.

~~B.C.~~ Suspension of Permit.

~~1. The Department may, without warning, notice or hearing, suspend the permit of any producer or distributor of raw milk whenever, in the opinion of the Department, an imminent health hazard exists. An~~

~~imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, or the presence of pathogenic organisms. Upon such suspension of permit, all bottling and/or distribution activities shall immediately cease and remain ceased while the permit is suspended. The suspension of permit shall remain in effect until the imminent health hazard has been corrected to the satisfaction of the Department.~~

~~2.1. The Department may otherwise temporarily suspend a permit for a violation of this Regulation when/whenever:~~

~~a. It has reason to believe that a public health hazard exists;~~

~~b. The permit holder has violated any of the requirements of this Regulation;~~

~~c. The permit holder has violated its permit or an order of the Department, including but not limited to, a hold order;~~

~~e.d. The permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or~~

~~e.e. The permit holder exhibits hostile behavior toward a representative of the Department during the performance of duty.~~

~~2. The Department may, without warning, notice, or hearing, immediately suspend the permit of any producer of raw milk or raw milk products whenever, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard may include, but is not limited to, a willful refusal to permit authorized inspection, serious or repeated violations of bacterial, coliform, somatic cell, or cooling temperature standards, violation of drug residue test standards, or the presence of pathogenic organisms. Upon such suspension of the permit, all processing, bottling, and/or distribution activities shall immediately cease and remain ceased while the permit is suspended. The suspension of permit shall remain in effect until the imminent health hazard has been corrected to the satisfaction of the Department.~~

~~3. A suspension of permit shall remain in effect until any violation has been corrected to the satisfaction of the Department.~~

~~C.D. Revocation of Permit. The Department may revoke a permit when:~~

~~— 1. the permit holder has repeated suspension(s); or~~

~~— 2. the permit holder physically threatens or intimidates a representative of the Department.~~

~~The Department may revoke a permit for serious or repeated violations of any of the requirements of this Regulation, the permit, or an order of the Department, or for interference with the Department or its representatives in the performance of its duties, including willful refusal to allow an authorized inspection/audit. Notwithstanding any other provisions of this Regulation, the permit may be revoked if any Department representative is threatened with bodily harm or physical interference in the performance of inspectional duties.~~

~~D.E. Reinstatement of Permit~~

~~1. Any producer whose permit has been suspended may make submit a written application for the reinstatement of the permit. Any application for the reinstatement of a suspended permit must be in writing~~

and must address all violations underlying the suspension and explain the steps taken to correct those violations.

2. Within ~~one week~~ seven (7) business days of the receipt of such an application, the Department shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine ~~that the applicant's establishment is complying with the requirements~~ whether the conditions cited in the notice of suspension no longer exist. When the findings justify, the permit shall be reinstated.

3. When the permit suspension has been due to a violation of any of the bacteriological, coliform, somatic cell, cooling temperature, or drug residue test standards, the Department may issue a temporary permit whenever resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section VII. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three ~~(3)~~-week period, and the Department shall reinstate the permit upon compliance with the appropriate standards as determined in accordance with Section ~~IV~~ V of this Regulation.

4. When a permit has been revoked, the holder of the revoked permit may ~~make~~ submit a written application for a new permit; however, the Department may deny a new permit based upon past history, including previous enforcement, suspension, or revocation history.

5. Any person whose permit is revoked shall not be eligible to apply for re-permitting within one (1) year from the date of revocation. Any person whose permit has previously been revoked and who obtains a subsequent permit and violates the provisions of this Regulation, resulting in revocation of the permit for a second time, shall not be granted another permit for a period of five (5) years.

~~E. Other Enforcement Provisions~~

~~1. In addition to the authority to suspend and revoke permits, the Department may seek enforcement and issue civil penalties in accordance with SC Code Ann. Section 44-1-150, S.C. Code of Laws, 1976, as amended. The Department shall have the authority to assess and suspend civil penalties if the violations of this Regulation are corrected in a period of time established by the Department.~~

~~2. A Department decision involving the issuance, denial, renewal, modification, suspension, or revocation of a permit may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23. Any person to whom an order or enforcement letter is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~

SECTION XIII. Delayed Implementation.

Existing raw milk or raw milk products permit holders in operation prior to the effective date of the below listed requirements of this Regulation may use labels that do not comply with those requirements (but which meet all labeling requirements previously in effect) until their existing supply of labels as of the effective date of the below requirements is exhausted or for no more than one (1) year from the effective date of these requirements, whichever is sooner:

1. As provided in Section VI.C.3, all labels shall include the following consumer advisory, in no smaller than six (6) point font: "Consuming raw milk products may increase your risk of foodborne illness."

2. As provided in Section VI.E, labels may only use the term Grade “A” Raw in conjunction with the designation of “SC,” to read “SC Grade ‘A’ Raw”. Other grade designations may not be used.

Raw milk or raw milk products permit holders permitted after the effective date of the requirements referenced in Section XIII.1 and XIII.2 above must comply with all of the labeling requirements of Section VI without any delayed implementation.

SECTION ~~XII~~ XIV. Severability Clause.

Should any section, paragraph, sentence, clause, or phrase of this Regulation be declared unconstitutional or invalid for any reason, the remainder of this Regulation shall not be affected thereby.

61-34.1. Pasteurized Milk and Milk Products.

Statutory Authority: S.C. Code Sections 44-1-140 and 44-1-150

SECTION I. APPLICABILITY OF THE GRADE “A” PASTEURIZED MILK ORDINANCE Applicability of the Grade “A” Pasteurized Milk Ordinance, 20132019 REVISION Revision

A. The following sections, appendices, and footnotes of the Grade “A” Pasteurized Milk Ordinance (PMO or Ordinance), 20132019 Revision, apply in their entirety:

1. Section 4~~r~~, Labeling;
2. Section 6~~r~~, The Examination Of Milk And/Or and/or Milk Products;
3. Section 7~~r~~, Standards Forfor Grade “A” Milk And/Or and/or Milk Products (including Items 1r through 19r, and 1p through 22p);
4. Section 8~~r~~, Animal Health;
5. Section 9~~r~~, Milk And/Or and/or Milk Products Which May Be Sold;
6. Section 10~~r~~, Transferring; Delivery Containers; Cooling;
7. Section 11~~r~~, Milk And/Or and/or Milk Products Fromfrom Points Beyond Thethe Limits Ofof Routine Inspection;
8. Section 12~~r~~, Plans Forfor Construction Andand Reconstruction;
9. Section 13~~r~~, Personnel Health;
10. Section 14~~r~~, Procedures When Infection Oror High Risk Ofof Infection Is Discovered;
11. Section 18~~r~~, Separability Clause;
12. Footnotes; and
13. Appendices A through S.

B. The following associated documents of the Grade “A” Pasteurized Milk Ordinance, ~~2013~~2019 Revision, apply in their entirety:

1. Procedures Governing the Cooperative State - Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, ~~2013~~2019 Revision (Procedures);
2. Methods of Making Sanitation Ratings of Milk Shippers, ~~2013~~2019 Revision (Methods); and
3. Evaluation of Milk Laboratories, ~~2013~~2019 Revision.

C. The following provisions of the Grade “A” Pasteurized Milk Ordinance, ~~2013~~2019 Revision, apply with the additions, exceptions, and superseding amendments specified below:

1. Section 1, Definitions applies with the following exceptions:

a. ~~The definition RR. Regulatory Agency applies with the following amendment: Definition YY, Regulatory Agency, shall be stricken, and the term “Regulatory Agency,” where used in the Pasteurized Milk Ordinance, 2019 Revision, shall be replaced with the term “Department.” The Department shall mean the South Carolina Department of Health and Environmental Control or its authorized representative.~~

~~**RR. REGULATORY AGENCY:** The Regulatory Agency shall mean the State of South Carolina’s Department of Health and Environmental Control (“the Department”) or their authorized representative. The term, “Regulatory Agency”, whenever it appears in the *Ordinance* shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this *Ordinance*.~~

b. Ordinance, as used in the Pasteurized Milk Ordinance, ~~2013~~2019 Revision, shall mean the provisions and appendices of the Pasteurized Milk Ordinance, ~~2013~~2019 Revision, as adopted by the South Carolina Department of Health and Environmental Control (“the Department”).

c. “... of ...”, as used in the Pasteurized Milk Ordinance, 2019 Revision, shall mean the state of South Carolina.

d. Cross-references to “Section 3. of this *Ordinance*” appearing in Section 5, Section 6, and Appendix N shall mean Section C.3 of this Regulation together with applicable portions of Section 3 of the *Ordinance*.

2. Section 2, ~~Adulterated Or~~ Adulterated Or ~~Misbranded Milk And/Or~~ Misbranded Milk And/Or ~~and/or Milk Products, applies with the following exceptions~~ in its entirety with the following additions:

a. The following applies in addition to Section 2:

Milk and milk products shall be examined by the ~~Regulatory Agency~~Department as often as may be necessary to determine freedom from adulteration or misbranding. The ~~Regulatory Agency~~Department may, upon written notice to the owner or person in charge, place a hold order on any milk or milk product which it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, milk or milk products shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on milk or milk products by the ~~Regulatory Agency~~Department, and neither such milk or milk products nor the containers thereof shall

be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the ~~Regulatory Agency~~Department, except on order by a court of competent jurisdiction.

Adding water to raw milk will be considered a violation of this Regulation if the raw milk contains in excess of three percent (3%) water. A cryoscope shall be used to determine percentage of water by measuring the freezing point of the raw milk. When the freezing point of milk and milk products, other than cultured products, is greater than ~~-0.525~~32.945°HF (~~-0.507~~25°C), the farm or plant owner or manager shall be notified that ~~apparently~~ the milk or milk product apparently contains added water. If a second violation of this freezing point standard occurs within two (2) years, ~~an observed milking or operation of processing operations shall~~may be observed, conducted and samples will be collected and analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point standard from the individual farm or plant. A violation of the determined freezing point standard for a specific operation by over three (3%) percent within two (2) years of setting the standard for the individual farm or plant shall call for a two (2) calendar day permit suspension or equivalent.

When milk or milk products ~~is~~are found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, ~~it~~they shall be ~~impounded~~placed under a hold order and additional samples analyzed. Milk or milk products found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk or milk products are positive for drug residues, the milk or milk products shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The ~~Regulatory Agency~~Department shall determine the producer(s) responsible for the drug residue violation and immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale or distribution of milk or milk products containing drug residues, and a penalty shall be imposed. Future pick-ups, sales, or distribution are prohibited until subsequent testing reveals the milk or milk product is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The ~~Regulatory Agency~~Department may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements. The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk or milk products for human food, when a representative sample taken from the producer's milk or milk products, prior to commingling with any other milk or milk product, is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated, and an investigation shall be made to determine the cause. The farm inspection ~~is~~must be completed by ~~The Regulatory Agency~~The Department to determine the cause of the residue and actions that must be taken to prevent future violations including:

i. On-farm changes in procedures necessary to prevent future occurrences as recommended by the ~~Regulatory Agency~~Department.

ii. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C: of the PMO.

When pasteurized milk or milk products are found to be adulterated by drugs, pesticides, herbicides, or other poisonous substances, the adulterated products shall be removed from the market, disposed of, and sale stopped until analysis proves the product to be free from adulteration.

b. The following applies in addition to the Administrative Procedures part of Section 2:

When two (2) of the last four (4) samples of a pasteurized product are in violation of the milkfat or milk solids not fat standard for that product a warning letter shall be issued by the Department. When three (3) of the last five (5) samples are in violation, the Department shall suspend the permit.

3. Section 3-2 Permits applies with the following exceptions:

a. The second paragraph on page 1617 of the PMO, 20132019 Revision (paragraph beginning with “Upon notification”) shall not apply.

b. The following replaces the entire Administrative Procedures part of Section 3:

ISSUANCE OF PERMITS: Every milk producer, milk product producer, milk distributor, milk products distributor, bulk milk hauler/sampler, milk tank truck⁵, milk transportation company, ~~and each~~ milk plant, receiving station, transfer station, and milk tank truck cleaning facility operator shall hold a valid permit prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this regulation. Permits shall not be transferable to other persons/locations or used by a person other than the permit holder. The permit for a milk tank truck(s) may be issued to the milk transportation company. Milk producers who transport milk or milk products only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk or milk products from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler’s permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

While compliance with the requirements for Grade “A” condensed and dry milk products is necessary to receive and retain a permit for these products, it is not the intent of this ~~Ordinance~~Regulation to limit the production of a milk plant that condenses and/or dries milk or milk products; to Grade “A” products.

The manufacture of ungraded products for other uses in milk plants operating under a permit for the manufacture of Grade “A” condensed and dry milk products is allowed under conditions specified in Section 7 of ~~this the Ordinance~~ and whereby such products are processed, packaged, and stored separately. In such cases, a second permit is required, which is issued with the understanding that ungraded products shall be handled in such a manner so as to avoid confusion with the Grade “A” production.

Either or both permits may be temporarily suspended for the violation of any applicable provision of this ~~Ordinance~~Regulation or the Ordinance, or revoked for a serious or repeated violation. Suspension of permits for violation of the sanitation Items of Section 7 is provided for in Section 5 of the Ordinance. In addition, the ~~Regulatory Agency~~Department may, at any time, institute court action under the provisions of Section 6 of the Ordinance. There is no specific frequency for the issuance of permits. This should be in accordance with the policies of the ~~Regulatory Agency~~Department and in agreement with those employed for the issuance of permits under this ~~Ordinance~~Regulation.

SUSPENSION OF PERMIT: ~~When any requirement(s) of this Ordinance is violated, the permit holder is subject to the suspension of their permit.~~

~~When the permit suspension is due to violations other than bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, the permit holder, manager or other authorized representative shall be notified by certified mail or hand delivery of the intent to suspend the permit in thirty days unless a written request for a hearing is filed with the Regulatory Agency. If no request is made in thirty (30) days, the permits shall be suspended until the violations are corrected.~~

The Department may temporarily suspend a permit whenever: it has reason to believe that a public health hazard exists; the permit holder has violated any of the applicable requirements of this Regulation

or the Ordinance; the permit holder has violated its permit or an order of the Department, including but not limited to a hold order; the permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or the permit holder exhibits hostile behavior toward a representative of the Department during the performance of its duties. A permit suspension shall remain in effect until any violation has been corrected to the satisfaction of the Department.

_____The Department may, without warning, notice, or hearing, immediately suspend a permit when, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard may include, but is not limited to, a willful refusal to permit authorized inspection, serious or repeated violations of bacterial, coliform, somatic cell, cooling temperature ~~or~~standards, violation of drug residue test standards, or the presence of pathogenic organisms.

_____Following permit suspension, all manufacturing, bottling, and/or distribution operations shall immediately cease and remain ceased while the permit is suspended. A suspension of the permit shall remain in effect until the violation(s) and any imminent health hazard have been corrected to the satisfaction of the Department.

REVOCATION OF PERMIT: The Department may revoke a permit whenever the permit holder: has committed serious or repeated violations of any of the applicable requirements of this regulation, the Ordinance, a permit, or an order of the Department, including but not limited to a hold order; or has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit. Notwithstanding any other provisions of this regulation, the permit may be revoked if any Department representative is threatened with bodily harm or physical interference in the performance of inspectional duties.

_____Following permit revocation, all manufacturing, bottling, and/or distribution operations shall immediately cease and remain ceased.

REINSTATEMENT OF PERMITS: Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations.

When the permit suspension has been due to a violation of any of the bacterial, coliform, or cooling temperature standards, the ~~Regulatory Agency~~Department, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the ~~Regulatory Agency~~Department may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7 of the Ordinance. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This accelerated sampling applies to bacteria, coliform, somatic cell count, and temperature. The ~~Regulatory Agency~~Department shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of ~~this~~the Ordinance.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test, or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such notification, the ~~Regulatory Agency~~Department shall make an inspection/audit of the applicant's facility, and as many additional inspections/audits thereafter as are deemed necessary, to determine that the

applicant's facility is complying with the requirements. When the findings justify, the permit shall be reinstated.

When a permit suspension has been due to a positive drug residue, the permit shall be reinstated in accordance with the provisions of Appendix N.

When a permit has been revoked, the holder of the revoked permit may make written application for a new permit; however, the Department may deny a new permit based upon past history, including previous enforcement, suspension, or revocation history. Any person whose permit is revoked shall not be eligible to apply for re-permitting within one (1) year from the date of revocation. Any person whose permit has previously been revoked and who obtains a subsequent permit and violates the provisions of this regulation, resulting in revocation of the permit for a second time, shall not be granted another permit for a period of five (5) years.

4. ~~Section 5, Inspection Of Dairy Farms And Milk Plants, applies with the replacement of language in the fifth paragraph on page 22 in the PMO, 2013 Revision within its entirety with the exception of:~~

~~One (1) copy of the inspection/audit report shall be provided to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request.~~

a. Paragraph 3.c on page 22 in the PMO, 2019 Revision, applies in its entirety with the exception that it shall not apply to milk plants that are not Interstate Milk Shippers (IMS) listed.

b. The fifth paragraph on page 23 in the PMO, 2019 Revision (paragraph beginning with "One (1) copy") is replaced by the following: A copy of the inspection report will be provided, either electronically or in paper form, to the permit holder, manager, or other duly authorized representative.

c. The last sentence of the first paragraph on page 25 in the PMO, 2019 Revision (sentence beginning with "After receipt of a notice of violation") is replaced by the following: After receipt of an inspection report identifying a violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor shall have an opportunity to request extension of the time allowed for correction.

5. Section 7, Item 7p, Water Supply, applies in its entirety with the addition of the following:

At a minimum, the water system must meet the state requirements for a category 3 small water system.

~~56. Section 15, Enforcement applies with the addition of the following~~The following replaces the language of Section 15, Enforcement, in its entirety:

a. This Regulation is adopted and enforced under the authority of S.C. Code Section 44-1-140 and Section 44-1-150. All applicable provisions of the Ordinance shall be enforced by the Department in accordance with this Regulation and the *Grade "A" PMO, with Administrative Procedures, current edition, as applicable.*

b. Compliance with all provisions of the Appendices adopted in this Regulation shall be deemed a requirement of the Ordinance and this Regulation.

c. Any person found to be in violation of this Regulation or an applicable requirement of the Ordinance, in noncompliance with an issued permit, or in violation of an order issued by the Department shall be subject to civil monetary penalties, permit suspension, and/or permit revocation.

67. The following replaces the language of Section 16~~7~~, Penalty~~2~~, in its entirety:

Violations shall be punishable in accordance with S.C. Code Section 44-1-150. Each day of continued violation shall be a separate offense.

78. Section 17~~7~~, Repeal ~~And~~ Date ~~Of~~ Effect of the PMO, ~~2013~~2019 Revision, shall not apply.

9. Appendix T applies in its entirety with the exception that it shall not apply to milk plants that are not IMS listed.

10. The following additional language applies in accordance with the Footnotes in the Ordinance:

The Department regulates cottage cheese, dry curd cottage cheese, and reduced fat or low-fat cottage cheese under the terms of the Ordinance. The additional provisions specified in Footnotes 7 through 13 for regulatory agencies that regulate such products are hereby adopted and incorporated by reference into the relevant portions of the Ordinance and this Regulation.

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL CHAPTER 61

Statutory Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

Notice of Drafting:

The Department of Health and Environmental Control (“Department”) proposes amending R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products. Interested persons may submit comment(s) on the proposed amendments to Sandra D. Craig, Director, Division of Food and Lead Risk Assessments, Bureau of Environmental Health Services; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; craigsd@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on April 27, 2020, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to R.61-34, Raw Milk for Human Consumption, the Department provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Department proposes amending R.61-34 to address the further processing and sale of raw milk products, such as cream and buttermilk, and any additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing (if allowed). The proposed revisions would also update raw milk standards if needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance (“PMO”).

Pursuant to R.61-34.1, Pasteurized Milk and Milk Products, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Department proposes incorporating requirements of the 2019 PMO through amendment of R.61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO would enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Department further proposes clarification of requirements for potable water sources.

The Department may also include changes to both regulations for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvement. Amendments to both regulations may also include updates to administrative and enforcement provisions.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

**R.61-34 Raw Milk for Human Consumption
As of the April 27, 2020, close of the Notice of Drafting comment period:**

Name	Section
Charity Allen President & Founder PBL Consulting 360-440-3968 charity@pblconsulting.org Elizabeth Moffat bethmoffat@callmc.com Bonnie Chudyk, ND, CCRN(r), IWS Sherri Jacobs	R. 61-34, Raw Milk for Human Consumption, generally
<p>Comment:</p> <p>1. The proposed amendments recognize consumer freedom of choice by increasing access to raw dairy products.</p> <p>2. Allowing raw milk dairy farmers to sell additional value-added products will enhance their ability to make a living.</p> <p>3. Raw cream and raw buttermilk have an excellent track record for food safety track In states where sales and/or distribution are legal.</p> <p>4. DHEC should also consider legalizing the sale of other raw dairy products such as butter and kefir in future rulemaking. These products also have great food safety records and are in high demand by consumers as well.</p> <p>Department Response:</p> <p>Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the requirements of proposed Section VIII. A. & B. to R. 61-34.</p> <p>Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.</p>	
Name	Section
Janet Kozlowski	R. 61-34, Raw Milk for Human Consumption, generally
<p>Comment:</p> <p>I am writing to you today to encourage you to support the dairy farmers with expanded raw dairy products. I would be in favor of purchasing raw cream and buttermilk from my grocery store.</p>	

Department Response: Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the requirements of proposed Section VIII. A. & B. to R. 61-34.	
Name	Section
Jenny Ewald	R.61-34, Raw Milk for Human Consumption, generally
Comment: Please support the amending of SC raw milk regulations to allow sales of raw cream and raw buttermilk. In these financially uncertain times, it will benefit dairy farmers to be able to sell a wider variety of products.	
Department Response: Adopted – Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.	
Name	Section
Moira Chance	R.61-34, Raw Milk for Human Consumption, generally
Comment: As a licensed PA in the state of South Carolina I would greatly appreciate the option to buy raw milk products. Please pass the amendment.	
Department Response: Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.	
Name	Section
Darrell Mordente	R.61-34, Raw Milk for Human Consumption, generally
Comment: I encourage you to work for including the sale of raw cream and buttermilk. Many health-conscious consumers would welcome the prospect of being able to obtain these and other value added raw milk products. Farmers would benefit in sales and consumers would benefit in choice.	
Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34. Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.	
Name	Section
hclunford	R.61-34, Raw Milk for Human Consumption, generally
Comment:	

I am in support of making raw milk and products available to those who wish to purchase it. I am in support of the amendment to allow more outlets to sell these products.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

R.61-34 does not address or restrict locations where permitted raw milk or raw milk products are sold.

Name	Section
Rebecca Zerwick	R.61-34, Raw Milk for Human Consumption, generally

Comment:

We would also love to be able to purchase cream, buttermilk and hopefully butter and kefir in the future.

States that can legally sell raw cream/buttermilk and butter have excellent records for food safety.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
Jessica Toland	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I am a regular consumer of raw milk and cheese and I think that it is a great idea that DHEC is considering legalizing the sale of raw buttermilk and raw cream. I have recently ended a near five year stint on a vegan diet, which did great harm to my health. Through the consumption of raw dairy products, which are more nutritious than conventional dairy products, I am regaining my health. I would love to be able to add raw buttermilk and raw cream to my diet and perhaps other raw dairy products in the future such as raw butter and raw kefir.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
Rena Henson	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: As citizen of SC and consumer of raw dairy products, I fully support legalizing the sale of raw cream and buttermilk. I believe it is an inherent right of the consumer to be able to choose raw dairy products. This will benefit the dairy farmers as well as consumers. Raw dairy has an excellent track record for safety. It is my hope that DHEC would also consider legalizing the sale of other raw dairy products such as butter and kefir as these are also in high demand and safe.</p> <p>Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34. Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.</p>	
Name	Section
Jeff Hatfield	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: The proposed amendments recognize consumer freedom of choice by increasing access to raw dairy products. By allowing raw milk dairy farmers to sell additional value-added products, South Carolina will enhance their ability to make a living. The products coming from Raw Dairy producers are superior to processed Milk products in every way and contain far more unmodified saturated fats (there are a great many in raw milk), vitamins, enzymes, and proteins that humans require to be healthy. Raw cream, butter, and raw buttermilk have an excellent track record for food safety track in states where sales and/or distribution are legal. DHEC should also consider legalizing the sale of other raw dairy products such as butter and kefir in future rulemaking. These products also have great food safety records and are in high demand by consumers as well.</p> <p>Department Response: Partially adopted - Consistent with the comment, the Department has proposed allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34. Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.</p>	
Name	Section
Reese Rushing	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: Supports the sale of raw buttermilk and cream.</p>	

Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.	
Name	Section
Matthew Donovan	R.61-34, Raw Milk for Human Consumption, generally
Comment: Supports local dairies to have the ability to sell raw milk and cheese, yogurt products. Let SC be a leader in this. Pasteurization obviously kills microbes AND beneficial bacteria's. Those with healthy immune systems benefit greatly from raw milk products as a way to help feed the gut healthy bacteria.	
Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34. Butter and cheese (including raw milk cheese) are regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.	
Name	Section
Donna Long	R.61-34, Raw Milk for Human Consumption, generally
Comment: I'm 61 yrs of age, and want to be an organic farmer. Raising anything that is healthy and nutrient-dense for our human and animal bodies! I want to appeal to you to please vote for the raw milk and other products when it comes time to vote. We all as Americans want and need to be our healthiest, to combat the evil doers against us!	
Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34. Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.	
Name	Section
Doris Jean	R.61-34, Raw Milk for Human Consumption, generally
Comment: I only buy raw dairy products. I refuse to buy any milk product that is not raw. Please support raw milk products for the many of us who only use raw milk products. There are many processed products available for those who want them, but very few choices for those of us who want only raw milk products.	

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
Kit Norton Burke	R.61-34, Raw Milk for Human Consumption, generally

Comment:

Allow the raw dairy farmers to sell these two additional products. Doing so will help them make a living and allow South Carolinians free choice

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
James Wittig	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I love raw milk and cheese. Would love to see permitted products expanded to include butter, buttermilk and raw cream

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Name	Section
Soren McMillan	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I support rule changes to allow licensed dairies to sell raw cream and raw buttermilk in this state. Especially with the probable difficult economic times ahead, I believe it is important to expand the economic opportunities of local dairies to sell products for which there is ample demand in the state of South Carolina.

Department Response: Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.	
Name	Section
Trudy A Phelps, Ph.D, L.D.H.S., PSc.D, C.N.H.P. Loomis Digestive Health Specialist TAP Into Life Health Tel: 803 548 3236 Email: office@tapintolifehealth.com	R.61-34, Raw Milk for Human Consumption, generally
Comment: I am writing to express my approval for expanding the rules that would allow SC dairies to sell more raw milk products. The raw milk products in the northern SC area are excellent, high quality products, that many of my clients use to help with dairy allergies and sensitivities that they experience when using regular pasteurized, homogenized milk – but do not experience with raw dairy products. Living near the NC state line, I observe many people come from Charlotte area into Fort Mill area in order to purchase this milk. It is good for health and good for SC business and dairies. At present, I have to separate the cream and make the butter and yoghurt myself if I want these. I would welcome the raw milk dairies being allowed to sell more raw milk products.	
Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34. Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.	
Name	Section
S Hotchkiss	R.61-34, Raw Milk for Human Consumption, generally
Comment: I support the proposed amendments legalizing the sale of raw cream and raw buttermilk by licensed dairies. I've been a raw dairy consumer for many years and my health has benefited significantly. It's the only dairy I can consume without suffering "lactose intolerance" symptoms. I avoid all pasteurized dairy due to the side effects and raw dairy allows me to consume a form of dairy that provides calcium and other nutrients that I would otherwise not be able to. I would love to be able to easily have access to more raw products such as butter, cream, and buttermilk especially from local farmers.	
Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.	

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and will not be addressed or permitted in this revision.

Name	Section
Bryan Harris bryan@sally.org.il	R.61-34, Raw Milk for Human Consumption, generally

Comment:
I'm in support of letting South Carolina dairy farmers sell raw cream and raw buttermilk. It's also very inconvenient for me to drive all the way to their farm, so I don't buy as much as I'd like. They only sell in a few stores, at least here in Charleston. Please consider letting licensed dairies sell products in more places.

Department Response:
Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

R.61-34 does not address or restrict locations where raw milk or raw milk products are sold.

Name	Section
Erin Soria	R.61-34, Raw Milk for Human Consumption, generally

Comment:
I live in Columbia, SC. I heard there was an amendment to expand the sale of raw cream and raw buttermilk in the state and wanted to voice my support! I have been a long-time purchaser of raw milk for my family of four young boys and would love to see these products become available for consumers. Passing this amendment would allow consumers the freedom to choice when it comes to these products. It would also bring more income for the small farmers, who we love to support!

Department Response:
Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
Bill Singleton	R.61-34, Raw Milk for Human Consumption, generally

Comment:
I hope you'll consider that SC citizens should be able to make decisions about healthy raw dairy products without government making it illegal. Raw buttermilk and cream have been found to be very safe in states where they are legal. Raw milk farmers would be able to make a better living and be able to increase their ability to provide more healthy products. Please consider making raw kefir legal also.

Department Response:
Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream by the addition of Section VIII. A. & B. to R. 61-34.

Kefir is regulated under R. 61-34.1 Pasteurized Milk, and raw milk kefir will not be addressed or permitted in this revision.

Name	Section
Stephen Heuer stephen@sygn44.com	R.61-34, Raw Milk for Human Consumption, generally

Comment:

It has been essential to my health to consume raw milk and I'm grateful that raw milk has been available here in South Carolina. It appears that government officials are considering expanding the availability of raw dairy in South Carolina to Cream and Buttermilk. I vote yes on this and ask the officials involved in this decision to do the same. Raw milk has healthfully nourished generations of people for thousands of years. Heat sterilized milk is denatured and oxidized and causes many health problems. For your education on this topic I recommend reading: "The Untold Story of MILK" by Ron Schmid ND.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
Rusty Overstreet	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I support the sale of raw dairy products by local dairies. I consume these products regularly and currently have trouble locating them. Please do what you can to open up this market.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

R.61-34 does not address or restrict locations where raw milk or raw milk products are sold.

Name	Section
Jackie Hutto	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I would definitely like to see the sale of raw buttermilk and cream legalized. It has shown it is safe in other states that have done so, and it should be up to the person if they wish

Department Response:

Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
------	---------

Margaret Day	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: I support purchasing raw cream and buttermilk in South Carolina for the following reasons (I have been purchasing these two items for ten years with no difficulties).</p> <p>Department Response: Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.</p>	
Name	Section
Linda	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: Please pass this</p> <p>Department Response: Acknowledged – The Department is proceeding with the proposed revisions as described in the Notice of Drafting.</p>	
Name	Section
Gail Fiverson	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: I strongly urge you to support Legalized Raw Cream and Buttermilk Sales.</p> <p>Department Response: Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.</p>	
Name	Section
Bethany Edge	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: I am excited to hear that it is proposed to legalize the sale of raw cream and buttermilk in South Carolina. I am emailing you as a resident of charleston county to let you know I am in favor of this amendment. This a great step toward expanding consumer freedoms that will also bring great economic value to our farmers. Both raw cream and raw buttermilk have excellent food safety track records in the states they are sold legally. Our family has experienced great health since switching to raw milk, and we are hopeful that more raw milk products will be available to us soon.</p> <p>Department Response:</p>	

Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
Sharon Hall	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I strongly support the proposed amendments which recognize consumer freedom of choice by increasing access to raw dairy products. Allowing raw milk dairy farmers to sell additional value-added products will enhance their ability to make a living. Raw cream and raw buttermilk have an excellent track record for food safety track In states where sales and/or distribution are legal.

DHEC should also consider legalizing the sale of other raw dairy products such as butter and kefir in future rulemaking. These products also have great food safety records and are in high demand by consumers as well.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
Natalee Whitesell	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I would love to have even more raw milk products. I have been buying raw milk for years now and I can tolerate it better than regular pasteurized milk. I would love even more options.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
Penny Bussiere	R.61-34, Raw Milk for Human Consumption, generally

Comment:

I want the freedom to make my own choice in regard to purchasing raw dairy products in S.C. Not just milk but, butter, cheese and any other raw dairy products.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter and cheese (including raw milk cheese) are regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.

Name	Section
Rachel Puckett	R.61-34, Raw Milk for Human Consumption, generally

Comment:
Supports legalizing the sale of raw cream and raw buttermilk. I am a raw milk consumer and look forward to increased access to raw dairy products in our state.

Department Response:
Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
Ralph Rodina	R.61-34, Raw Milk for Human Consumption, generally

Comment:
Supports expanding the sale of raw dairy products.

Department Response:
Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
Shaun Riffle	R.61-34, Raw Milk for Human Consumption, generally

Comment:
Support of the proposed amendments to the SC dairy law to allow raw cream and buttermilk to be sold. These amendments recognize consumer freedom of choice by increasing access to raw dairy products.
Allowing raw milk dairy farmers to sell additional value-added products will enhance their ability to make a living. DHEC should also consider legalizing the sale of other raw dairy products such as butter.

Department Response:
Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Name	Section
Jonathan Burroughs	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: I strongly favor legalizing the sale of raw dairy products in SC. It will be a win for SC farmers and for consumers.</p> <p>Department Response: Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.</p>	
Name	Section
Coleen Thornton	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: Amend South Carolina raw milk regulations to legalize the sale of raw cream and raw buttermilk by licensed dairies. Also consider future rulemaking to legalize other raw dairy products such as raw butter and kefir. This is very, very important for our health.</p> <p>Department Response: Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the requirements of Section VIII. A. & B. to R. 61-34.</p> <p>Butter is regulated under R. 61-36, Manufactured Grade Dairy Products. Kefir is regulated under R. 61-34.1, Pasteurized Milk. Raw milk butter and kefir will not be addressed or permitted in this revision.</p>	
Name	Section
Nicole Vieth Bill Huey + Associates, Inc 843.805.6700 nicole@hueyarchitect.com & Josh Putnam Josh@liollio.com	R.61-34, Raw Milk for Human Consumption, generally
<p>Comment: I would like to encourage you and your team to legalize the sale of raw cream and raw buttermilk by licensed dairies, and further explore the further legalization of other raw dairy products such as raw butter.</p> <p>The proposed amendments will allow consumers to exercise their freedom of choice, give the dairy farmers more of an opportunity to make a decent living by selling these products, as the demand increases. Consumers are realizing the health benefits of the raw dairy products, and the raw cream and buttermilk have been safely tracked in other states where these products are legal.</p> <p>Department Response:</p>	

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Name	Section
Dina Holland	R.61-34, Raw Milk for Human Consumption, generally

Comment:
I am writing today to encourage DHEC to engage in future rulemaking to legalize the sale of raw cream and raw buttermilk by licensed dairies. As a South Carolina resident with several food sensitivities I appreciate the freedom to take care of my body without restrictions from my state government. Thank you for helping SC residents to remain free in their food choices!

Department Response:
Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream by the addition of Section VIII. A. & B. to R. 61-34.

Name	Section
Yvonne Lucas yvonne@aboutyourhealthsc.com	R.61-34, Raw Milk for Human Consumption, generally

Comment:
I would like to encourage freedom of choice for all foods as I believe that is our inherent right. I am a consumer of raw dairy and have used raw dairy for years to improve my health. I would love to have more raw dairy products available to consumers.

Department Response:
Adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Name	Section
Richard Mayson	R.61-34, Raw Milk for Human Consumption, generally

Comment:
Please add cream, butter, and buttermilk to the allowed list of raw milk products. This is the only way that we are able to use milk products and strongly believe that we should be allowed the option to purchase these natural products.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Name	Section
Margaret Mayson	R.61-34, Raw Milk for Human Consumption, generally

Comment:

My nephew buys raw milk for me every week. I grew up drinking milk from my grand parents' farm. Now, this is the only way that I will drink milk. Sadly, I do not have a raw milk option for butter or buttermilk. I would very much appreciate your adding these products to the allowed list in South Carolina. please add cream too

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Name	Section
Richard Mayson Organically You, LLC 5979 Jefferson Davis Highway North Augusta, SC 29841 (803) 279-9534 www.organicallyyou.biz	R.61-34, Raw Milk for Human Consumption, generally

Comment:

As a local organic store that sells raw milk in North Augusta, I have requests for raw cream, butter and buttermilk on a regular basis. Fortunately, we are able to provide raw whole milk to our very loyal customers on a regular basis, even through the coronavirus shutdown; however, we are constantly having to tell people that we are unable to provide them with any additional raw milk products. I, along with my customer base, would very much appreciate your adding these products to the approved list of raw dairy products that can be sold. This is a consumer choice for a very well informed and educated group of buyers.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Name	Section
Kevin Warning 1462 Rainbow Falls Road North Augusta, SC 29860 B and R Herbs bandrherbs@gmail.com	R.61-34, Raw Milk for Human Consumption, generally

Comment:

Supports allowing additional raw milk products to be sold in South Carolina. In addition to raw milk, I would love to be able to buy cream, butter and buttermilk.

Department Response:

Partially adopted - Consistent with the comment, the Department has proposed to allow the production of raw milk buttermilk and cream pursuant to a permit and in accordance with the proposed requirements of Section VIII. A. & B. to R. 61-34.

Butter is regulated under R. 61-36, Manufactured Grade Dairy Products, and raw milk butter will not be addressed or permitted in this revision.

Date: January 7, 2021

To: South Carolina Board of Health and Environmental Control

From: Division of Healthcare Quality

Re: Continuation of Public Hearing for Notice of Final Regulation Amending R.61-24, *Licensed Midwives*, Document No. 4974

I. Introduction

The Division of Healthcare Quality (“Healthcare Quality”) proposes amending Regulation 61-24, *Licensed Midwives*, pursuant to South Carolina Code Sections 44-1-140 *et seq.*, which enables the Department of Health and Environmental Control (“Department”) to establish and enforce basic standards for the licensure of midwives and midwifery services to ensure the safe and adequate treatment of persons served in this state. The proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to the terminology widely used and understood within the provider community, and revise requirements for scope of practice, incident reporting, continuing education training requirements, prescription medication administration, client and neonate care and services, infection control, monetary penalties, and other requirements for licensure. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

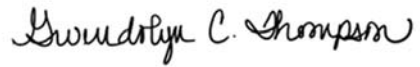
1. A Public Hearing for Notice of Final Regulation Amending R.61-24, *Licensed Midwives*, Document No. 4974, was conducted before the Board on November 12, 2020. After hearing comments from the public, the Board decided to continue the Public Hearing to the December 10, 2020, Board meeting. Specifically, the Board directed Department staff to provide additional information and revisions to the proposed regulations as it relates to the use of Lidocaine, the use of antihemorrhagics, mandatory 911 transport, physician sign-off on low risk birth, and any other items mentioned or reviewed in the comments. Attachment A presents staff’s review of these issues and contains pertinent sections of the current regulation, the proposed language as presented, justification for the proposed amendments, and potential alternative language for the Board’s consideration.

2. A Continuation of the Public Hearing for Notice of Final Regulation Amending R.61-24, *Licensed Midwives*, Document No. 4974, was conducted before the Board on December 10, 2020. After the presentation from Department staff, the Board decided to continue the Public Hearing to the January 7, 2021, Board meeting. Specifically, the Board directed Department staff to meet with two (2) representatives from the Midwifery Advisory Council (“MAC”) review the proposed alternative text in Attachment A, and provide the Board an update at the January 7, 2021, Board meeting.

3. On December 22, 2020, Department staff met with the two (2) representatives from the MAC to conduct a review of the proposed alternative text in Attachment A.

III. Request for Approval

Healthcare Quality respectfully requests the Board find need and reasonableness of its proposed amendments of R.61-24, *Licensed Midwives*, for submission to the General Assembly.



Gwen Thompson
Deputy Director
Healthcare Quality

Attachments:

A. Summary of Additional Information and Revisions, Presented at December 10, 2020, Board Meeting

ATTACHMENT A

SUMMARY OF ADDITIONAL INFORMATION AND REVISIONS

R. 61-24, *Licensed Midwives*

Use of Lidocaine

Issue:

Some commenters stated they cannot suture without injectable lidocaine and the proposed amendment only allows topical lidocaine.

Current Regulation:

Section N. Prohibitions in the Practice of Midwifery.

1. Medications. The midwife shall not administer any drugs or injections of any kind, except as indicated in Sections G.5 and M.2.b.

Section G. 5. Medications. Drugs or medications shall be administered only after consultation with and prescription by, a physician. The midwife shall not administer any drugs or medications except:

- a. For control of postpartum hemorrhage;*
- b. When administering medication in accordance with regulations governing the prevention of infant blindness;*
- c. When administering RhoGAM in accordance with accepted standards of professional practice.*

Section M.2. Examples of Emergency Measures. These are:

- b. Intramuscular administration of Pitocin for the control of postpartum hemorrhage.*

Notice of Final Regulation (NFR) R. 61-24:

B. The Midwife shall only administer Medications as prescribed by the Physician or other Authorized Healthcare Provider. The Midwife shall only administer the following Prescription Medications:

- 5. Topical Lidocaine;*

Justification:

Intravascular Lidocaine can cause life threatening hypotension, arrhythmias and cardiac arrest. Physician and other authorized healthcare providers support the use of topical Lidocaine in the out of hospital setting, but state that the injection of Lidocaine is risky and should not be required in the setting of a normal, uncomplicated birth. The only reason injected Lidocaine would be required is if women have complex perineal lacerations and for these repairs should be transferred to the hospital for surgical evaluation.

Alternative to NFR:

Section 1200. B. The Midwife shall only administer Medications as prescribed by the Physician or other Authorized Healthcare Provider. The Midwife shall only administer the following Prescription Medications:

- 5. Topical or one percent (1%) injectable Lidocaine*

Use of Antihemorrhagics

Issue:

Some commenters requested misoprostol in addition to oxytocin as an antihemorrhagic.

Current Regulation:

G. 5. Medications. Drugs or medications shall be administered only after consultation with and prescription by, a physician. The midwife shall not administer any drugs or medications except:

a. For control of postpartum hemorrhage;

Notice of Final Regulation (NFR) R. 61-24:

Section 1200. B. The Midwife shall only administer Medications as prescribed by the Physician or other Authorized Healthcare Provider. The Midwife shall only administer the following Prescription

Medications:

4. Oxytocin;

Justification:

Postpartum hemorrhage (PPH), the leading cause of maternal morbidity and mortality globally, is responsible for 130,000 maternal deaths annually. In the United States, 125,000 (2.9%) women who give birth will experience postpartum hemorrhage each year. Postpartum hemorrhage is defined as blood loss of 500 ml or more within 24 hours of birth. The average amount of blood loss after the birth of a single baby in vaginal delivery is about 500 ml (or about a half of a quart). The loss of 1000 ml or more is defined as major PPH. The average amount of blood loss for a cesarean birth is approximately 1,000 ml (or one quart).

Licensed midwives are trained experts in the management of low-risk pregnancy and birth outside of the hospital. PPH with blood loss above 1000 ml would elevate the birth to high risk, and thus it is outside the midwife's scope of practice. Midwives are required to initiate a medical consultation when high risk medical complications arise such as major PPH. The goal of the consultation is care and interventions that reduce the risk level such that care remains the responsibility of the midwife. A transfer of care is required when the primary care responsibilities required for the appropriate care of the client fall outside of the midwife's scope of practice.

Oxytocin is the recommend drug of choice for PPH as the first line medication. Studies, cited by some midwives, state that in third world countries other medications may be used. However, their use is recommended only when oxytocin is not available.

Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage, and if the hemorrhaging goes beyond use of oxytocin, it has elevated to high risk beyond the midwife's scope of practice.

Alternative to NFR:

Healthcare Quality does not propose potential alternative text for this issue.

Mandatory 911 Transport

Issue:

On the requirement to call 911 for transfer of care when a delivery proceeds beyond a midwife's scope of care, some commenters stated EMTs do not always arrive in the fastest time and are not trained in neonatal resuscitation and 911 should not be the only option for non-emergent transfer of care.

Current Regulation:

Not specifically addressed in the current regulation.

Notice of Final Regulation (NFR) R. 61-24:

Section 1500. A and B.

A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife's scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or Neonate and/or normally requires emergency intervention.

B. Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the Midwife shall transfer the care of the Client to the emergency medical services personnel, Physician, or other Authorized Healthcare Provider. The Midwife shall provide information as requested by the emergency medical services personnel, Physician, or other Authorized Healthcare Provider.

Justification:

The transfers in this section of the proposed amendments are emergent transfers only. When emergent events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required.

EMS personnel are trained to identify anatomical and physiological changes that occur during pregnancy, demonstrate normal and abnormal deliveries, summarize signs and symptoms of common gynecological emergencies, and perform neonatal resuscitation. EMS personnel are required by statute to be NREMT certified. This certification includes completing a state certified training program that includes training in these areas and successfully passing the NREMT Cognitive and Psychomotor examinations which include questions and skill testing in obstetrics.

Each permitted ambulance in the state is required to have an obstetric kit and neonatal resuscitation equipment on board. EMS Agencies are required to have Protocols including standing orders for the administration of medications and the provision of treatment for mothers and infants.

EMS personnel are required to maintain online medical control with a physician via two way radio, have the knowledge of which hospitals have the perinatal levels of care for the specific patient, and transport patients to the nearest hospital to meet the needs and care of both the Client and the infant. EMS Agencies are required to have staffing patterns and, if necessary, mutual aid agreements to ensure that an ambulance is en route with at least one EMT and one driver onboard to all emergent responses within

five (5) minutes or the next closest staffed ambulance must be dispatched, excluding prearranged transports.

Alternative to NFR:

1501. Non-emergent Transfer of Care

A. The Midwife shall develop, prior to thirty-six (36) weeks gestation, a written non-emergent transfer plan with participation of the Client, as evidenced by their signatures and date. The Midwife shall implement the written plan at the time of need and maintain documentation of the plan in the Client's record.

B. In the event of non-emergent transfer of care for a Client the Midwife shall accompany the Client to the hospital and remain with the Client until Transfer of Care is complete. If the Client declines the midwife accompanying the Client to the hospital and remaining with the Client until Transfer of Care is complete, then the Midwife shall secure documentation, evidenced by signature and date, that the Client declines the midwife's care. The Midwife shall not be the driver of the vehicle transporting the Client.

1502. Emergent Transfer of Care

A. The Midwife shall immediately initiate an emergent Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife's scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or Neonate and/or normally requires emergency intervention.

B. Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the Midwife shall transfer the care of the Client to the emergency medical services personnel, Physician, or other Authorized Healthcare Provider. The Midwife shall provide information as requested by the emergency medical services personnel, Physician, or other Authorized Healthcare Provider.

Physician Sign-off on Low Risk

Issue:

Public comments were made that a written and signed statement by the Physician or other Authorized Healthcare Provider that he or she has determined to the best of his or her ability that the pregnancy is a Low Risk Pregnancy is not possible.

Current Regulation:

D. Scope of Practice. The licensed midwife may provide care to low-risk women and neonates determined by medical evaluation to be prospectively normal for pregnancy and childbirth

F. Prenatal Care.

1. Required Visits. The midwife shall, upon acceptance of a woman for care, require her to have two visits with a physician, community health center or health department. One of these visits must be in the final six weeks of pregnancy. The midwife shall make entries in the patient's record of the physician, health center, or health department visits.

Notice of Final Regulation (NFR) R. 61-24:

1101. A. Initial Physical Examination:

1. The Midwife shall require the Client to undergo an initial Physical Examination completed by a Physician or other Authorized Healthcare Provider between ten (10) weeks and twenty (20) weeks of gestation. The Midwife may accept Clients after twenty (20) weeks of gestation provided the Client has undergone a Physical Examination that meets the requirements in Section 1100.A.2.

2. The Midwife shall ensure the initial Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement by the Physician or other Authorized Healthcare Provider that he or she has determined to the best of his or her ability that the pregnancy is a Low Risk Pregnancy as defined by this regulation; and

b. Identification of special conditions and/or care required.

B. Second Physical Examination:

1. The Midwife shall require the Client to undergo a second Physical Examination completed by a Physician or other Authorized Healthcare Provider after thirty-four (34) weeks of gestation.

2. The Midwife shall ensure the second Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement from the Physician or other Authorized Healthcare Provider that the pregnancy remains a Low Risk Pregnancy and the fetus is in the vertex position; and

b. Orders for Medications needed for intrapartum and postpartum.

Justification:

This requirement is a clarification of the current required documentation. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.

Alternative to NFR:

1101. Initial Physical Examination:

A. The Midwife shall require the Client to undergo an initial Physical Examination completed by a Physician or other Authorized Healthcare Provider between eight (8) weeks and twenty (20) weeks of gestation. The Midwife may accept Clients after twenty (20) weeks of gestation provided the Client has undergone a Physical Examination that meets the requirements in Section 1100.A.2.

B. The Midwife shall ensure the initial Physical Examination of the Client is documented in the Client's record and includes a written and signed documentation by the Physician or other Authorized Healthcare Provider verifying the following information:

1. The Client's name and date of birth;
2. The address of the facility and date of the appointment;
3. The estimated gestational age;
4. Identification of special conditions and/or care required; and
5. The Physician or other Authorized Healthcare Provider has determined to the best of his or her ability at the time of the appointment that:
 - a. The Client has no evidence of hypertension;
 - b. The Client has no evidence of uncontrolled diabetes;
 - c. The Client is HIV negative;
 - d. The Client is negative for Hepatitis B and C;
 - e. The Client has no evidence of anemia; and
 - f. The Client has no evidence of multiple gestations.

1102. Second Physical Examination:

A. The Midwife shall require the Client to undergo a second Physical Examination completed by a Physician or other Authorized Healthcare Provider after thirty four (34) weeks of gestation .

B. The Midwife shall ensure the second Physical Examination of the Client is documented in the Client's record and includes written and signed documentation by the Physician or other Authorized Healthcare Provider verifying the following information:

1. The Client's name and date of birth;
2. The address of the facility and the date of the appointment;
3. The estimated gestational age;
4. Identification of special conditions and/or care required; and
5. The Physician or other Authorized Healthcare Provider has determined to the best of his or her ability at the time of the appointment that:
 - a. The Client has no evidence of proteinuria and/or ketonuria
 - b. The Client has no evidence of gestational diabetes;
 - c. The Client has no evidence of active genital herpes;
 - d. The Client has no evidence of multiple gestations;
 - e. The Client has no evidence of anemia;
 - f. The Neonate is in the vertex position;
 - g. There is no decrease in fetal movement;
 - h. There is no evidence of abnormal fetal heart tones; and
 - i. There is no evidence of abnormal fetal size for gestation.
6. Orders for maternal and neonatal Medications needed for intrapartum, and postpartum and newborn periods.

Emergent Blood Loss Amount

Issue:

Public comment made related to the amount of blood loss due to PPH.

Current Regulation:

K. Maternal Conditions Requiring Physician Referral or Consultation. At any time in the maternity cycle, the midwife shall obtain medical consultation, or refer for medical care, any woman who:

43. Has bleeding of over three cups before or after delivery of placenta;

Notice of Final Regulation (NFR) R. 61-24:

1300. B. The Midwife shall obtain a Medical Consultation for Clients or Neonates presenting any of the following conditions:

3. Postpartum to include:

b. Hemorrhage greater than one thousand milliliters (1000 ml), and bleeding is uncontrolled;

Justification:

Postpartum hemorrhage (PPH), the leading cause of maternal morbidity and mortality globally, is responsible for 130,000 maternal deaths annually. In the United States, 125,000 (2.9%) women who give birth will experience postpartum hemorrhage each year. Postpartum hemorrhage is defined as blood loss of 500 ml or more within 24 hours of birth. The average amount of blood loss after the birth of a single baby in vaginal delivery is about 500 ml (or about a half of a quart). The loss of 1000 ml or more is defined as major PPH. The average amount of blood loss for a cesarean birth is approximately 1,000 ml (or one quart). The amount identified in the current regulation equates to approximately 700 ml.

Studies show that visual estimation of blood loss increases in error as the amount of blood loss increases. Visual estimation is the means by which the amount of blood loss during delivery is determined. When determining how much blood can be lost before the situation is determined to be emergent, one should take into account a margin of error along with the loss of blood that will occur while waiting for transport and arrival to the hospital.

Licensed midwives are trained experts in the management of low-risk pregnancy and birth outside of the hospital. PPH with blood loss above 1000 ml would elevate the birth to high risk, and thus it is outside the midwife's scope of practice. Midwives are required to initiate a medical consultation when high risk medical complications arise such as major PPH. The goal of the consultation is care and interventions that reduce the risk level such that care remains the responsibility of the midwife. A transfer of care is required when the primary care responsibilities required for the appropriate care of the client fall outside of the midwife's scope of practice.

Alternative to NFR:

1300. B. The Midwife shall obtain a Medical Consultation for Clients or Neonates presenting any of the following conditions:

3. Postpartum to include:

b. Hemorrhage greater than seven hundred fifty milliliters (750 ml), and bleeding is uncontrolled;

Vaginal Birth after Cesarean (VBAC)

Issue:

Some commenters state that it should be within the scope of practice of Certified Professional Midwives to attend VBACs.

Current Regulation:

D. Scope of Practice. The licensed midwife may provide care to low-risk women and neonates determined by medical evaluation to be prospectively normal for pregnancy and childbirth

Notice of Final Regulation (NFR) R. 61-24:

Section 400. D. The Midwife shall not perform any of the following:

2. Provision of care for a Client with a previous cesarean section;

Justification:

It was and is the Department's position that VBACs are not low-risk deliveries and are therefore outside the scope of practice for licensed midwives. VBAC deliveries require continuous electronic fetal monitoring and attendance by licensed health care personnel familiar with potential complications. Uterine rupture often is sudden and may be catastrophic, and no accurate antenatal predictors of uterine rupture have been identified. However the most common sign indicative of uterine rupture is fetal heart rate abnormality, which has been associated with up to 70% of cases of uterine ruptures. Licensed Midwives do not provide continuous fetal heart rate monitoring in the home. Not only have they requested to do intermittent fetal heart rate monitoring, they have requested to perform the monitoring at a less frequent rate than best practice.

The South Carolina Board of Nursing does not endorse Certified Nurse Midwives to perform VBAC deliveries out of the acute care (hospital) setting and acknowledges that VBAC deliveries only be performed within facilities capable of implementing emergency and surgical interventions.

There was mention of information comparing VBAC outcomes in South Carolina home births as compared to other states. This data is unavailable as VBACs are currently outside the scope of practice for South Carolina licensed midwives.

A VBAC is the result of a successful Trial of Labor after Cesarean (TOLAC). TOLAC is associated with the risk of uterine rupture which can cause brain damage or death of the baby and result in serious hemorrhage or hysterectomy in the mother. VBAC poses more medical risks to the baby than a scheduled repeat c-section. A repeat c-section poses more medical risks to the mother than VBAC. A C-section after a failed TOLAC is associated with more risks than a c-section done before labor has begun.

Of the states that regulate midwives, nine do not permit VBACs, eleven allow them with stringent restrictions, and seven allow them with informed consent of the risks.

Alternative to NFR:

Healthcare Quality does not propose alternative text for this issue.

Definition of Preceptor.

Issue:

Some commenters state that the definition in the proposed revisions may not be consistent with that suggested by NARM

Current Regulation:

Section A. 2.

m. Midwifery Instructor. A physician, certified nurse-midwife or licensed midwife, licensed in the State of South Carolina, who has a supervisory relationship with an apprentice midwife.

Notice of Final Regulation (NFR) R. 61-24:

101.Z. Midwifery Preceptor. A Physician, Certified Nurse-Midwife, or Midwife, licensed in South Carolina, who has a supervisory relationship with an Apprentice Midwife.

Justification:

A NARM Registered Preceptor is a midwife who meets requirements for supervising CPM candidates and has current, approved registration through NARM.

The Registered Preceptor must be credentialed as a Certified Professional Midwife (CPM), Certified Nurse Midwife (CNM), Certified Midwife (CM); or he or she must be a licensed practitioner legally recognized by a state/jurisdiction to provide maternity care. A preceptor must have an additional three years of experience after credentialing or fifty primary births beyond entry-level CPM requirements. Additionally, he or she must also have ten continuity of care births beyond entry-level CPM requirements. A preceptor must have attended a minimum of ten out-of-hospital births in the last three years.

The proposed regulation allows midwives licensed in South Carolina to practice the full scope of midwifery care and services as required by NARM for an apprentice midwife to practice and to show evidence of mastering skills through demonstration. There are some skills required by NARM for the apprentice to learn but that are not within the scope of practice in current and proposed regulation. NARM has allowed for those skills to be “simulated” by the apprentice as many states do not permit such skills to be included in the scope of practice for a direct entry midwife.

Twenty-five Apprentice Midwives have received their NARM certification since the promulgation of the current regulation in 2013.

Alternative to NFR:

Healthcare Quality does not propose potential alternative text for this issue.

Laceration Repairs.

Issue:

Some commenters stated that the performance of first and second-degree laceration repairs is within the scope of direct entry midwives. Other commenters, representing obstetricians and physicians, indicate that there could be long-term damage if these procedures are not performed properly and with adequate training.

Current Regulation:

N. Prohibitions in the Practice of Midwifery.

2. Surgical Procedures. The midwife shall not perform any operative procedures or surgical repairs other than artificial rupture of membranes at the introitus, and clamping and cutting of the umbilical cord or as noted above in an emergency.

Notice of Final Regulation (NFR) R. 61-24:

C. The Midwife and Apprentice Midwife may perform any of the following after submitting signed and dated documentation to the Department of the Midwifery Bridge Certificate, Midwifery Education Accreditation Council, American College of Nurse-Midwives, or other Department-approved training course completion on the topic:

2. Suturing of first-degree and second-degree tears; and

Justification:

A vaginal tear is a laceration to the perineum (the area between the vagina and rectum) that occurs when the baby is pushed out. The tears are spontaneous, meaning no one made a cut. Vaginal tears are very common as 85% - 90% of first-time births result in vaginal tears. Rates of tearing are lower for subsequent births, roughly 60% tear, as well as for those giving birth with midwives.

There are four degrees of vaginal tears. A first degree tear is a shallow tear to the skin of the perineum. Sometimes a first degree tear needs stitches, and other times it can heal without stitches. A Second degree tear is a tear to the skin and muscle layers of the perineum. Second degree tears heal better when they are repaired with stitches. A third degree tear is a tear through the perineal muscles and into the ring-shaped muscle that surrounds the anus (the anal sphincter). A fourth degree tear goes through the anal sphincter and into the anus.

Alternative to NFR:

C. The Midwife and Apprentice Midwife may perform any of the following after submitting signed and dated documentation to the Department of the Midwifery Bridge Certificate, Midwifery Education Accreditation Council, American College of Nurse Midwives, or other Department approved training course completion on the topic:

2. Suturing of first degree tears; and

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

January 7, 2021

(X) ACTION/DECISION
() INFORMATION

I. TITLE: Request for a nine-month Board extension of Certificate of Need (“CON”) SC-18-37, issued to Trident Medical Center, LLC d/b/a Trident Medical Center (“TMC”) for development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric beds and the relocation of 17 psychiatric beds from the TMC main campus for a total of 60 beds

II. SUBJECT: Request for a nine-month Board extension of Certificate of Need (CON) SC-18-37 issued to Trident Medical Center, LLC d/b/a Trident Medical Center

III. FACTS:

CON SC-18-37 was issued to TMC on August 6, 2018 for development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric beds and the relocation of 17 psychiatric beds from the TMC main campus for a total of 60 beds. The original CON SC-18-37 had an expiration date of August 6, 2019.

TMC requested a first staff extension of the CON on July 1, 2019, which was more than 30 days prior to expiration. TMC received an extension, CON SC-18-37-EXT-1, on August 9, 2019, and it was valid until May 6, 2020, a period of nine months from original expiration of the CON.

TMC requested a second staff extension of the CON on April 2, 2020, which was 30 days prior to expiration. The Department engaged with TMC to more fully understand the circumstances behind the request, and held multiple conversations with Trident leadership, including their new planning executive. These conversations were of an extended nature due to the time necessary for Department staff to make inquiries of TMC and for TMC to respond. CON SC-18-37-EXT-1 was tolled for the duration of this engagement. Ultimately, TMC received CON SC-18-37-EXT-2 on September 16, 2020, which will expire on February 6, 2021. Pursuant to Regulation 61-15, *Certification of Need for Health Facilities and Services*, Section 601, TMC submitted a third extension request to the Department on November 6, 2020 which is 90 days prior to expiration.

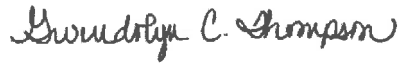
IV. ANALYSIS:

Department staff reviewed all relevant information concerning this third extension request and find that circumstances beyond the control of TMC have contributed to the need for further extension of CON SC-18-37. Specifically, TMC references delays resulting from COVID-19 response as the primary driver of the request for extension. TMC has provided with its extension request an updated timeline for the project, which Department staff believe is achievable given the significant expertise and resources available to TMC. Department staff expect that subsequent extensions by the Board may be unnecessary given TMC’s timeline showing execution of a construction contract for the Project on or about August 1, 2021. This contract will satisfy the requirement for implementation of the Project pursuant to Regulation 61-15, *Certification of Need for Health Facilities and Services* and will render moot the need for further extension of CON SC-18-37.

V. RECOMMENDATION:

Department staff recommend the Board finds that TMC has demonstrated extenuating circumstances beyond its control that have prevented the Project from advancing, that the Project is likely to be implemented during the period of extension, and that a nine-month extension of CON SC-18-37 be granted.

Submitted by:



Gwen. C. Thompson
Director
Healthcare Quality

Attachments:

- A. CON SC-18-37
- B. Letter granting first extension of CON
- C. Letter granting second extension of CON
- D. Letter requesting third extension of CON

South Carolina Department of Health
and Environmental Control



Certificate of Need

SC-18-37

IS HEREBY ISSUED TO: Trident Medical Center, LLC d/b/a Trident Medical Center

LOCATION: Charleston County

LICENSEE: Trident Medical Center

AGENT: Matt Hasbrouck, Chief Operating Officer

FOR: Development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric bed and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds.

TOTAL PROJECT COST: \$34,825,000

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

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

This Certificate of Need is valid until August 6, 2019 which is a period of twelve (12) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 6th day of August, 2018.

A handwritten signature in black ink, appearing to read "Louis W. Eubank", written over a horizontal dashed line.

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



Healthy People. Healthy Communities.



Article #: 92148969009997901415568690

August 9, 2019

VIA EMAIL AND CERTIFIED MAIL

William R. Thomas, Esquire
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-18-37

Project: Development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric bed and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds.
Charleston County, South Carolina

Dear Mr. Thomas:

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

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a first nine (9) month extension** for Certificate No. SC-18-37. The Department's decision is based on the following findings:

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

In order to grant further extensions, the Department will may require you to provide evidence of substantial progress towards completion of the project.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Louis Eubank", is written over a horizontal line.

Louis Eubank, Chief

Bureau of Healthcare Planning and Construction

Enclosures: Guide to Board Review.
CON SC-18-37-EXT-1

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

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

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

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

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision;
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
South Carolina Board of Health and Environmental Control
Attention: Clerk of the Board
2600 Bull Street
Columbia, South Carolina 29201
Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

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

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

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

II. Final Review Conference Scheduling

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

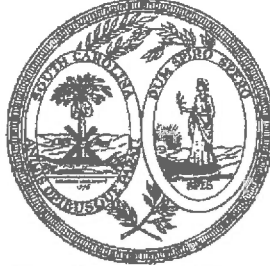
III. Final Review Conference and Decision

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

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

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

South Carolina Department of Health
and Environmental Control



Certificate of Need

SC-18-37-EXT-1

IS HEREBY ISSUED TO: Trident Medical Center, LLC d/b/a Trident Medical Center

LOCATION: Charleston County

LICENSEE: Trident Medical Center

AGENT: Matt Hasbrouck, Chief Operating Officer

FOR: Development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric bed and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds.

TOTAL PROJECT COST: \$34,825,000

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

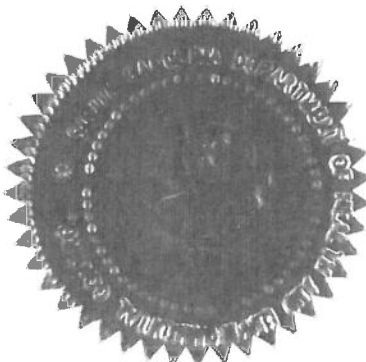
In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code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

This Certificate of Need is valid until May 6, 2020 which is a period of nine (9) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 9th day of August, 2019.

A handwritten signature in black ink, appearing to read "L. Eubank", written over a horizontal dashed line.

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



Healthy People. Healthy Communities



September 16, 2020

VIA EMAIL AND CERTIFIED MAIL

William R. Thomas, Esquire
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-18-37

Project: Development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric bed and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds.
Charleston County, South Carolina

Dear Mr. Thomas:

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

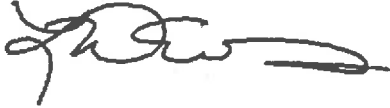
Based on the material you and Trident Medical Center provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-18-37. The Department's decision is based on the following findings:

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

In order to grant further extensions, the Department will may require you to provide evidence of substantial progress towards completion of the project.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Eubank', with a long horizontal flourish extending to the right.

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: Sylvia Simmons (via email to sylvia.simmons@hcahealthcare.com)

Enclosures: Guide to Board Review.
CON SC-18-37-EXT-2



William R. Thomas
Partner
t: 803.253.8658
f: 803.255.8017
willthomas@parkerpoe.com

Atlanta, GA
Charleston, SC
Charlotte, NC
Columbia, SC
Greenville, SC
Raleigh, NC
Spartanburg, SC
Washington, DC

November 6, 2020

VIA EMAIL AND HAND DELIVERY

The Honorable M. Denise Crawford
Clerk of the Board
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201



Re: SC-18-37, Application #2512
Trident Medical Center, LLC d/b/a Trident Medical Center
Development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric beds and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds

THIRD EXTENSION REQUEST AND QUARTERLY PROGRESS REPORT

Dear Ms. Crawford:

On behalf of Trident Medical Center, LLC d/b/a Trident Medical Center ("Trident") and pursuant to S.C. Code Ann. § 44-7-230(D) and S.C. Reg. 61-15, §§ 601 – 603, Trident respectfully requests an extension of the above-referenced Certificate of Need (SC-18-37). The CON is due to expire on February 6, 2021. Thus, Trident is requesting that the Board extend the SC-18-37 expiration date to November 6, 2021. As required, Trident is submitting this request more than three months before the expiration date of the Certificate of Need, and is providing the information required under Sections 601(4), 602 and 603. Trident is also submitting the following information to the Department in accordance with S.C. Reg. 61-15, § 607, representing its November quarterly progress report.

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

Aside from this project being delayed as discussed in response to d. below, the Department has permitted Trident to add eight of the approved beds slated for the psychiatric hospital to its present complement of 17 psychiatric beds at its main hospital so that Trident can manage its overwhelming mental health population that presents to its emergency room. There have been no other changes in configuration, costs, services or scope of this project.

To date, Trident has incurred approximately \$4,748,456 in project costs representing the land cost, construction costs, architect's fees, and the Department's CON fees.

b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.

The funds for this project have been secured, and the architectural contract has been executed (see Attachment 1). The architectural and engineering team has completed 85% of the schematic design phase, and design is ongoing.

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

Trident believes that the following represents an achievable timetable for the project:

Activity	CON SC-18-37 Amended Timetable
Architectural Contract	Completed
Architectural Design	March 28, 2021
Permits Obtained	March 2021-August 2021
Construction Contract	August 1, 2021
Start of Construction	August 31, 2021
Completion of Construction	November 30, 2022

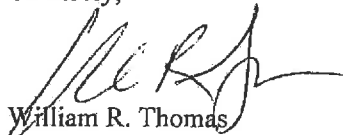
d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstances beyond the control of the applicant if the timetable was not met.

The timetable for this project has been amended as shown above due to unforeseen delays as a result of this project being under competitive review, the CON not issued until August 2018, and events surrounding the ongoing COVID-19 pandemic as further explained in Trident's second extension request (see Attachment 2).

Accordingly, Trident respectfully requests that the Department issue a nine month extension of the February 6, 2021 expiration date of CON SC-18-37. Should you have any questions, please do not hesitate to contact me.

With best regards, I am

Sincerely,



William R. Thomas

WRT/ccq
Attachments

cc: Margaret P. Murdock, Esquire (w/attachments)

Attachment 1

**AGREEMENT BETWEEN OWNER AND ARCHITECT FOR DESIGN AND
CONSTRUCTION ADMINISTRATION SERVICES AT A STIPULATED FEE**

THIS AGREEMENT is effective the 28th day of August, in the year 2020, by and between the following Owner and Architect, as it relates to the Project identified below:

OWNER:

Trident Regional Medical Center, d/b/a Trident Medical Center LLC
9330 Medical Plaza Drive
Charleston, South Carolina 29406

ARCHITECT:

HKS, Inc.
350 North Saint Paul Street, Suite 100, Dallas, Texas 75201

PROJECT:

TRIDET-Freestanding Behavioral Health Hospital – 3400100031

For purposes of this agreement the Owner Project Manager shall be:

Name: Ryan Rohe
Address: One Park Plaza
Nashville, TN 37203
Office number: 615-344-5610
Email: ryan.rohe@hcahealthcare.com

For the purposes of this agreement the Owner's Senior Representative shall be:

Name: Brent Clark
Address: One Park Plaza
Nashville, TN 37203
Office number: 615-344-1231
Email: brent.clark@hcahealthcare.com

For purposes of this agreement the Architect's Representative shall be:

Name: Tim Solohubow
Address: 350 North Saint Paul Street, Suite 100
Dallas, Texas 75201
Office number: 214-969-5599
Email: tsolohubow@hksinc.com

For purposes of this agreement the Architect's Senior Representative shall be:

Name: Jeffrey Stouffer
Address: 350 North Saint Paul Street, Suite 100
Dallas, Texas 75201
Office number: 214-969-5599
Email: jstouffer@hksinc.com

For purposes of this agreement any notice required by the Architecture Agreement in Section 12.1 shall be addressed or delivered to the respective addresses set forth below,

To Owner:

Name: Bryan Seely
Address: One Park Plaza
Nashville, TN 37203
Office number: 615-344-1231
Email: bryan.seely@hcahealthcare.com

To Architect:

Name: Jeffrey Stouffer
Address: 350 North Saint Paul Street, Suite 100
Dallas, Texas 75201
Office number: 214-969-5599
Email: jstouffer@hksinc.com

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS OF THE OBLIGATIONS HEREIN, the parties have executed this Agreement, this the 28th day of August, 2020.

OWNER:

DocuSigned by:

Brent Clark

Authorized Signature
Brent Clark

Printed Name

VP Capital Deployment, CAMS and Design

Title

ARCHITECT:

Jeffrey C. Stouffer

Authorized Signature

Jeffrey C. Stouffer

Printed Name

Executive Vice President, Global Director

Title

Attachment 2



William R. Thomas
Partner
t: 803.253.8658
f: 803.255.8017
willthomas@parkerpoe.com

Atlanta, GA
Charleston, SC
Charlotte, NC
Columbia, SC
Greenville, SC
Raleigh, NC
Spartanburg, SC
Washington, DC

April 2, 2020

VIA HAND DELIVERY

Margaret P. Murdock, Esquire
Director, Certificate of Need Program
Bureau of Healthcare Planning and Construction
SC Department of Health and Environmental Control
301 Gervais Street
Columbia, South Carolina 29201

*Re: SC-18-37, Application #2512
Trident Medical Center, LLC d/b/a Trident Medical Center
Development of a freestanding psychiatric hospital and behavioral health unit with the
addition of 43 psychiatric beds and the relocation of 17 psychiatric beds from Trident's
main campus for a total of 60 beds*

SECOND EXTENSION REQUEST

Dear Ms. Murdock:

On behalf of Trident Medical Center, LLC d/b/a Trident Medical Center ("Trident") and pursuant to S.C. Reg. 61-15, Sections 601 and 602, we are submitting this request for an extension of the above-referenced Certificate of Need. As required, we are forwarding this request more than thirty (30) days prior to the expiration date of the Certificate of Need ("CON"), and we are providing the information required under Section 602(2).

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

RESPONSE: Aside from the Department permitting Trident to add eight of the approved beds slated for the psychiatric hospital to its present complement of 17 psychiatric beds at its main hospital, there have been no changes in the configuration, costs, services, or scope of the project.

b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.

RESPONSE: As previously reported, projected construction estimate increases affected the potential sizing of the building. The corporate development team then worked with the planners, hospital and HCA Behavioral Health Services to accommodate the site and ensure that construction costs would come within budget. Sizing of the building was finalized, and Trident had plans to release architectural bids for selection, with design to begin next quarter. However, due to the COVID-19 pandemic, the

associated operational and financial effects resulting therefrom, as well as the uncertainty of this pandemic, Trident has found it necessary to devote a majority of its resources towards combatting the pandemic, which has resulted in a temporary pause of this project until the COVID-19 crisis is resolved. See also responses to c. and d. below.

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

RESPONSE: Due to the uncertainty of COVID-19, Trident has adjusted its timetable as follows:

	Original Timetable	Amended Timetable
Site Acquisition	May 2018	Completed
Architectural Contract	June 2018	2 months after COVID-19 resolution
Architectural Design	January 2019	7 months after COVID-19 resolution
Construction Contract	March 2019	14 months after COVID-19 resolution
Permits Obtained	June 2019	14 months after COVID-19 resolution
Start of Construction	July 2019	15 months after COVID-19 resolution
Completion of Construction	July 2020	27 months after COVID-19 resolution

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

RESPONSE: The timetable for this project has been amended as shown above due to unforeseen delays as a result of this project being under competitive review, the CON not issued until August 2018, and events surrounding the COVID-19 pandemic. With considerable uncertainty surrounding the COVID-19 pandemic, as well as elective cases being cancelled or delayed throughout the Trident Health System, the full operational and financial effects of this pandemic have not been fully realized. Therefore, due to extenuating circumstances beyond its control, Trident has found it necessary to temporarily interrupt work on this project, devote its resources towards combatting the COVID-19 pandemic, and respectfully requests that the Department issue a nine month extension of the May 6, 2020 expiration date of CON SC-18-37.

If you have any questions, please do not hesitate to contact me

With best regards, I am

Sincerely,



William R. Thomas

**South Carolina Board of Health and Environmental Control
Final Review Conference
January 7, 2020**

Final Review Conference -Docket No. 20-RFR-54, Ambulatory Partners, LLC - Issuance of denial of application for a Certificate of Need for the construction of a 16,640 sf Multi-Specialty Ambulatory Surgery Facility with 2 operating rooms and diagnostic imaging in Orangeburg county at a total project cost of \$12,537,535, Matter No. 2781

Counsel of Record –
Wes Jackson for Ambulatory Partners, LLC
Vito Wicevic for SCDHEC

Table of Contents

Note: Page #s for this record are located on the bottom of the page.

Staff Decision (Denial of Application for Certificate of Need, Matter No. 2781 – page 1 of 64
Request for Final Review – page 9 of 64
Staff Response – page 19 of 64
Acknowledgment Memorandum from Clerk – page 61 of 64
Notice of Final Review Conference – page 63 of 64