SOUTH CAROLINA STATE REGISTER DISCLAIMER

SOUTH CAROLINA STATE REGISTER

PUBLISHED BY
THE LEGISLATIVE COUNCIL
of the
GENERAL ASSEMBLY

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This issue contains notices, proposed regulations, emergency regulations, final form regulations, and other documents filed in the Office of the Legislative Council, pursuant to Article 1, Chapter 23, Title 1, Code of Laws of South Carolina, 1976.

SOUTH CAROLINA STATE REGISTER

An official state publication, the *South Carolina State Register* is a temporary update to South Carolina's official compilation of agency regulations--the *South Carolina Code of Regulations*. Changes in regulations, whether by adoption, amendment, repeal or emergency action must be published in the *State Register* pursuant to the provisions of the Administrative Procedures Act. The *State Register* also publishes the Governor's Executive Orders, notices or public hearings and meetings, and other documents issued by state agencies considered to be in the public interest. All documents published in the *State Register* are drafted by state agencies and are published as submitted. Publication of any material in the *State Register* is the official notice of such information.

STYLE AND FORMAT

Documents are arranged within each issue of the *State Register* according to the type of document filed:

Notices are documents considered by the agency to have general public interest.
Notices of Drafting Regulations give interested persons the opportunity to comment during the initial drafting period before regulations are submitted as proposed.
Proposed Regulations are those regulations pending permanent adoption by an agency.
Pending Regulations Submitted to the General Assembly are regulations adopted by the agency pending approval by the General Assembly.
Final Regulations have been permanently adopted by the agency and approved by the General Assembly.
Emergency Regulations have been adopted on an emergency basis by the agency.
Executive Orders are actions issued and taken by the Governor.

2004 PUBLICATION SCHEDULE

Documents will be accepted for filing on any normal business day from 8:30 A.M. until 5:00 P.M. All documents must be submitted in the format prescribed in the *Standards Manual for Drafting and Filing Regulations.*

To be included for publication in the next issue of the *State Register*, documents will be accepted no later than 5:00 P.M. on any closing date. The modification or withdrawal of documents filed for publication must be made **by 5:00 P.M.** on the closing date for that issue.

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Submission Deadline	1/9	2/13	3/12	4/9	5/14	6/11	7/9	8/13	9/10	10/8	11/12	12/10
Publishing Date	1/23	2/27	3/26	4/23	5/28	6/25	7/23	8/27	9/24	10/22	11/26	12/24

REPRODUCING OFFICIAL DOCUMENTS

Documents appearing in the *State Register* are prepared and printed at public expense. Media services are encouraged to give wide publicity to documents printed in the *State Register*.

PUBLIC INSPECTION OF DOCUMENTS

Documents filed with the Office of the State Register are available for public inspection during normal office hours, 8:30 A.M. to 5:00 P.M., Monday through Friday. The Office of the State Register is in the Legislative Council, Fourth Floor, Rembert C. Dennis Building, 1000 Assembly Street, in Columbia. Telephone inquiries concerning material in the *State Register* or the *South Carolina Code of Regulations* may be made by calling (803) 734-2145.

ADOPTION, AMENDMENT AND REPEAL OF REGULATIONS

To adopt, amend or repeal a regulation, an agency must publish in the *State Register* a Notice of Drafting; a Notice of the Proposed Regulation that contains an estimate of the proposed action's economic impact; and, a notice that gives the public an opportunity to comment on the proposal. If requested by twenty-five persons, a public hearing must be held at least thirty days after the date of publication of the notice in the *State Register*.

After the date of hearing, the regulation must be submitted to the General Assembly for approval. The General Assembly has one hundred twenty days to consider the regulation. If no legislation is introduced to disapprove or enacted to approve before the expiration of the one-hundred-twenty-day review period, the regulation is approved on the one hundred twentieth day and is effective upon publication in the *State Register*.

EMERGENCY REGULATIONS

An emergency regulation may be promulgated by an agency if the agency finds imminent peril to public health, safety or welfare. Emergency regulations are effective upon filing for a ninety-day period. If the original filing began and expired during the legislative interim, the regulation can be renewed once.

REGULATIONS PROMULGATED TO COMPLY WITH FEDERAL LAW

Regulations promulgated to comply with federal law are exempt from General Assembly review. Following the notice of proposed regulation and hearing, regulations are submitted to the *State Register* and are effective upon publication.

EFFECTIVE DATE OF REGULATIONS

Final Regulations take effect on the date of publication in the *State Register* unless otherwise noted within the text of the regulation.
Emergency Regulations take effect upon filing with the Legislative Council and remain effective for ninety days. If the original ninety-day period begins and expires during legislative interim, the regulation may be refiled for one additional ninety-day period.

SUBSCRIPTIONS

Subscriptions to the *South Carolina State Register* are available electronically through the South Carolina Legislature Online website at www.scstatehouse.net via an access code, or in a printed format. Subscriptions run concurrent with the State of South Carolina's fiscal year (July through June). The annual subscription fee for **either** format is $95.00. Payment must be made by check payable to the Legislative Council. To subscribe complete the form below and mail with payment. Access codes for electronic subscriptions will be e-mailed to the address submitted on this form.

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South Carolina General Assembly Home Page: www.scstatehouse.net

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2 REGULATIONS SUBMITTED TO GENERAL ASSEMBLY

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WITHDRAWN:

DOC NO.	DATE	SUBJECT	AGENCY
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2729	2-04-03	Fees	LLR: Board of Pharmacy

2004-11

WHEREAS, by Executive Order 2003-14, Oconee County Supervisor Ann Hughes was suspended from office until such time as the indictments against her for embezzlement of public funds were resolved; and

WHEREAS, by letter dated April 19, 2004, the prosecuting solicitor has indicated that all criminal charges pending against Ann Hughes in Oconee County have been dismissed; and

WHEREAS, the suspension ordered by Executive Order 2003-14 was based entirely on the pending indictments.

NOW, THEREFORE, pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby rescind Executive Order 2003-14, and thereby reinstate Ann Hughes as the Oconee County Supervisor.

GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 19th DAY OF APRIL, 2004.

MARK SANFORD
Governor

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Notice of General Public Interest
Public Notice #04-516-GP-N
May 28, 2004

The South Carolina Department of Health and Environmental Control (DHEC), Bureau of Air Quality, does hereby give notice of authorization being granted to the following sources who have requested coverage under General Conditional Major Operating Permit (GCMP-02) "Fuel Combustion Operations." This general permit was previously opened for a thirty (30) day public comment period on December 28, 2000, with final issuance on August 1, 2001. Pursuant to South Carolina Regulation 61-62.1, Section II G(7)(a)&(b), the Department may now grant coverage to those qualified sources seeking to operate under the terms and conditions of this general permit. The authorization of each facility's coverage shall be a final permit action for purposes of administrative review.

In accordance with the provisions of the Pollution Control Act, Sections 48-1-50(5) and 48-1-110(a), the 1976 Code of Laws of South Carolina, as amended, and Regulation 61-62.1 "Air Pollution Control Regulations and Standards," these sources are hereby granted permission to discharge air contaminants into the ambient air. The Bureau of Air Quality authorizes the operation of these sources in accordance with the plans, specifications, and other information submitted by each facility in its General Conditional Major Permit application. Facilities operating under this permit seek to limit their potential to emit below the thresholds which define a major source by complying with the federally enforceable conditions contained in this permit. Permit coverage is subject to and conditioned upon the terms, limitations, standards, and schedules contained in or specified on said permit.

Interested persons may review the final general permit, materials submitted by the applicant, and any written comments received, during normal business hours, at the following location: SC DHEC, Bureau of Air Quality, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

This notice is given pursuant to the requirements of South Carolina Regulation 61-62.1, Section II G(7)(c). Comments and questions concerning any of the following individual facility's coverage under this permit should be directed to: Mr. Carl W. Richardson, P.E., Director, Engineering Services Division, Bureau of Air Quality, SC DHEC, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

Edgefield County

Federal Bureau of Prisons (Edgefield Correctional Complex)
501 Gary Hill Rd
Edgefield, South Carolina
(Permit No. GCM02-0980-0026)

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Notice of General Public Interest
Public Notice #04-517-GP-N
May 28, 2004

The South Carolina Department of Health and Environmental Control (DHEC), Bureau of Air Quality, does hereby give notice of authorization being granted to the following sources who have requested coverage under General Conditional Major Operating Permit (GCMP-03) "Hot Mix Asphalt Plants." This general permit was previously opened for a thirty (30) day public comment period on March 28, 2001, with final issuance on February 1, 2002. Pursuant to South Carolina Regulation 61-62.1, Section II G(7)(a)&(b), the Department may now grant coverage to those qualified sources seeking to operate under the terms and conditions of this general

permit. The authorization of each facility's coverage shall be a final permit action for purposes of administrative review.

In accordance with the provisions of the Pollution Control Act, Sections 48-1-50(5) and 48-1-110(a), the 1976 Code of Laws of South Carolina, as amended, and Regulation 61-62.1 "Air Pollution Control Regulations and Standards," these sources are hereby granted permission to discharge air contaminants into the ambient air. The Bureau of Air Quality authorizes the operation of these sources in accordance with the plans, specifications, and other information submitted by each facility in its General Conditional Major Permit application. Facilities operating under this permit seek to limit their potential to emit to below the thresholds which define a major source by complying with the federally enforceable conditions contained in this permit. Permit coverage is subject to and conditioned upon the terms, limitations, standards, and schedules contained in or specified on said permit.

Interested persons may review the final general permit, materials submitted by the applicant, and any written comments received, during normal business hours, at the following location: SC DHEC, Bureau of Air Quality, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

This notice is given pursuant to the requirements of South Carolina Regulation 61-62.1, Section II G(7)(c). Comments and questions concerning any of the following individual facility's coverage under this permit should be directed to: Mr. Carl W. Richardson, P.E., Director, Engineering Services Division, Bureau of Air Quality, SC DHEC, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

Jasper County

APAC Southeast, Inc. (Hardeeville Asphalt Plant)
South Carolina Highway 27 & 413
Hardeeville, South Carolina
(Permit No. GCM03-9900-0271)

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Notice of General Public Interest
Public Notice #04-518-GP-N
May 28, 2004

The South Carolina Department of Health and Environmental Control (DHEC), Bureau of Air Quality, does hereby give notice of authorization being granted to the following sources who have requested coverage under General Conditional Major Operating Permit (GCMP-04) "Concrete Batch Plants." This general permit was previously open for a 30 day public comment period on March 28, 2001, with final issuance on November 1, 2001. Pursuant to South Carolina Regulation 61-62.1, Section II G(7)(a)&(b), the Department may now grant coverage to those qualified sources seeking to operate under the terms and conditions of this general permit. The authorization of each facility's coverage shall be a final permit action for purposes of administrative review.

In accordance with the provisions of the Pollution Control Act, Sections 48-1-50(5) and 48-1-110(a), the 1976 Code of Laws of South Carolina, as amended, and Regulation 61-62.1 "Air Pollution Control Regulations and Standards," these sources are hereby granted permission to discharge air contaminants into the ambient air. The Bureau of Air Quality authorizes the operation of these sources in accordance with the plans, specifications, and other information submitted by each facility in its General Conditional Major Permit application. Facilities operating under this permit seek to limit their potential to emit to below the thresholds which define a major source by complying with the federally enforceable conditions contained in this permit. Permit coverage is subject to and conditioned upon the terms, limitations, standards, and schedules contained in or specified on said permit.

Interested persons may review the final general permit, materials submitted by the applicant, and any written comments received, during normal business hours, at the following location: SC DHEC, Bureau of Air Quality, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

This notice is given pursuant to the requirements of South Carolina Regulation 61-62.1, Section II G(7)(c). Comments and questions concerning any of the following individual facility's coverage under this permit should be directed to: Mr. Carl W. Richardson, P.E., Director, Engineering Services Division, Bureau of Air Quality, SC DHEC, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

Greenville County

Metromont Materials Corporation
2802 White Horse Road
Greenville, South Carolina
(Permit No. GCM04-1200-0088)

Horry County

APAC Carolina, Inc. (Conway Plant)
130 Winyah Road
Conway, South Carolina
(Permit No. GCM04-9900-0412)

Lexington County

Hardaway Concrete Company
Lake Murray Dam
Lexington, South Carolina
(Permit No. GCM04-9900-0182)

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

In accordance with Section 44-7-200(C), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication May 28, 2004, for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull St., Columbia, SC 29201 at (803) 545-4200.

Affecting Beaufort County

Development of a freestanding outpatient imaging center providing Magnetic Resonance Imaging (MRI) to replace the existing MRI currently operated by Beaufort Open MRI, Computerized Tomography (CT), and x-ray services.
Beaufort Imaging Center
Port Royal, South Carolina
Project Cost: $3,706,155

Establish an outpatient narcotic treatment program to be located at 1 Sheridan Park, Bluffton, South Carolina 29910. (Methadone Treatment Center)
Choices, Inc.
Bluffton, South Carolina
Project Cost: $841,819

Affecting Charleston County

Purchase of a Computed Tomography (CT) Simulator and lease of additional space for the Hollings Cancer Center Radiation Therapy Center at East Cooper Regional Medical Center.
Medical University of South Carolina Medical Center
Hollings Cancer Center Radiation Therapy Center at East Cooper
Charleston, South Carolina
Project Cost $1,445,444

Affecting Cherokee County

Replace existing single-slice Computed Tomography (CT) scanner with a Multi-Slice CT scanner.
Upstate Carolina Medical Center
Gaffney, South Carolina
Project Cost: $809,817

Affecting Greenwood County

Upfit of eighth floor shelled space to house the replacement of thirty-two (32) existing general acute care beds with no change in the existing licensed bed capacity at the hospital.
Self Regional Healthcare
Greenwood, South Carolina
Project Cost: $5,090,232

Affecting Jasper County

Construction for the addition of a Magnetic Resonance Imaging (MRI) unit.
Coastal Carolina Medical Center
Hardeeville, South Carolina
Project Cost: $3,201,000

Establish an outpatient narcotic treatment program to be located at 124 Boardwalk Drive, Unit A, Oakatie, South Carolina 29909. (Methadone Treatment Center)
Recovery Concepts, LLC
Oakatie, South Carolina
Project Cost: $218,255

Affecting Lexington County

Development of an adult open heart surgery program with one dedicated operating room (OR), one back-up OR and the addition of a second cardiac catheterization laboratory with the development of a therapeutic cardiac catheterization program.
Lexington Medical Center
West Columbia, South Carolina
Project Cost: $5,607,408

Upfit of shelled space for the relocation of the Radiology Department.
Lexington Medical Center
West Columbia, South Carolina
Project Cost: $11,855,109

In accordance with S.C. DHEC Regulation 61-15, the public and affected persons are hereby notified that the review cycle has begun for the following project(s) and a proposed decision will be made within 60 days beginning May 28, 2004. "Affected persons" have 30 days from the above date to submit comments or requests for a public hearing to Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull Street, Columbia, S.C. 29201. For further information call (803) 545-4200.

Affecting Charleston County

Purchase of a Computed Tomography (CT) Simulator and lease of additional space for the Hollings Cancer Center Radiation Therapy Center at East Cooper Regional Medical Center.
Medical University of South Carolina Medical Center
Hollings Cancer Center Radiation Therapy Center at East Cooper
Charleston, South Carolina
Project Cost: $1,445,444

Affecting Darlington County

Construction for the addition of 50 general acute care beds, resulting in a total licensed bed capacity of 166 general acute care beds; renovation and expansion of the emergency department and addition of a Computed Tomography (CT) scanner.
Carolina Pines Regional Medical Center
Hartsville, South Carolina
Project Cost: $28,887,720

Affecting Greenwood County

Upfit of eighth floor shelled space to house the replacement of thirty-two (32) existing general acute care beds with no change in the existing licensed bed capacity at the hospital.
Self Regional Healthcare
Greenwood, South Carolina
Project Cost: $5,090,232

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC NOTICE

Section IV of R.61-98, the State Underground Petroleum Environmental Response Bank (SUPERB) Site Rehabilitation and Fund Access Regulation, requires that the Department of Health and Environmental Control evaluate and certify site rehabilitation contractors to perform site rehabilitation of releases from underground storage tanks under the State Underground Petroleum Environmental Response Bank (SUPERB) Act. Pursuant to Section IV.B.1., the Department is required to place a list of those contractors requesting certification on public notice and accept comments from the public for a period of thirty (30) days. If you wish to provide comments regarding the companies and individuals listed below, please submit your comments in writing, no later than June 30, 2004 to:

Contractor Certification Program
South Carolina Department of Health and Environmental Control
Underground Storage Tank Program
Attn: Barbara Boyd
2600 Bull Street
Columbia, SC 29201

The following companies and individuals have applied for certification as Underground Storage Tank Site Rehabilitation Contractors:

Class I

Class II

EI, Inc. – Greenville
Envirotrac - Alpharetta
PGP Services
TN & Associates, Inc.

DEPARTMENT OF LABOR, LICENSING AND REGULATION
BUILDING CODES COUNCIL

NOTICE OF GENERAL PUBLIC INTEREST

Notice is hereby given that, in accordance with Section 6-9-40 of the 1976 Code of Laws of South Carolina, as amended, the South Carolina Building Codes Council intends to update the International Building Code, 2000 Edition, to the International Building Code, 2003 Edition, International Residential Code, 2000 Edition, to the International Residential Code, 2003 Edition, as modified below:

International Fire Code, 2000 Edition, to the International Fire Code, 2003 Edition.
International Plumbing Code, 2000 Edition, to the International Plumbing Code, 2003 Edition.
International Mechanical Code, 2000 Edition, to the International Mechanical Code, 2003 Edition.
International Fuel Gas Code, 2000 Edition, to the International Fuel Gas Code, 2003 Edition, and
International Energy Conservation Code, 2000 Edition, to the International Energy Conservation Code, 2003 Edition. These codes will become effective January 1, 2005.

The Council also intends to modify the following sections of the International Residential Code, 2003 Edition:

Section R202
Section R301.2(2)
Section R301.2.2
Section R301.2.2
Figure R307.2
Section R311.4.3
Section R311.5.3
Section R311.5.6.1
Table R402.2
Section R403.1.4.2
Section R403.1.6
Section R403.1.7
Table R502.5(1)
Section R502.11.4

Section R602.10.5
Section R802.10.1
Chapter 11
Section G505.1.1
Section G505.1.1
Section M1411.4

The South Carolina Building Codes Council has accepted comments and convened a study committee pursuant to 6-9-40 for the consideration of the 2003 Edition of the International Building Codes. After receipt of the study committee's report, the South Carolina Building Codes Council proposes to modify sections of the International Residential Code. All proposed modifications must provide a reasonable degree of public health, safety, and welfare. The study committee met on December 17, 2003, January 28, 2004, and February 20, 2004. The Council approved the modifications on February 25, 2004. Written comments may be submitted to Gary Wiggins, Board Administrator, at 110 Centerview Drive, 1st Floor, Columbia, South Carolina, 29211-1329, (803) 896-4688.

DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL

NOTICE OF GENERAL PUBLIC INTEREST

Notice is hereby given that, in accordance with Section 1-34-30 of the 1976 Code of Laws of South Carolina, as amended, the Department of Labor, Licensing and Regulation, Office of State Fire Marshal hereby adopts the latest edition of the following nationally recognized code.

1. National Fire Protection Association 2001, Standard on Clean Agent Fire Extinguishing Systems, 2004 Edition

2. The original promulgating authority for this code is:
   National Fire Protection Association
   1 Batterymarch Park
   Quincy, Massachusetts 02269

3. This code is referenced by:
   South Carolina Regulation 71-8307.3(A)(9)(i)

The Office of State Fire Marshal specifically requested comments concerning sections of these editions which may be unsuitable for enforcement in South Carolina. Therefore, the Office of State Fire Marshal hereby promulgates this latest edition.

DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL

NOTICE OF GENERAL PUBLIC INTEREST

Notice is hereby given that, in accordance with Section 1-34-30 of the 1976 Code of Laws of South Carolina, as amended, the Department of Labor, Licensing and Regulation, Office of State Fire Marshal hereby adopts the latest edition of the following nationally recognized code.

1. National Fire Protection Association 12A, Standard on Halon 1301 Extinguishing Systems, 2004 Edition

2. The original promulgating authority for this code is:
   National Fire Protection Association
   1 Batterymarch Park
   Quincy, Massachusetts 02269

3. This code is referenced by:
   South Carolina Regulation, Section 71-8307.3(A)(9)(d)

The Office of State Fire Marshal specifically requested comments concerning sections of these editions which may be unsuitable for enforcement in South Carolina. Therefore, the Office of State Fire Marshal hereby promulgates this latest edition.

CLEMSON UNIVERSITY
STATE LIVESTOCK-POULTRY HEALTH COMMISSION
CHAPTER 27
Statutory Authority: 1976 Code Section 47-4-30 and 47-17-130

Notice of Drafting:

The Livestock-Poultry Health Commission is considering modernizing, clarifying and updating existing regulations which govern, to the extent authorized by S. C. Code, Title 47, Chapter 4, the inspection or meat and meat food products produced for intrastate commerce.

Interested parties should submit written comments to Dr. Daniel E. Lafontaine, Director, State Meat-Poultry Inspection Department, P. O. Box 102406, Columbia, S. C. 29224-2406. To be considered comments should be received no later than June 28, 2004, the close of the drafting comment period.

Synopsis:

This regulation is being promulgated to comply with the Federal Meat Inspection Act (21 USDA 661, Section 301) which establishes Federal-State Cooperative Meat Inspection Programs. This is a grant program with equal federal-state funding. A cooperating state is required to adopt regulations at least as stringent as those adopted by the United States Government. This regulation will, in effect, adopt the current Federal Meat Inspection Regulations with some minor exceptions for some state specific requirements, such as utilizing state marks of inspection, designating use of state holidays and other similar requirements.

This regulation will not require legislative action.

CLEMSON UNIVERSITY
STATE LIVETOCK-POULTRY HEALTH COMMISSION
CHAPTER 27
Statutory Authority: 1976 Code Sections 47-4-30, 47-19-30, and 47-19-170

Notice of Drafting:

The Livestock-Poultry Health Commission is considering modernizing, clarifying and updating existing regulations which govern, to the extent authorized by S.C. Code, Title 47, Chapter 4, the inspection of poultry products produced for intrastate commerce.

Interested parties should submit written comments to Dr. Daniel E. Lafontaine, Director, State Meat-Poultry Inspection Department, P. O. Box 102406, Columbia, S.C. 29224-2406. To be considered comments should be received no later than June 28, 2004, the close of the drafting comment period.

Synopsis:

This regulation is being promulgated to comply with the Poultry Products Inspection Act (21 USCA 454, Section 5) which establishes Federal-State Cooperative Poultry Inspection Programs. This is a grant program with equal federal-state funding. A cooperating state is required to adopt regulations at least as stringent as those adopted by the United States Government. This regulation will, in effect, adopt the current Federal Poultry Products Inspection Regulations with some minor exceptions for some state specific requirements, such as utilizing state marks of inspection, designating use of state holidays, and other similar requirements.

This regulation will not require legislative action.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 30

Statutory Authority: S.C. Code Sections 48-39-10 *et seq*.

Notice of Drafting:

The Department of Health and Environmental Control proposes to amend R.30-1, *Statement of Policy*, and R.30-12, *Specific Project Standards for Tidelands and Coastal Waters*, two of the Department's Coastal regulations related to permitting in the critical areas of the Coastal Zone. Interested persons should submit their views in writing to: Ms. Debra L. Hernandez, Office of Ocean and Coastal Resource Management, S.C. Department of Health and Environmental Control, 1362 McMillan Avenue, Suite 400, Charleston, S.C., 29405. To be considered, comments should be received no later than June 28, 2004, the close of the initial drafting comment period.

Synopsis:

The Department proposed to amend R.30-1 and R.30-12 pursuant to S.C. Code Section 48-39-10 *et seq*. The proposed amendment will clarify the definitions for docks and marinas in R.30-1(D) and make stylistic and content changes to the current standards for docks and marinas in R.30-12(A) and (E). The intent of the changes is to distinguish the standards that apply to all docks from those that apply only to private, commercial or community docks. The Department also intends to make changes that will provide incentives for the construction of community docks in lieu of multiple private docks. Additionally, new standards for marinas will be proposed to address a recent trend in marina development away from traditional commercial marinas that are open to the public to private marinas for the exclusive use of condominium or other property owners in an associated land development.

DEPARTMENT OF LABOR, LICENSING AND REGULATION
SOUTH CAROLINA BUILDING CODES COUNCIL

CHAPTER 9

Statutory Authority: 1976 Code Section 6-9-40

Notice of Drafting:

Notice is hereby given that, in accordance with Section 6-9-50 of the 1976 Code of Laws of South Carolina, as amended, the South Carolina Building Codes Council intends to update the International Residential Code, 2000 Edition, to the International Residential Code, 2003 Edition.

The Council also is considering modification to the following sections of the International Residential Code, 2003 Edition:
Section R202
Section R301.2(2)
Section R301.2.2
Section R301.2.2
Figure R307.2
Section R311.4.3
Section R311.5.3
Section R311.5.6.1
Table R402.2
Section R403.1.4.2
Section R403.1.6
Section R403.1.7

Table R502.5(1)
Section R502.11.4
Section R602.10.5
Section R802.10.1
Chapter 11
Section G505.1.1
Section G505.1.1
Section M1411.4

The Council specifically requests comments concerning sections of this edition which may be unsuitable for enforcement in South Carolina. Written comments may be submitted to Gary Wiggins, Board Administrator, at 110 Centerview Drive, 1st Floor, Columbia, South Carolina, 29211-1329, (803) 896-4620.

Synopsis:

The South Carolina Building Codes Council accepted comments and convened a study committee pursuant to 6-9-40 for consideration of the 2003 Edition of the International Residential Code. After receipt of their report, the South Carolina Building Codes Council proposes to modify sections of the International Residential Code. All proposed modifications must provide a reasonable degree of public health, safety, and welfare. The study committee met on December 17, 2003, January 28, 2004, and February 25, 2004. The Council approved the modifications on February 25, 2004.

DEPARTMENT OF REVENUE

Chapter 7

Statutory Authority: 1976 Code Sections 12-4-320 and 61-2-60

Notice of Drafting:

The South Carolina Department of Revenue is considering amending SC Regulation 7-200.1 to repeal subsection F and indicate that it is "Reserved" at this time, and to amend subsection J to clarify that the request for refund applies to the permit or license fee. The proposal to amend SC Regulation 7-200.1 is needed to ensure that taxpayers understand (1) that only a cooking license is needed if a location that offers meals to the public purchases liquor for use solely in the cooking and preparing meals served by the location and not for sale to the public, and (2) that only the permit or license fee is refundable if a timely refund request is received with respect to a permit or license that was not used.

Interested persons may submit written comments to Meredith F. Cleland, South Carolina Department of Revenue, Legislative Services, P.O. Box 125, Columbia, SC 29214. To be considered, comments must be received no later than 5:00 p.m. on June 29, 2004.

Synopsis:

The South Carolina Department of Revenue is considering amending SC Regulation 7-200.1 to repeal subsection F and indicate that it is "Reserved" at this time, and to amend subsection J to clarify that the request for refund applies to the permit or license fee.

Document No. 2912
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Section 48-1-10 *et seq*

Regulation 61-62, *Air Pollution Control Regulations and Standards,* and the South Carolina State Implementation Plan

Preamble:

On July 18, 1997, the United States Environmental Protection Agency (EPA) promulgated amendments to the National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter. The amendments revised the existing 1-hour ozone standard to an 8-hour ozone standard at a level of 0.08 parts per million based on the 3-year average of the annual fourth-highest daily maximum 8-hour ozone concentration. Two new $PM_{2.5}$ standards were also added. One is an annual standard set at 15 micrograms per cubic meter based on the 3-year average of annual arithmetic mean. The other is a 24-hour standard set at 65 micrograms per cubic meter based on the 3-year average of the 98^{th} percentile $PM_{2.5}$ concentration.

Shortly after promulgation, the amendments were challenged in the federal courts. On February 27, 2001, the United States Supreme Court issued a decision upholding how the EPA sets air pollution standards and affirming the principle that national air quality standards must be set to protect public health and cost does not have to be taken into consideration when the national standards are established. The court also ruled that the EPA did not exceed its authority to set standards without Congressional review. However, the court sent back to EPA the question of how or when to implement measures to improve air quality. The issue of implementation of the standards has delayed the EPA's designation of areas as being in either attainment or nonattainment of the new standards. The EPA has now made clear their intentions to designate areas for the 8-hour standard by April 15, 2004, and to designate areas for the $PM_{2.5}$ standards by December 31, 2004.

The Department proposes to amend Regulation 61-62.5, Standard No. 2*, Ambient Air Quality Standards,* and the SIP, to incorporate the new Federal amendments to the ozone and $PM_{2.5}$ NAAQS. While EPA's intent is to replace the 1-hour ozone standard with the 8-hour ozone standard, the method by which the 1-hour standard will be replaced has not been finalized. Therefore, the Department will leave the 1-hour ozone standard in place until such time that the EPA decides the implementation schedule for revocation of the 1-hour standard.

The proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards,* are necessary to maintain consistency with Federal rules and will not require legislative review.

A Notice of Drafting for these proposed changes was published in the *State Register* on August 22, 2003. Since this amendment is consistent with Federal law, neither a preliminary fiscal impact statement nor a preliminary assessment report is required.

Discussion of Proposed Revisions:

SECTION CITATION:	EXPLANATION OF CHANGE:
R.61-62.5, Standard No. 2	Add new Ozone measuring interval to 8 hours and standard to 0.08 ppm.
	Add new Particulate Matter (PM) standard 2.5 µg and designate new standard for annual and 24 hour standards.

Notice of Staff Informational Forum:

Staff of the Department of Health and Environmental Control invite interested members of the public to attend a staff-conducted informational forum to be held on June 28, 2004 at 10:00 a.m. in room 2280 at the Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The purpose of the forum is to receive comments from interested persons on the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards*.

Interested persons are also provided an opportunity to submit written comments to Thomas J. Flynn, III at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201. To be considered, comments must be received no later than 5:00 p.m. on June 28, 2004. Comments received shall be submitted to the Board in a Summary of Public Comments and Department Responses.

Copies of the proposed regulation for public notice and comment may be obtained by contacting Thomas J. Flynn, III at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-3251.

Notice of Public Hearing and Opportunity for Public Comment Pursuant to S.C. Code Sections 1-23-110 and 1-23-111:

Interested members of the public and regulated community are invited to comment on the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards* at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly-scheduled meeting on August 12, 2004. The public hearing is to be held in room 3420 (Board Room) of the Commissioner's Suite, third floor, Aycock Building of the Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda to be published by the Department twenty-four hours in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less, and as a courtesy are asked to provide written copies of their presentation for the record.

Interested persons are also provided an opportunity to submit comments on the proposed amendments to Thomas J. Flynn, III at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, Regulatory Development Section, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-3251. To be considered, comments must be received no later than 5:00 p.m. on June 28, 2004. Comments received shall be considered by the staff in formulating the final proposed regulation for public hearing on August 12, 2004, as noticed above. Comments received shall be submitted to the Board in a Summary of Public comments and Department Responses.

Statement of Need and Reasonableness:

This statement of need and reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: Amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards.*

Purpose of Regulation: These amendments will maintain conformity with Federal requirements and ensure compliance with Federal standards.

Legal Authority: The legal authority for Regulation 61-62, *Air Pollution Control Regulations and Standards*, is S.C. Code Section 48-1-10 *et seq.*

Plan for Implementation: The proposed amendments will take effect upon approval and adoption by the South Carolina Board of Health and Environmental Control and publication in the *State Register.*

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

On July 18, 1997, the United States Environmental Protection Agency (EPA) promulgated amendments to the National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter. The amendments revised the existing 1-hour ozone standard to an 8-hour ozone standard at a level of 0.08 parts per million based on the 3-year average of the annual fourth-highest daily maximum 8-hour ozone concentration. Two new $PM_{2.5}$ standards were also added. One is an annual standard set at 15 micrograms per cubic meter based on the 3-year average of annual arithmetic mean. The other is a 24-hour standard set at 65 micrograms per cubic meter based on the 3-year average of the 98^{th} percentile $PM_{2.5}$ concentration.

Shortly after promulgation, the amendments were challenged in the federal courts. On February 27, 2001, the United States Supreme Court issued a decision upholding how the EPA sets air pollution standards and affirming the principle that national air quality standards must be set to protect public health and cost does not have to be taken into consideration when the national standards are established. The court also ruled that the EPA did not exceed its authority to set standards without Congressional review. However, the court sent back to EPA the question of how or when to implement measures to improve air quality. The issue of implementation of the standards has delayed the EPA's designation of areas as being in either attainment or nonattainment of the new standards. The EPA has now made clear their intentions to designate areas for the 8-hour standard by April 15, 2004, and to designate areas for the $PM_{2.5}$ standards by December 31, 2004.

The Department proposes to amend Regulation 61-62.5, Standard No. 2*, Ambient Air Quality Standards,* and the SIP, to incorporate the new Federal amendments to the ozone and $PM_{2.5}$ NAAQS. While EPA's intent is to replace the 1-hour ozone standard with the 8-hour ozone standard, the method by which the 1-hour standard will be replaced has not been finalized. Therefore, the Department will leave the 1-hour ozone standard in place until such time that the EPA decides the implementation schedule for revocation of the 1-hour standard.

The proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards,* are necessary to maintain consistency with Federal rules and will not require legislative review.

DETERMINATION OF COSTS AND BENEFITS:

There will be no increased cost to the State or its political subdivisions as a result of these amendments. The standards to be adopted are already effective and applicable to the regulated community as a matter of Federal law.

UNCERTAINTIES OF ESTIMATES:

EPA has not provided cost estimates due to interpretation of section 109 of the Clean Air Act, which requires NAAQS to be set to protect public health, without consideration of costs.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

Adoption of the recent changes in Federal law through the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards*, will provide more protection of the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

While there is no specific detrimental effect on the environment and public health, the State's authority to implement Federal requirements, which are believed to be beneficial to the public health and environment, would be compromised if these amendments are not adopted in South Carolina.

Text:

The full text of this regulation is available on the South Carolina General Assembly Home Page: **http://www.scstatehouse.net/regnsrch.htm.** Full text may also be obtained from the promulgating agency.

Document No. 2875
STATE BOARD OF EDUCATION
CHAPTER 43
Statutory Authority: S.C. Code Ann. Sections 59-5-60 (1990) and 59-25-110 (1990)

R 43-54. Additional Areas of Certification

Synopsis:

The State Department of Education recommends that the State Board of Education promulgate the repeal of R 43-54. The intent of this regulation will be merged into R 43-62.

Section-by-Section Discussion

The intent of this regulation is being merged into R 43-62.

Instructions: Repeal in its entirety R 43-54, Additional Areas of Certification, to Chapter 43 regulations.

Text:

Areas of Certification

Additional areas of certification may be added to a valid Professional South Carolina teaching credential. To add an additional area, an applicant must:

1. Complete the requirements established for certification area as adopted by the State Board of Education.

2. Submit the required score on the teaching area examination(s).

3. Submit a written request and all required documentation to the Office of Teacher Education, Certification and Evaluation for the additional area of certification.

Statement of Rationale: The proposed repeal and addition of the regulation's amended text to R 43-62 will serve to further clarify requirements for additional areas of certification.

Fiscal Impact Statement: There will be no increased costs to the state or its political subdivisions.

Document No. 2868
STATE BOARD OF EDUCATION
CHAPTER 43
Statutory Authority: S. C. Code Ann. Sections 59-5-60 (1990), 59-18-110 (Supp. 2002), 59-29-10, *et seq*. (1990 and Supp. 2002), 59-29-200 (1990), 59-33-30 (1990), 59-53-1810 (1990), 20 U.S.C. Section 1232(g), and 20 U.S.C. Section 6301 *et seq.* (2001)

43-234. Defined Program, Grades 9–12

Synopsis:

The State Board of Education proposes amending Regulation 43-234, Defined Program, Grades 9–12. This regulation requires all public high schools to provide a rigorous, relevant curriculum to help students meet the

requirements for the state high school diploma. This regulation also provides for the administration and operation of high school programs.

The Notice of Drafting was published in the *State Register* on June 27, 2003.

Section-by-Section Discussion

Section I(A)	Deletes pre-algebra completing the phase out of general curriculum courses. Mathematics for the technologies 3 is added as a course required to be offered. AP calculus is added as an alternative offering to calculus, a course required to be offered. Changes discrete mathematics to a course recommended to be offered and deletes integrated science as a course required to be offered. A requirement that each student must take physical science prior to taking the exit examination at the end of the tenth grade is added. Text related to the STAR diploma is deleted. Maintains the requirement that environmental studies must be offered and deletes the requirement that the subject must be offered as a separate one semester elective course.
Section I(E)	New language is inserted requiring core unit alternative courses to be aligned with curriculum standards and requires schools to reapply for approval when substantial changes are made to course content.
Section I(F)(4)	Adds provisions for granting high school credit earned in adult education aligning with R 43-259, Graduation Requirements.
Section I(F)(5)	Moves the provision for accepting credits from schools accredited by regional accrediting associations from Section I(G)(4) to this section.
Section I(G)(4)	Adds an additional provision for the issuance of dual credit aligning with R 43-259, Graduation Requirements.
Section I(I)(5)	New language is inserted regarding a modified school day under certain conditions for pupils with disabilities.
Section III(A)	Deletes the twenty-unit high school diploma requirements.
Section III(A)(2)	Former Footnote 1. Adds language regarding prerequisites for business and marketing computer courses aligning with R 43-259, Graduation Requirements.
Section III(A)(3)	Former Footnote 2.
Section III(A)(4)	Former Section C.
Section III(A)(5)	Former Section D.
Section III(A)(6)	Former Section E. Inserts text referencing the inclusion of Appendix B, Exit Examination, in R 43-262, Assessment Program.
Section III(B)(1)	New text addressing the phase-out of out-of-field teaching permits in special education under the federal No Child Left Behind Act, 20 U.S.C. Section 6301 *et seq.* (2001) has been inserted. Inserts a relocated footnote concerning the certification status of a teacher of students with disabilities. Inserts language for clarification of special needs student placement in alignment with text from R 43-259, Graduation Requirements.

Section V	Deletes out-dated language defining a student identified as a Tech Prep completer.
Section VI	The listing of other State Board of Education regulation titles related to this regulation is updated.
Section VII(3)	New language adds a reference to the Family Education Rights and Privacy Act (20 U.S.C. § 1232(g)) regarding student records.
Section VIII	Language is updated to reflect procedure changes.
Appendix A	The List of Courses and Activity Codes are removed, since the listing will be available on the Department of Education Web site.
Appendix B	Deletes the exit exam regulations since Appendix B is included in Regulation 43-262, Assessment Program.

Instructions: Amend in its entirety R 43-234, Defined Program Grades 9–12, and delete Appendices A and B, to Chapter 43 regulations.

Text:

Defined Program Grades 9–12

Each school district board of trustees will ensure quality schooling by providing a rigorous, relevant curriculum for all students.

Each school district must use the academic achievement standards adopted by the State Board of Education to push schools and students toward high performance by aligning the state assessments to those standards and linking policies and criteria for performance standards, accreditation, reporting, school rewards, and targeted assistance.

The curriculum may include noncredit academic assistance designed to accelerate the learning of students who test below grade level.

I. Curriculum, Grades 9–12:

The College Prep curriculum consists of courses required for entrance into South Carolina's public colleges and universities.

The Tech Prep curriculum consists of courses required for entrance into post-secondary education and the completion of a career major.

A. Required and Recommended Courses

1. South Carolina high schools must offer specific courses in the subject areas listed below. Courses designated with an asterisk are those that the State Board of Education recommends but does not require schools to offer.

English/language arts:
English 1, 2, 3, 4
Communication for the Workplace 3, 4

Mathematics:
Algebra 1, Mathematics for the Technologies 1, 2, 3
Algebra 2, Geometry
Pre-Calculus, Calculus or AP Calculus
Discrete Mathematics*, Probability and Statistics

Science:
Physical Science
Earth Science
Biology 1, Biology 2*, Applied Biology 1, 2*
Chemistry 1, Chemistry 2*, Chemistry for the Technologies
Physics, Physics for the Technologies 1, 2*

Social Studies:
U.S. History and the Constitution
U.S. Government
Economics
Global Studies—World History, Global Studies—World Geography

2. Schools must also offer courses in each of the following subject areas:

computer science (including keyboarding)
driver education
foreign language(s)
health education
PE (or Junior ROTC)
visual and performing arts (including band, chorus, instrumental music, dance, and drama)

3. Advanced Placement courses must be offered.

4. Career and technology education courses must be offered.

5. Beginning with the 2005-06 school year, every student must take one unit of physical science by the end of the tenth grade prior to taking the exit examination.

6. The required PE course shall occur over two semesters. For one semester, a personal fitness and wellness component must be taught, and for one semester a lifetime fitness component must be taught either over the semester or in two nine-week divisions.

7. At least one time during the four years of grades nine through twelve, each student must receive a program of instruction in comprehensive health education that includes the following subjects:

community health
consumer health
environmental health
growth and development
nutritional health
personal health
prevention and control of diseases and disorders
safety and accident prevention
substance use and abuse
dental health

mental and emotional health
reproductive health
pregnancy prevention
sexually transmitted diseases**
family life (option in grades 9–12)

**Instruction in sexually transmitted diseases (STDs), including AIDS education, must be provided within the reproductive health, family life, or pregnancy prevention education components for a minimum of 15 hours or must be presented as a separate component S.C. Code Ann. § 59-32-30(E)(1990). Students may be exempted from this instruction with written parental permission.

8. All high schools must include Environmental Studies as a part of the instructional program.

B. Alcohol and Drugs

Schools must provide age-appropriate instruction regarding the dangers in the use and abuse of alcohol, tobacco, and other drugs. Instruction must emphasize the negative effects that the use of such substances can have on the total community. Instruction must be offered in all schools of the State and must be presented thoroughly and in the same manner as all other required subjects in grades nine through twelve.

C. Guidance Program

1. A comprehensive guidance program, including career development, is required in schools encompassing any combination of grades nine through twelve.

2. Each school district must offer a range of mentoring opportunities for students. In order to participate in any of the work-based programs, students must have the written permission of their parents or legal guardians in order to engage in such experiences. Adult supervision must be provided for mentoring experiences.

3. Every student and his or her parents, or legal guardian, in collaboration with appropriate school personnel, must review and revise the student's career planning record on a yearly basis. The record is to include an appropriate program of high school study based on a major plan and an alternate plan for career options for the student to achieve his or her individual career goals.

D. Library/Media Program

Library/media programs and technology resources must be available and accessible to all students and staff and must be appropriate for the accomplishment of the strategies and goals in each school renewal or district strategic plan.

E. Innovative Approaches

1. A school encompassing any combination of grades nine through twelve may implement an innovative approach if it is approved by the local board of trustees and is incorporated in the school and district plans. To award core unit credit for a course that is an alternative to those on the list of approved courses, the school must ensure that the course is aligned with state curriculum standards and is approved by the local board of trustees and the State Superintendent of Education. A school must reapply for approval of the innovative approach if there is substantial change in the content of a core course. If state or federal career and technology funds are to be used for an innovative course or program, an application must be completed by the district and submitted in writing to the Office of Career and Technology Education for approval.

2. The list of state-approved courses with instructional activity codes will be available from the Office of School Quality at the State Department of Education. The list of approved courses will also be updated on the State Department of Education's Web site.

F. Provisions for Granting High School Credit

1. Accredited secondary schools may award and accept credit in terms of one-fourth, one-half, or one unit.

2. One unit of credit is granted for the satisfactory completion of an approved course in which a student attends at least 120 hours of instruction, one-half unit is granted for 60 hours, and one-fourth unit is granted for 30 hours.

3. Credit for distance learning courses may be allowed when approved specifically by the local superintendent or his or her designee.

4. High school credit earned in an approved adult education program may be used to meet regular high school graduation requirements if (a) a minimum of 120 hours of attendance has been completed for each unit being transferred and (b) the teacher providing the instruction is properly certified and highly qualified to teach the course. After June 30, 2006, out-of-field permits may no longer be issued to teachers who teach core academic subjects as specified by the No Child Left Behind Act of 2001, 20 U.S.C. Section 6301 et seq. (2001). The core academic subjects are English, reading or language arts, mathematics, science, foreign languages, civics, government, economics, history, geography, and the arts. Approval for exceptions to this standard must be requested in writing by the high school principal and must be granted by the director of the Office of School Quality.

5. Credit will be accepted when official transcripts are received from schools that are accredited by a state or by the New England Association of Colleges and Schools, the Middle States Association of Colleges and Schools, the Southern Association of Colleges and Schools, the North Central Association of Colleges and Schools, the Western Association of Colleges and Schools or the Northwest Association of Colleges and Schools. If a student transfers from a school that is not accredited, he or she shall be given tests to evaluate prior academic work and/or be given a tentative assignment in classes for a probationary period.

G. Dual Credit

College courses credit may be earned by students in grades nine through twelve and applied to the 24 units required for a state high school diploma. The acceptance of credits for college course work is subject to the following conditions:

1. Local school boards may allow students to take college courses for Carnegie units of credit. Courses may be offered through distance learning and cooperative agreements with institutions of higher education.

2. A three-semester-hour college course shall transfer as one-half Carnegie unit.

3. Tuition and other college course fees are the expense of the individual student or his or her parent(s) or legal guardian unless otherwise specified in local school district policy.

4. Students enrolled in a South Carolina public school for Carnegie credit may take only courses that are applicable to baccalaureate degrees or to associate degrees in arts or in science offered by institutions accredited by the New England Association of Colleges and Schools, Middle States Association of Colleges and Schools, Southern Association of Colleges and Schools, North Central Association of Colleges and Schools, Western Association of Colleges and Schools, or Northwest Association of Colleges and Schools.

H. Correspondence Courses Credit

Credit may be awarded for a correspondence course only upon the approval of the local superintendent or his or her designee.

I. Length of School Day

1. The instructional day for secondary students must be at least 6 hours, excluding lunch, or its equivalent weekly.

2. The minimum length of a class period must be 50 minutes, excluding change of class time. Each instructional week must equate to 1,675 minutes.

3. A maximum of 25 minutes will be allowed for changing classes as part of the 6-hour instructional day. If the changing of classes requires more than 25 minutes, the additional time will be added to the 6-hour instructional day.

4. Homeroom will not count as part of the instructional day. When no homeroom period is utilized, the administrative time used to determine attendance, make announcements, or complete other tasks normally accomplished during homeroom period will not be considered as part of the instructional day.

5. Schools may exercise options and vary the minimum number of minutes in the instructional week, provided that such variation is approved by the local board of trustees and the State Superintendent of Education. Time requirements for students who are receiving supplemental instruction (e.g., Title I, Academic Assistance, Gifted and Talented) may be modified. Time requirements for students with disabilities may be modified as determined and documented by the student's individualized education program (IEP) team.

II. Class Size, Grades 9–12

A. The maximum teacher load must not exceed 150 students daily. Maximum class size must not exceed 35 students.

B. In certain circumstances, the above-stated maximums do not apply.

1. A maximum of 40 students per period with a total teaching load of 240 students daily is permitted for PE teachers. If PE and health are taught on alternate days to the same class, the 40-student maximum and 240 student totals are also permitted for health. When health is taught as a separate subject, the teaching load is a maximum of 35 students per period and a total of 150 students per day.

2. Music teachers may teach a maximum of 240 pupils daily. No class may exceed 40 students in membership. However, when band, chorus, or orchestra require rehearsals of the entire membership, any number of students is acceptable if adequate space is available.

3. When a teacher's daily schedule includes a combination of subjects, the maximum daily teaching load will be calculated on the basis of 30 students per academic class and 40 students for each music or PE class. (Example, 3 classes of math of 30 each = 90 + 2 classes of PE of 40 each = 80. In this example, the teacher is not overloaded but teaches maximum allowable.)

Maximum teacher load requirements and individual class size limits are the same for mini-courses as any other classes.

III. Graduation Requirements

A. Curriculum Requirements for a South Carolina High School Diploma

1. The student must earn a total of 24 units of credit in state-approved courses. The unit requirements are distributed as follows:

	Unit Requirements
English/language arts	4.0
mathematics	4.0
science	3.0
U.S. History and Constitution	1.0
economics	0.5
U.S. Government	0.5
other social studies	1.0
PE or Junior ROTC	1.0
computer science (including keyboarding)	1.0
foreign language or career and technology education	1.0
Electives	7.0
	24.0 Total

2. The student must demonstrate computer literacy. For all business and marketing computer courses, Keyboarding for one-half credit or the equivalent keyboarding skill based on the Keyboarding course competencies is a prerequisite.

3. The student in a College Prep program must earn one unit in a foreign language (most four-year colleges/universities require at least two units of the same foreign language). The student in a Tech Prep program must earn one unit in career and technology education course work.

4. The student must complete a study and pass a final examination on the provisions and principles of the United States Constitution, the Declaration of Independence, the Federalist papers, and American institutions and ideals. This instruction shall be given for a period of at least one year or its equivalent, either within the required U.S. History course and/or within another course using a suitable text recommended by the State Superintendent of Education and approved by the State Board of Education.

5. The student must attend the high school issuing the diploma for at least the semester immediately preceding graduation except in case of a bona fide change of residence to a location in which the sending school will not grant the diploma. Units earned in a summer school program do not satisfy this requirement.

6. The student must pass the South Carolina high school exit exam in addition to passing the required courses. (For specific regulations regarding the exit examination, see Regulation 43-262, "Assessment Program.")

B. Special Education Minimum Curriculum Completion Requirements

1. A state high school diploma or a certificate designed and issued by the school district shall be awarded students who complete a program of prescribed special education. If a determination is made that a student with a disability shall pursue credits toward a state high school diploma, the following two alternatives apply:

Alternative 1. Credits toward a state high school diploma may be awarded only by persons certified or who hold an out-of-field-permit (permits will not be issued in special education after June 30, 2006) in the subject in which credit is earned. A student with a disability receiving such credits shall do so only after successfully attaining similar course objectives prescribed for students without disabilities and in accordance with

cooperative instructional arrangements between regular education and special education as set forth in the student's IEP.

Alternative 2. Students properly in membership in programs for students with disabilities may receive a state high school diploma provided they earn a total of at least 24 units, 17 of which are the same required of students without disabilities. Seven of the 24 units may be earned in special education courses. When an elective course credit is to be issued for a student in any category of disability, the competencies and criteria for successful completion must be specified in the IEP.

A teacher of students with disabilities in the resource or itinerant model must be certified or have a permit (permits will not be issued in special education after June 30, 2006) in the area of disability in which the majority of his or her students are classified, or such a teacher must be certified in one area of disability in which he or she is teaching and must successfully complete 6 semester hours annually toward certification in the area in which the majority of his or her students are classified.

Pupils participating in self-contained programs must be of the same category of disability except when the IEP team determines, on an individual basis, that a student may be more appropriately served in another placement. Students classified as having a mental disability (mild, moderate, or severe) may not be commingled without an innovative approach. Approval for an innovative approach must be sought from the Office of School Quality. The teacher must be certified or hold an out-of-field permit (permits will not be issued in special education after June 30, 2006) in the area of disability of the majority of the pupils served.

IV. Report of Follow-Up Study of Graduates

On or before May 1, each high school that issues a state high school diploma must submit the following data on the previous year's graduates to the State Superintendent of Education on prescribed forms:

1. the number of high school graduates who entered the freshman class of an institution of higher learning for whom a first semester report was received,

2. a breakdown of courses passed,

3. a breakdown of courses failed, and

4. the number and job titles of employed graduates

High schools must request scholastic data of previous graduates who attend out-of-state institutions of higher learning.

V. Report of Follow-Up on Career and Technology Education Completers

Ten months after graduation, districts must survey all high school graduates identified as career and technology completers to determine their placement status with regard to employment, postsecondary education, and military service. Districts must submit the results annually to the South Carolina Department of Education for federal and state accountability requirements. A Career and Technology Education completer is a student with an assigned Classification of Instructional Programs (CIP) code who has earned at least four Carnegie units in career and technology education course work leading to a career goal.

VI. Additional State Board of Education Regulatory Requirements

Additional regulatory requirements related to the basic program include, but are not limited to, the following:

Gifted and Talented Regulation (43-220)
School-to-Work Regulation (43-225)
Health Education Requirement Regulation (43-238)
Summer Programs Regulation (43-240)
Driver Training Regulation (43-242)
Special Education Regulation * (43-243, 43-243.1, and 43-243.4)
Advanced Placement Regulation (43-258.1)
Academic Assistance Programs (43-268)
Career or Technology Center/Comprehensive High Schools (43-236)

VII. Student Records

1. Each school must have an appropriate means of reporting academic achievement to parents.

2. Each school district must maintain accurate student data according to the pupil accounting system prescribed by the State Department of Education. A record of all dropouts must be filed by school, grade, race, and sex. The district superintendent must verify the accuracy of the enrollment attendance, membership by category, and dropout reports submitted to the Office of Finance, State Department of Education.

3. All schools should ensure that they comply with the Family Educational Rights and Privacy Act (FERPA) regarding student records (20 U.S.C. § 1232(g)).

VIII. Emergency Closings

Full days missed because of weather or other circumstances must be made up. Early dismissal days must be reported to and approved by the director of the Office of School Quality.

Statement of Rationale: The proposed amendments reflect program changes and recommendations from school and district administrators and collaborative efforts of numerous Department of Education divisions. The proposed amendments provide alignment with other State Board regulations and the No Child Left Behind Act of 2001 (20 U.S.C. Section 6301 *et seq*. (2001)).

Fiscal Impact Statement: The Department of Education anticipates there will be additional costs to the State or its political subdivisions. Implementation of the requirement that every student must take physical science by the end of the tenth grade prior to taking the exit examination will require the purchase of additional textbooks. Estimating a fiscal impact required the use of 2002–03 SASI course enrollment data and use of Appendix B, Acceptable Areas of Certification for teacher certification and staffing considerations. In 2002–03, over 70 percent of the freshman class enrolled in physical science.

Currently, the physical science textbook adoption bid is scheduled to be opened in December 2005, with new books in the classroom in August 2007. This would mean that if most ninth graders enroll in physical science in the 2005–06 and 2006–07 years, there will be an additional cost to purchase more current textbooks. If all ninth graders took the course in one year, 20,602 additional books would be needed for a cost of $1,111,889.90 at $53.97 per book. There should be no additional cost for facilities.

To teach physical science, a teacher must hold certification in one of these four areas: science, general science, chemistry, or physics. Since a majority of high school science teachers would hold one of these areas of certification, the current pool of teachers should be sufficient to cover student enrollment.

Implementation of the physical science course requirement prior to taking the new High School Assessment Program Science examination will provide students the opportunity to be prepared to take the exam.

Resubmitted: February 11, 2004

Document No. 2880
STATE BOARD OF EDUCATION
CHAPTER 43
Statutory Authority: S.C. Code Ann. §§ 59-5-60 (1990), 59-5-65 (Supp. 2002), 59-18-300 (Supp. 2002), 59-18-310(B) (Supp. 2002) and 59-18-320(C) (Supp. 2002)

R 43-262.4. End-of-Course Tests

Synopsis:

The State Department of Education recommends that the State Board of Education promulgate amendments to R 43-262.4, End-of-Course Tests. The regulation is being amended to remove course numbers that may be inaccurate and are subject to change. The amendments also clarify that eligible examinees are those students who are enrolled in courses that cover the content standards for the gateway courses irrespective of course titles, numbers or grade level in school.

The Notice of Drafting was published in the State Register on September 26, 2003.

Section-by-Section Discussion

Section I	Removes course numbers that may be inaccurate and are subject to change and also clarifies that eligible examinees are those students who are enrolled in courses that cover the content standards for the gateway courses irrespective of course titles, numbers or grade level in school.
Section I(A)	The first sentence is being amended as follows: “The following courses ~~and course codes~~ in State Board Regulation 43-234, Defined Program, Grades 9-12, are “gateway” and “benchmark” courses.

Instructions: Amend in its entirety R 43-262.4, End-of-Course Tests, to Chapter 43 regulations.

Text:

End-of-Course Tests

I. Courses Tested

A. The following courses in State Board Regulation 43-234, "Defined Program, Grades 9–12," are "gateway" and "benchmark" courses. For the purposes of this regulation, however, these courses shall be referred to only as "gateway" courses.

1. English/language arts: English 1

2. Mathematics: Algebra 1. After completion of Mathematics for the Technologies 2 students shall be administered the end-of-course examination for Algebra 1.

3. Science: Biology and Physical Science After completion of Applied Biology 2, students shall be administered the end-of-course assessment for Biology .

4. Social Studies: United States History and Constitution

5. A course by any title for which the instructional basis is the curriculum standards for any of the abovementioned courses will be considered the equivalent of the appropriate abovementioned gateway course and one for which an end-of-course test must be administered.

B. The end-of-course tests shall be administered to all public school students who take a gateway courses for which credit can be applied toward the requirements for a high school diploma, regardless of the grade in which a student takes the course.

II. Purposes and Uses

The purposes and uses of the end-of-course tests shall be as follows:

A. The tests shall promote instruction in the specific academic standards for the courses, encourage student achievement, and document the level of students' mastery of the curriculum standards.

B. The tests shall serve as indicators of program, school, and school district effectiveness in the manner prescribed by the Education Oversight Committee in accordance with the provisions of the Education Accountability Act of 1998 (EAA).

C. The tests shall be weighted 20 percent in the determination of students' final grades in the gateway courses.

The test may be used for such other purposes as the State Board of Education may determine to be appropriate and consistent with the Standards for Educational and Psychological Testing (Joint Standards) of the American Psychological Association, the American Educational Research Association, and the National Council on Measurement in Education.

III. Content of the Tests

The content of the subject-area tests that are selected or developed pursuant to the provisions of this policy shall be aligned with the curriculum standards approved by the State Board of Education. For mathematics, English/language arts and social studies, end-of-course tests will be based on the revised Board-approved standards following the first cyclical review of the standards required by the EAA.

IV. Student Performance Standards

Student performance standards for the tests shall be established by the State Department of Education.

V. Review of Curriculum Standards and End-of-Course Tests

The curriculum standards for the tests shall be reviewed on a schedule that is consistent with the requirements of the EAA. Following any revisions of the academic standards, the tests will be reviewed and revised as necessary to ensure their continued alignment with the standards.

VI. Notice to Students

Students who are enrolled in the gateway courses shall be provided with copies of the curriculum standards that pertain to those particular courses. Students will be advised that the final examination for each gateway course will be based on the skills and content represented in the curriculum standards. District personnel shall provide this information to students not later than the first day of instruction in the course.

Statement of Rationale: To ensure course content, and not course numbers, will drive the End-of-Course Examination Program (EOCEP) since numbers are subject to change.

Fiscal Impact Statement: None

Document No. 2841
FORESTRY COMMISSION
CHAPTER 55
Statutory Authority: 1976 S. C. Code Sections 48-23-10 et seq. and Section 50-1-90

55-1 General Regulations on South Carolina Forestry Commission Lands

Synopsis:

The regulation combines, under one regulation, the general rules and regulations for hunting, fishing and recreational activities on all South Carolina Forestry Commission Lands. The repealed regulations 55-1, General Regulations and Hunting Regulations in the Area known as Manchester State Forest in Sumter County, 55-2, General Regulations and Hunting Regulations in the Area known as Cassatt State Forest in Kershaw County, 55-3, General Regulations and Hunting Regulations in the Area known as Sand Hills State Forest in Chesterfield County, 55-4 General Regulations and Hunting Regulations in the Area known as Harbison State Forest in Richland County and 55-5 Hunting and Fishing Regulations in the Areas known as C.H. Neiderhof Seed Orchard in Jasper County were approved at various times beginning in 1975 as acreage was acquired by the S. C. Forestry Commission. The new regulation, 55-1, will bring uniformity and conformity to rules and regulations for all S. C. Forestry Commission lands. The new regulation will also conform to the Department of Natural Resources Wildlife Management Area (WMA) regulations where S. C. Forestry Commission lands are leased in the WMA program.

Instructions: Repeal R.55.1 through R.55.5. Replace with new R.55.1, General Regulations on South Carolina Forestry Commission Lands. Place in Chapter 55.

Text: R.55-1. General Regulations on South Carolina Forestry Commission Lands.

1. Entry onto South Carolina Forestry Commission lands is done wholly and completely at the risk of the individual. The State of South Carolina nor the South Carolina Forestry Commission accepts any responsibility for acts, omissions or activities or conditions on these lands which cause or may cause personal injury or property damage.
2. All persons must obey all special rules and regulations for South Carolina Forestry Commission lands including those found in hunting schedules, maps, brochures, permits, any oral/written instructions issued by South Carolina Forestry Commission personnel or those instructions posted on South Carolina Forestry Commission lands.
3. Trespassing, fishing, hunting, killing, capturing or taking any fish or game, other recreational activities, or attempting such act, are prohibited, except as may be authorized under these rules and regulations, by permit or special authorization. On South Carolina Forestry Commission lands, where an agreement is made between the South Carolina Forestry Commission and the South Carolina Department of Natural Resources to make the lands Wildlife Management Areas as established by Section 50-11-2200 of the South Carolina Code of Laws, hunting and fishing rules and regulations will be regulated by the South Carolina Department of Natural Resources regulation 123-40.
4. On South Carolina Forestry Commission lands, no motor driven land conveyances shall be operated on any road or trail, other than a public road, except by permit or special authorization, unless otherwise specified. Roads or trails which are closed by barricades and/or signs either permanently or temporarily, are off limits to motor driven land conveyances.
5. Motor driven land conveyances shall be operated in a safe manner while on South Carolina Forestry Commission lands.

6. On South Carolina Forestry Commission lands, any person found guilty in a court of law of undesirable or unsafe conduct, may, at the discretion of the Forest Director, forfeit all permits and privileges thereto and/or all future permits dependent upon the seriousness of the offense.
7. On South Carolina Forestry Commission lands, during periods when hunting is not permitted, all weapons must be unloaded and secured in a case, or in the trunk of a vehicle, or in a locked toolbox. During periods when hunting is permitted, all weapons must be unloaded on roads open to vehicular traffic and all weapons, transported in or on a vehicle, must be unloaded. Any weapon with a shell in the chamber or magazine, or muzzleloader with a cap on the nipple or flintlock with powder in the flash pan is considered loaded. Provisions in #7 are not applicable to pistols as prescribed in statute 16-23-20 of the South Carolina Code of Laws.
8. On South Carolina Forestry Commission lands, no target practice is permitted except in designated areas.
9. The hours for hunting and fishing shall be published. The said hours may be set short of state and federal regulations.
10. Any attempt to move/flush/drive/pursue game to or into hunters on lands adjoining South Carolina Forestry Commission lands is prohibited.
11. Waiting for game to cross county or state roads on South Carolina Forestry Commission lands is prohibited.
12. Molesting, injuring, poisoning, destroying, or attempting such acts, of any plant or animal life on South Carolina Forestry Commission lands are prohibited except by permit.
13. Entry onto South Carolina Forestry Commission lands constitutes consent to an inspection and search of the person, game bag, or creel and any vehicle, trailer, conveyance or container.
14. On all lands owned by the South Carolina Forestry Commission, the removal of artifacts or ecofacts from the surface or subsurface is prohibited except when approved by the State Historic Preservation Office and carried out in accordance with their guidelines.
15. In accordance with Section 48-23-70(b), 1976 S. C. Code of Laws, as amended, any person violating this section will be guilty of a misdemeanor and upon conviction, must be fined not more than two hundred dollars or imprisoned for not more than thirty days.
16. The penalty for fishing or hunting on any forest area, other than those times specified by the South Carolina Forestry Commission, shall be as prescribed by § 50-1-90, 1976 South Carolina Code of Laws, as amended.
Except as modified or changed hereby, all prevailing laws, rules and regulations concerning the South Carolina Forestry Commission shall remain in full force and effect.

Fiscal Impact Statement:

The agency anticipates no financial impacts or additional costs to state or local government.

Statement of Rationale:

There are currently five separate sets of regulations pertaining to South Carolina Forestry Commission lands. The need to bring uniformity and conformity to rules and regulations for all Forestry Commission lands is the rationale behind the development of this new regulation. The proposed regulation repeals the existing regulations and combines, under one regulation, the general rules and regulations for hunting, fishing and recreational activities on all Forestry Commission lands. The repealed regulations were developed at various times since 1975 as the public use of lands increased. The new regulation will address expanded use of lands by the public and also conform to the Department of Natural Resources Wildlife Management Area (WMA) regulations where Forestry Commission lands are leased in the WMA program.

Document No. 2854
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 48-1-10 et seq.

R.61-69, *Classified Waters*

Synopsis:

Section 303(c) of the Federal Clean Water Act (CWA) requires that South Carolina establish water quality standards that are sufficiently protective to maintain the existing and classified uses of all waters of the State. The Department recently was asked to reevaluate a site-specific standard for dissolved oxygen (DO) currently established for the lower Saluda River (Main Stem) from the Lake Murray Dam to the confluence with the Broad River, which is classified as Trout Put, Grow, and Take (TPGT). In accordance with both State and Federal statutory and regulatory requirements, State water quality standards must be established using scientifically-defensible data and information and must provide for the protection and maintenance of the established beneficial uses of the waters of the State. Based upon the results of a site-specific study, as well as existing data and information, the Department is proposing a new site-specific DO standard for the lower Saluda River that will provide for the protection and maintenance of the classified uses of TPGT and the existing balanced indigenous aquatic community.

There are also tributaries associated with this waterbody that are unnamed in R.61-69 and, by default, may have assumed the TPGT classification (excluding the site-specific standard). These waters do not support trout species and the Department proposes to retain the appropriate classification of Freshwaters for these tributaries and to list them separately in R.61-69.

Discussion of Revisions:

SECTION	REVISION
R.61-69	Replace the site-specific dissolved oxygen water quality standard from the main stem of the lower Saluda River from the Lake Murray Dam to the confluence with the Broad River.
R.61-69	Retain the classification of Freshwaters for all tributaries of the main stem of the lower Saluda River from the Lake Murray Dam to the confluence with the Broad River.

Instructions: Amend the regulation by deleting the existing site-specific standard for the main stem of the Saluda River and adding the following language.

Waterbody Name	**Counties**	**Class**	**Waterbody Description and (Site Specific Standard)**
SALUDA RIVER (MAIN STEM)	Lxtn,Rlnd	TPGT	That portion from the Lake Murray Dam to the confluence with the Broad River (D.O. not less than daily average 5 mg/l, a running thirty day average of 5.5 mg/l, with a low of 4.0 mg/l)

SALUDA RIVER (MAIN STEM) UNNAMED TRIBUTARIES	Lxtn, Rlnd	FW	All tributaries to the main stem of the Saluda River from the Lake Murray Dam to the confluence with the Broad River

Fiscal Impact Statement:

No costs to the State or significant cost to its political subdivisions as a whole should be incurred by these amendments. See Statement of Need and Reasonableness below.

Statement of Need and Reasonableness:

The statement of need and reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: Amendment of Regulation 61-69, *Classified Waters*.

Purpose: This amendment of R.61-69 will replace the site-specific standard for dissolved oxygen (DO) in the main stem of the lower Saluda River in order to protect survival and growth of trout populations and make the water quality standard consistent with Section 303(c) of the Federal Clean Water Act.

Legal Authority: S.C. Code Sections 48-1-40, 48-1-60, and 48-1-80, implementing the Clean Water Act.

Plan for Implementation: This amendment will be incorporated within R.61-69 upon approval of the General Assembly and publication in the State Register. The proposed amendment will be implemented in the same manner in which the present regulation is implemented.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFIT: This amendment is required to comply with Federal requirements of Section 303(c) of the Clean Water Act.

In accordance with both State and Federal statutory and regulatory requirements, State water quality standards must be established using scientifically-defensible data and information and must provide for the protection and maintenance of the established beneficial uses of the waters of the State.

The main stem of the lower Saluda River from the Lake Murray Dam to the confluence with the Broad River is currently classified as Trout Put, Grow, and Take (TPGT). R.61-69 currently establishes a site-specific standard for DO of a daily average of not less than 5.0 mg/l with no minimum requirement. DHEC granted an applicant the time for a site-specific study to determine what level of dissolved oxygen was necessary to provide for the protection and maintenance of the TPGT classification. Numeric aquatic life criteria are expressed as short-term (acute) and long-term (chronic) concentrations in order that the criteria provide protection against lethality and sublethal effects in waters of the State. It is the combination of the two criteria that provides protection of aquatic life and sustains the aquatic life uses. Minimum DO criteria prevent acutely toxic conditions instream (hypoxia) and are crucial to the survival of all species. Trout populations are exceptionally sensitive to DO and scientifically-defensible data (i.e., EPA's Ambient Water Quality Criteria for Dissolved Oxygen, EPA 440/5-86-003) clearly demonstrate that trout species need higher DO levels in order to survive and flourish. Based upon the results of the site-specific study, as well as existing data and information, the Department proposes to amend the site-specific DO standard for the lower Saluda River.

DETERMINATION OF COSTS AND BENEFITS: Existing staff and resources will be utilized to implement this amendment to the regulation. No additional cost will be incurred by the State if the revisions are implemented and, therefore, no additional state funding is being requested. In reviewing the potential for significant economic impact of the proposed amendment, the Department specifically evaluated situations in which costs would most likely be incurred by the regulated community. A single entity will be incurring costs associated with

improvements to meet the existing water quality standards and to meet the proposed revised standard. The Department found that the overall impact to the State=s political subdivisions or the regulated community as a whole was not likely to be significant in that the existing standards would have incurred similar cost or the fact that the design standards required under the amendment will be substantially consistent with the current guidelines and review guidelines utilized by the Department. Further, much of the proposed amendment, for which an estimated cost may be incurred by the regulated community at the time of permit issuance, are essential and necessary to protect and maintain the existing uses supported by the water quality standards and are therefore, beyond the scope of cost analysis in that they provide the minimum level of protection for aquatic life and human health as required by the Federal CWA. Further, this section of the lower Saluda River is used extensively by the public as a recreationally-significant water where anglers are aware of the stocking of trout species by the South Carolina Department of Natural Resources and regularly fish for trout and bass in this area. This trout stream provides an economic benefit to the surrounding metropolitan area by increasing hotel, restaurant, bait and tackle shops, and associated revenues from visiting fishermen. While no specific estimate was provided, there is an associated detriment to the surrounding economy

UNCERTAINTIES OF ESTIMATES: Minimal to moderate.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: Implementation of this amendment will not compromise the protection of the environment or the health and safety of the citizenry of the State. The amendment will promote and protect survival and growth of trout populations as well as other resident freshwater aquatic life by the regulation of minimum DO levels in this water of the State.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: Failure by the Department to incorporate this revision will result in instream consequences for trout species, as well as resident aquatic life species, in the lower Saluda River. Extremely low DO levels can cause fishkills and impair growth of trout species which are a significant and costly impairment to these stocked populations.

Statement of Rationale:

The statement of rationale was determined by staff analysis pursuant to S.C. Code Section 1-23-110(A)(3)(h).

This amendment will replace a site-specific standard for dissolved oxygen on the main stem of the lower Saluda River. The Department proposes to allow a new site-specific standard based upon data and information gathered at the site as well as existing data and information to become the scientifically-defensible dissolved oxygen standard for the waterbody. See Statement of Need and Reasonableness above.

Document No. 2857
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Ann. Sections 44-1-140 *et seq*., 44-1-140(11); 1-23-10; -110 (1976, as amended)

R.61-36. Manufacture, Distribution, and Sale of Frozen Dairy Foods and Frozen Desserts

Synopsis:

R.61-36. Manufacture, Distribution, and Sale of Frozen Dairy Foods and Frozen Desserts, was promulgated pursuant to S.C. Code Section 44-1-140 *et seq*, and was last amended in 1956. These amendments will bring the Regulation in compliance with the latest Frozen Dessert guidelines of the United States Public Health Service, Food and Drug Administration and assure consumers that the latest sanitation requirements are being met by the dairy industry. The majority of these latest requirements and guidelines have already been implemented by the Department under the authority of the FDA; these amendments will incorporate these requirements into South

Carolina's regulation. Amendments will also insure that the regulation complies with the requirements of the South Carolina Administrative Procedures Act, is compatible with R.61-34.1 *Pasteurized Milk and Milk Products*, and will strengthen the Department's enforcement capability. The title of the regulation will be changed to R.61-36, Frozen Desserts. See Statements of Need and Reasonableness and Rationale below.

Discussion of Revisions:

SECTION/REVISION

Title Title simplified – products covered now referred to as frozen desserts by definition. This change is consistent throughout the revised regulation.

Contents Table of Contents added.

61-36.I. Twelve new definitions added to be consistent with those found in R.61-34.1 *Pasteurized Milk & Milk Products*; two definitions revised to be more consistent with R.61-34; two new definitions added specifically for frozen dessert manufacturing; and six existing definitions updated.

61-36.II. Moved from Section 3 and rewritten to be consistent with R. 61-34.1. The Department given additional authority for examining frozen desserts to determine freedom from adulteration or misbranding and for impounding or placing hold orders on products believed to be adulterated or misbranded. It also requires that adulterated products be removed from the market, disposed of, and sale stopped until analysis reveals the products to be free from adulteration.

61-36.III. Moved from Section 2. The name of section changed from "Permits" to "Compliance Procedures" to include all requirements of the South Carolina Administrative Procedures Act and to be consistent with R.61-34.1.

61-36.IV. The obsolete term "Placarding" has been removed from the title. The requirement to label mix as either "pasteurized" or "raw" has been deleted since, by definition, all "mix" shall now be pasteurized. The use of a plant code on a mix or frozen dessert product in lieu or in addition to the name and address of the plant was added. Also the additional requirement of all finished product labeling having to meet all applicable federal and state labeling laws was added since this regulation does not address specific labeling requirements such as standardized product name (ice cream, lowfat ice cream, nonfat ice cream, etc.), ingredients, nutrition facts, net contents, etc., regulated by the United States Department of Agriculture, the United States Food and Drug Administration, and locally by the South Carolina Department of Agriculture.

61-36.V.A. Revised to be consistent with R.61-34.1. Specifically, added the requirement that all frozen desserts manufacturers must be inspected by the Department prior to a permit being issued.

61-36.V.B. Revised to be consistent with R.61-34.1. Specifically, a minimum inspection criteria of at least once every three months was added.

61-36.V.C. Revised to be consistent with R.61-34.1. Added the requirement to allow for a minimum of 3 days before reinspecting a facility after a violation in Section VI or VII is found to exist.

61-36.V.D. Revised to be consistent with R.61-34.1. Includes specific actions that must be taken when a critical processing element violation occurs.

61-36.V.E. Revised to be consistent with R.61-34.1. Includes specific actions to be taken when critical processing violations are found with aseptically processed mix or frozen desserts.

61-36.V.F. Revised to be consistent with R.61-34.1. Deleted specific requirement for plants to keep inspection reports for a period of 12 months.

61-36.V.G. Added to be consistent with R.61-34.1. Allows the Department to have access to frozen dessert plants and records to determine compliance with the provisions of this Regulation.

61-36.V.H. Added to be consistent with R.61-34.1. It makes it unlawful for any person, who, in an official capacity, obtains any information under the provisions of this regulation to use such information to his own advantage or reveal it to any unauthorized person.

61-36.VI.A. Revised to be consistent with R.61-34.1. Allows for the exception of two samples being collected in the same month as long as the sampling dates are separated by at least 20 days.

61-36.VI.B.1. Revised to be consistent with R.61-34.1. It eliminates the antiquated requirement "average reduction time" and adds specific coliform determination requirements. It eliminates logarithmic averages with arithmetic averages.

61-36.VI.B.1. Added to delineate handling of a positive phosphatase test.

61-36.VI.B.3. Added to be consistent with R.61-34.1. It specifically provides for actions to be taken when a pesticide residue test is positive.

61-36.VI.B.4. Added to be consistent with R.61-34.1. It specifically provides for actions to be taken when a drug residue test is positive.

61-36.VI.B.5. Added to be consistent with R.61-34.1. It specifically provides for actions to be taken when containers of aseptically processed mix are found to be unsterile due to underprocessing.

61-36.VI.C. Added to be consistent with R.61-34.1. It also replaces antiquated sample method references in Section 6. It also gives the Department authority to do examinations and tests to detect adulterants on samples, as deemed necessary.

61-36.VII.A.1.a.(1) Added to be consistent with R.61-34.1. It specifically adds temperature standards for raw milk and milk products used in frozen dessert manufacturing.

61-36.VII.A.1.a.(2) Revised to be consistent with R.61-34.1. It reduces the bacterial limits for raw milk and milk products from 200,000 to 100,000 per mL, but adds an allowance for up to 300,000 per mL for commingled milk prior to pasteurization to be consistent with R.61-34.1.

61-36.VII.A.1.a.(3) Added to be consistent with R.61-34.1. It specifically adds a limit for the somatic cell count for milk and milk products used in frozen dessert manufacturing.

61-36.VII.A.1.a.(4) Added to be consistent with R.61-34.1. It specifically adds appropriate methods for drug residue screening for raw milk and raw milk products used in frozen desserts and to be consistent with current FDA standards for milk and milk product drug residue testing.

61-36.VII.A.1.b.(1) Revised to be consistent with R.61-34.1. It reduces the cooling temperature requirement of milk and milk products in Section 7, Item 17, from 50º F or less to 45ºF or less, and applies these requirements also to heat-treated, bulk-shipped milk products.

61-36.VII.A.1.b.(2) Revised to lower the bacterial limits for non-cultural frozen desserts from the current 50,000 per gram limit in Section 7. Item 24 to 30,000 per mL as recommended by FDA. Also, deleted the requirement in Section 7. Item 25 for milk and milk products used as ingredients in the pasteurized, condensed, evaporated, or

dried state to have an average bacterial plate count not exceeding 50,000 per cubic centimeter or per gram and for doubling these limits for cream since this is now covered in Section VII A.1.a(2), and apply these requirements to heat-treated, bulk-shipped milk products.

61-36.VII.A.1.b.(3) Added to be consistent with R.61.34.1. It specifically adds a coliform limit not to exceed 100 per mL for heat-treated, bulk-shipped milk products.

61-36.VII.A.1.b.(4) Testing limits and criteria updated to be consistent with current FDA standards for milk and milk product phosphatase testing.

61-36.VII.A.1.b.(5) Added to be consistent with R.61-34.1. It specifically adds appropriate methods for drug residue screening in milk and milk products to be consistent with current FDA standards for milk and milk product drug residue testing.

61-36.VII.A.1.c. Added to be consistent with R. 61-34.1. It includes current FDA standards for aseptically processed milk and milk products.

61-36.VII.A.2. Added to be consistent with R.61.34.1. It specifically insures that no unapproved process or manipulation is applied to mix or frozen desserts for the purpose of removing or deactivating microorganisms.

61-36.VII.B.1. Revised to be consistent with R.61-34.1. It, however, does not include the requirement for having floor drains either inside cold rooms of the floor or the cold room sloped to drain to one or more exits due to the use of some walk-in coolers and freezers that are not water flushed for cleaning. Also, the requirement to keep the floors clean in Section 7, Item 1, has been moved to Section B.9., Frozen Dessert Plant Cleanliness.

61-36.VII.B.2. Revised to be more consistent with R.61-34.1. Specifically, deleted the exception for hardening and storage rooms to not have light-colored finishes. Also, the requirement to keep the walls and ceilings clean in Section 7, Item 2, has been moved to Section B.9., Frozen Dessert Plant Cleanliness.

61-36.VII.B.3. Revised to be more consistent with R.61-34.1. Specifically added the requirement to protect access by rodents and allow the use of closed windows and effective air curtains as effective means for vector control.

61-36.VII.B.4.a. Revised to be more consistent with R.61-34.1. Added specific minimum lighting levels of 20 foot-candles in working areas and 5 foot-candles in dry storage and cold storage rooms.

61-36.VII.B.4.b. Added to be consistent with R.61-34.1. Specifically, added a requirement for filtering pressurized air intakes.

61-36.VII.B.5.a. Revised to be consistent with R.61-34.1. However, the requirement for separate rooms was previously found in Section 7, Item 5.

61-36.VII.B.5.b. Added to be consistent with R.61-34.1. Specifically added the requirement for processing, washing and storage areas not opening directly into any stable area and that all rooms shall be of sufficient size for their intended purposes.

61-36.VII.B.5.c. Revised to be consistent with R.61.34.1. Specifically added the requirement that designated areas or rooms shall be provided for the receiving, handling and storage of returned mix and frozen desserts.

61-36.VII.B.6. Revised to be consistent with R.61.34.1. Specifically, flush type toilet requirement conforming with South Carolina State Board of Health requirements changed to toilet facilities conforming with state and local plumbing laws, regulations and codes. Added requirement that toilet rooms shall be well lighted and that waste be disposed of in a system approved by the Department.

61-36.VII.B.7. Revised to be consistent with R.61.34.1. Added a requirement for the Department to take water samples for bacteriological testing at prescribed intervals and that these samples be analyzed in official laboratories with records maintained.

61-36.VII.B.8. Revised to be consistent with R.61.34.1. Specifically, require that "individual" towels or approved hand drying devices be used for drying hands and that hand-washing facilities be kept in good repair.

61-36.VII.B.9. Sections added to be consistent with R61-34.1. Requirements for cleaning were previously found in Section 7, Items 1 and 2. Added the requirement that only equipment directly related to processing operation or to handling of containers, utensils and equipment shall be permitted in processing and storage rooms.

61-36.VII.B.10. Revised to be consistent with R.61.34.1. Specific FDA construction criteria for sanitary piping, fittings, and connections were added.

61-36.VII.B.11. Revised to be consistent with R.61.34.1. Specific FDA construction criteria for containers and equipment was added.

61-36.VII.B.12. Revised to be consistent with R.61.34.1. Specifically, the requirements to clean all product contact surfaces at least daily and all storage tanks when emptied, but at least once every seventy-two hours, were added; except that the Department may grant permission for longer than 72 hours. Also, the requirement for equipping storage tanks holding products greater than twenty-four hours with either temperature recording devices or other secondary device for evaluating the cleaning and sanitizing regimen was added. Information needed on the recording charts and the requirement for the Department to review charts was also added.

61-36.VII.B.13. Revised to be consistent with R.61.34.1. Specifically, the words "cleaned," "utensils," and "transported" were added and the requirement to store in a manner to assure complete drainage was added.

61-36.VII.B.14. Revised to be consistent with R.61.34.1. Specifically, the name of the section was changed to also include other materials that cannot be identified as either single service containers or utensils. The acceptable method of storage for these items and their ingredients was expanded to include wrappings or cartons and a specific requirement to keep them in a clean, dry place "until used" was added.

61-36.VII.B.15. Added to be consistent with R.61.34.1. However, most of the requirements in this section were generally covered under Items 5, 19, and 20. Specifically added is the requirement that the storage, handling, and use of poisonous or toxic materials shall be performed to avoid contamination of food and product contact surfaces and that air under pressure and steam used in the manufacture of frozen desserts meet the applicable FDA standards.

61-36.VII.B.16.a. Revised to be consistent with R.61.34.1. Aseptic processing, an alternate, FDA acceptable means of processing mix, which was unknown when R.61-36 was last revised, was added.

61-36.VII.B.16.b. Revised to ensure that all pasteurization is done properly according to the latest FDA requirements.

61-36.VII.B.17. Revised to be consistent with R.61.34.1. Specifically, the temperature for milk and fluid milk products used in frozen dessert manufacturing was lowered from 50º F to 45º F for better protection from the growth of pathogenic organisms and to meet FDA Grade A milk and milk product requirements. Also, added the requirement that mix not frozen at the plant at which it was pasteurized also be maintained at a temperature of 45º F or below; that every room or tank holding milk products or mix be equipped with a thermometer meeting FDA requirements; and that recirculated cooling agents be sampled and meet FDA requirements.

61-36.VII.B.18. Language changed to be more consistent with R.61-34.1. Specifically, drip deflectors and shielding are required to protect against contamination. Also, specific guidance given regarding when hand capping/packaging will be allowed.

61-36.VII.B.19. Revised to ensure that all milk and milk products used in frozen dessert manufacturing are from Grade A domestic sources as defined by FDA or from other sources generally recognized as "manufactured grade milk" if approved by the Department. Currently, all fluid milk and milk products used for manufacturing frozen desserts in South Carolina are from Grade A sources; however, some dry milk powder may not always be. This gives the Department more latitude in determining the approved source of milk ingredients used in frozen dessert manufacturing and does not require that detailed "animal health" requirements be added. Also, criteria for acceptable ingredients that can be added to frozen desserts after pasteurization is added and taken verbatim from FDA's Frozen Dessert Processing Guidelines.

61-36.VII.B.20. Revised to be consistent with R.61-34.1. Specifically, the requirements that all employees must thoroughly wash hands after visiting the toilet room, that adequate hair coverings must be worn, and that no tobacco can be used while processing were added.

61-36.VII.B.21. Section added to be consistent with R.61-34.1. All requirements pertaining to vehicles, however, previously covered under Section 7, Item 23.

61-36.VII.B.22. Section added to be consistent with R.61-34.1. Surroundings, however, generally covered under Section 7, Item 23. The requirement to keep surroundings free from conditions which might attract vectors or constitute a nuisance and the requirement to only use Department and/or EPA approved insecticides and rodenticides was added.

61-36.VIII. Revised to include updated language concerning the Department. Also, inserted the work "substantially" before equivalent since there are no uniform frozen dessert laws and regulations among the states and, therefore, very difficult to determine actual equivalency.

61-36.IX. Revised to be consistent with R.61.34.1. However, requirements basically do not change.

61-36.X. Revised to be consistent with R.61.34.1. Contains updated language.

61-36.XI. Revised to be consistent with R. 61-34.1. Specific measures are added regarding what shall be done when reasonable causes exist to suspect the possibility of transmission of infection from any person concerned with the manufacture of frozen desserts.

61-36.XII. Section added for guidance to manufacturers concerning recall actions.

61-36.XIII. Section revised to meet current administrative procedure requirements.

61-36.XIV. Section revised to meet current administrative procedure requirements.

61-36.XV. Section revised to meet current administrative procedure requirements.

Instructions: Replace R.61-36 in its entirety by this amendment:

Text:

R. 61-36 FROZEN DESSERTS

TABLE OF CONTENTS

SECTION I. DEFINITIONS

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

ADULTERATED FROZEN DESSERTS - a frozen dessert is deemed to be adulterated if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health;

2. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal regulation, or in excess of such tolerance if one has been established;

3. Consists, in whole or in part, of any substance unfit for human consumption;

4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;

5. 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; or

6. 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.

7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342) will be considered as a violation of this Regulation.

AND/OR - “and” shall apply where appropriate, otherwise “or” shall apply.

ASEPTICALLY PROCESSED MIX – a frozen dessert mix that is hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of this Regulation so as to render the product free or microorganisms capable of reproducing in the product under normal non-refrigeration conditions

of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

ASEPTIC PROCESSING – a process whereby the mix has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 and the provisions of Section VII (B), Item 16, of this Regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.

DEPARTMENT - the authorized representative of the South Carolina Department of Health and Environmental Control.

DRUG – shall mean:

1. articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

2. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

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

4. articles intended for use as a component of any articles specified in clauses 1, 2, or 3, but does not include devices or their components, parts, or accessories.

FOUNTAIN FREEZER - a freezer which is installed and used for freezing frozen desserts which are held in the freezer under refrigeration until they are served for immediate consumption.

FROZEN DESSERTS - frozen desserts as used in this regulation shall be defined in S.C. Code Ann. Section 39-37-10 (1976, as amended). They shall also include mixes used for frozen dessert manufacturing and products such as gelato and sorbetto made in semblance of those products defined in Section 39-37-10.

FROZEN DESSERTS MANUFACTURER - any person, except frozen dairy foods retailer, who manufactures, processes, or freezes any frozen desserts for distribution or sale.

FROZEN DESSERTS PLANT - any place or premises except frozen dairy foods retailers where frozen desserts are manufactured, processed, or frozen for distribution or sale.

FROZEN DESSERTS RETAILER - any person who sells, serves, dispenses or processes by fountain freezing, frozen desserts at retail which have been processed in an approved frozen desserts plant.

HERMETICALLY SEALED CONTAINER - a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

MIX - the unfrozen combination of ingredients of frozen desserts except such fruits, nuts, flavors, color, and other ingredients as may be exempted by the Department. Mix shall be pasteurized.

NOVELTIES – Frozen desserts, either alone or in combination with other foods such as cookies, wafers, cones, coating, confections, etc., which are packaged in single-serving units.

PASTEURIZATION - the process of heating every particle of mix in properly designed and operated equipment to one of the temperatures given in the following table, and held continuously at or above that temperature for at least the corresponding specified time:

TEMPERATURE / TIME
155 degrees F / 30 Minutes
175 degrees F / 25 Seconds
180 degrees F / 15 Seconds
191 degrees F / 1.0 Second
194 degrees F / 0.5 Second
201 degrees F / 0.1 Second
204 degrees F / 0.05 Second
212 degrees F / 0.01 Second

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the United States Food and Drug Administration (FDA) to be equally efficient and which is approved by the Department.

PERSON - any individual, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

OFFICIALLY DESIGNATED LABORATORY - 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 Grade A raw milk for pasteurization and commingled milk tank truck samples of raw milk for antibiotic residues and bacterial limits.

OFFICIAL LABORATORY - a biological, chemical, or physical laboratory which is under the direct supervision of the Department.

SANITIZATION - 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 practicable. 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.

STERILIZED - the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.

ULTRA-PASTEURIZED - mix that has been thermally processed at or above 138ºC (280ºF) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

SECTION II. ADULTERATED OR MISBRANDED FROZEN DESSERTS

A. No person shall within the State of South Carolina, or its jurisdiction, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell any frozen dessert which is adulterated or misbranded. Any frozen dessert which may contain any unwholesome substance, or which if defined in this Regulation does not conform with the definition, shall be deemed adulterated and/or misbranded.

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

C. Frozen desserts shall be examined by the Department as often as may be necessary to determine freedom from adulteration or misbranding. The Department may, upon written notice to the owner or person in charge, place a hold order on any frozen dessert which it determines or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, frozen desserts 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 frozen desserts by the Department, and neither such frozen desserts nor the containers thereof shall be relabeled, repacked,

reprocessed, altered, disposed of, or destroyed without permission of the Department, except on order by a court of competent jurisdiction.

D. When frozen desserts 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 provides the product to be free from adulteration.

SECTION III. COMPLIANCE PROCEDURES:

A. PERMIT:

1. It shall be unlawful for any person who does not possess a permit from the Department to bring into, send into, or receive into South Carolina or its jurisdiction, for sale, or to sell, or offer for sale therein, or to have in storage any frozen dessert defined in this Regulation: Provided, that grocery stores, restaurants, soda fountains, and similar establishments where frozen desserts are served or sold at retail, but not processed, other than fountain freezing of approved pasteurized mix, may be exempt from the requirements of this section.

2. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Every frozen dessert manufacturer shall have a permit. Permits shall not be transferred with respect to persons and/or locations.

B. SUSPENSION OF PERMIT:

1. The Department shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this Regulation; or whenever the permit holder has interfered with the Department in the performance of its duties: Provided, that the Department shall, in all cases except where the frozen desserts involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the permit holder, manager or other duly authorized representative, a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in questions and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the Department before making any order of suspension effective. A suspension shall remain in effect until the violation has been corrected to the satisfaction of the Department.

2. When the permit suspension is due to violations other than bacterial, coliform, cooling temperature standards or adulteration by drugs, the permit holder, manager or other duly authorized representative, is notified of the intent to suspend the permit in fifteen days unless a written request for a hearing is filed by the permit holder within such fifteen day period with the Department. If the hearing upholds the findings of the Department, the permit shall be suspended until the reasons for the suspension have been corrected.

3. The Department may without warning, notice, or hearing suspend a permit to operate a frozen dessert plant when it is determined that the operation of the frozen dessert plant constitutes an imminent health hazard, e.g., violations of bacterial, coliform, cooling temperatures, or adulteration by growth inhibitors (drugs) or other deleterious substances. Following immediate permit suspension, all manufacturing operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended, and that an opportunity for a hearing will be provided if a written request for a hearing is filed with the Department by the permit holder, manager or other duly authorized representative, within fifteen days. If no written request for a hearing is filed within fifteen days, the suspension is sustained. During the process, the permit shall remain suspended unless the imminent health hazard has been corrected.

4. Hearings on suspension of permits provided for in this section shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, S.C. Code Ann. Section 1-23-310 *et. seq*., 1976, as amended) and applicable regulations.

5. Any frozen dessert or mix manufacturer whose permit has been suspended may make written application for the reinstatement of his permit.

6. Within one week of receiving the written application, the Department shall make inspections and/or collect samples for analysis to determine the applicant's establishment is in substantial compliance with this Regulation. If conditions warrant, the permit will be reinstated.

C. REVOCATION OF PERMIT:

1. The Department may revoke a permit after an opportunity for a hearing has been provided for repeated critical violations of any of the requirements of this regulation, or for interference with the Department of the performance of duty. Notwithstanding any other provisions of this regulation, the permit shall be revoked if the Department is threatened with bodily harm or physical interference in the performance of inspectional duties.

2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit shall be revoked at the end of the fifteen days following service of such notice unless a written request for a hearing is filed with the Department by the permit holder, manager or other duly authorized representative, within such fifteen day period.

3. 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.

4. The revocation of a permit, provided for in this chapter, shall be conducted in accordance with the South Carolina Administrative Procedures Act.

5. A notice provided for in this regulation is properly served when it is delivered to the permit holder, manager or other duly authorized representative, or when it is sent by registered or certified mail, return receipt requested and delivery restricted to the addressee, to the last known address of the frozen dessert plant's permit holder.

6. The hearings provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, S.C. Code Ann. Section 1-23-310 et. seq. (1976, as amended). and applicable regulations.

SECTION IV. LABELING

All cans, packages, and other containers enclosing mix and frozen desserts or their ingredients derived from milk or edible food fats, except those filled from labeled bulk containers in retail dispensing, shall be plainly labeled or marked with: (1) the name of the contents; and (2) the name and address of the plant at which the contents were placed in the container. A frozen desserts manufacturing plant may be identified by a code when the Department is given advance notice of the coding. The label shall be in letters of an approved size, kind, and color and shall contain no marks or words which are misleading. All finished product labeling (name of product, ingredients, nutrition facts, net contents, etc.) shall conform to applicable federal and state labeling laws.

SECTION V. INSPECTION OF FROZEN DESSERT PLANTS:

A. Each frozen desserts manufacturer whose frozen desserts are intended for consumption within South Carolina or its jurisdiction shall be inspected by the Department prior to the issuance of a permit.

B. Following the issuance of a permit, the Department shall inspect each frozen dessert manufacturer at least once every three months.

C. If a violation of any requirement set forth in Section VI or Section VII is 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 days; this second inspection shall be used to determine compliance with the requirements of Section VI or VII. Any violation of the same requirement of Section VI or VII on such second inspection shall call for permit suspension in accordance with Section III and/or court action.

D. Provided, that when the Department finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of mix or frozen desserts may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or

2. A cross connection exists whereby direct contamination of pasteurized mix or frozen dessert is occurring; or

3. Conditions exist whereby direct contamination of pasteurized mix or frozen desserts is occurring, the Department shall take immediate action to prevent further processing of such mix or frozen dessert until such violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the Department shall take prompt action to suspend the permit as provided for in Section III of this Regulation.

E. Provided, that in the case of a mix plant producing aseptically processed mix, when an inspection of the mix plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to the public health and the Department shall take immediate action to suspend the permit of the plant for the sale of aseptically processed mix in conformance with Section III of this Regulation.

F. One copy of the inspection report shall be handed to the operator, 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.

G. Every frozen desserts plant operator shall, upon request of the Department, permit access of officially designated persons to all parts of his establishment or facilities to determine compliance with the provisions of this Regulation. A plant operator shall furnish the Department, upon request, for official use only, a true statement of the actual quantities of frozen desserts purchased and sold, and a list of all sources of such frozen desserts, records of inspections, tests, and pasteurization time and temperature records.

H. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this Regulation which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of frozen desserts, or results of inspections or tests thereof) to use such information to his own advantage or to reveal it to any unauthorized person.

SECTION VI. THE EXAMINATION OF FROZEN DESSERTS

A. SAMPLING CRITERIA:

1. During any consecutive six months, at least four samples of pasteurized mix and a variety of different flavors, types and sizes of containers of frozen desserts and frozen dessert novelties defined in this Regulation, except aseptically processed mix, shall be collected in at least four separate months, except when three months

show a month containing two sampling dates separated by at least twenty days, from every frozen desserts plant by the Department.

2. Samples of frozen desserts shall be taken while in the possession of the manufacturer and/or distributor at any time prior to delivery to the store or consumer.

3. Samples of frozen desserts from stores, cafes, soda fountains, restaurants, and other places where frozen desserts are sold may be examined as often as the Department may require.

B. SAMPLING ENFORCEMENT:

1. Whenever two of the last four consecutive bacterial counts (except those for aseptically processed mix), coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for frozen desserts, 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 of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within twenty-one days of the sending of such notice, but not before the lapse of three days. Immediate suspension of permit in accordance with Section III, and/or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed mix), coliform determinations, or cooling temperatures.

2. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any mix or frozen desserts involved shall not be offered for sale.

3. 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 frozen desserts 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.

4. Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provision of Section II of this Regulation.

5. Whenever a container or containers of aseptically processed mix is found to be unsterile due to under-processing, the Department shall consider this to be an imminent hazard to public health and shall suspend the permit of the mix plant for the sale of aseptically processed mix. No aseptically processed mix or frozen desserts made from the mix, shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products, including frozen desserts, manufactured from the lot found to contain one or more unsterile units shall be recalled and disposed of as directed by the Department.

C. SAMPLING METHODS:

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 *Standard Methods for the Examination of Dairy Products* of the American Public Health Association, and the certification of sample collectors, and examinations shall be evaluated in accordance with the United States Public Health Service/FDA *Evaluation of Milk Laboratories.* Aseptically processed mix packaged in hermetically sealed containers shall be tested in accordance with the FDA's *Bacteriological Analytical Manual*. Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Department requires.

SECTION VII. FROZEN DESSERT PLANTS

A. TEMPERATURE, BACTERIOLOGICAL AND CHEMICAL REQUIREMENTS

1. All frozen desserts shall be produced, processed, and pasteurized, ultra-pasteurized, aseptically processed and frozen to conform with the following temperature, bacteriological, and chemical standards and the sanitation requirements of this section:

a. Raw Milk and Milk Products for Pasteurization, Ultra Pasteurization, and Aseptic Processing:

(1) Temperature - 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. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

(2) Bacterial Limits - Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization.

(3) Somatic Cell Count - Individual producer milk not to exceed 750,000 per mL. Goat milk not to exceed 1,000,000 per mL.

(4) Drugs - No positive results on drug residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade A PMO as amended.

b. Pasteurized Frozen Desserts and Heat-Treated, Bulk-Shipped Milk Products:

(1) Temperature – Cooled to 7°C (45°F) or less and maintained thereat.

(2) Bacterial limits* - 30,000 per mL.

(3) Coliform - Not to exceed 10 per mL: provided that, in the case of bulk milk transport tank shipments, where contents are to be repasteurized, shall not exceed 100 per mL.

(4) Phosphatase** - Less than 500 milliunits/L by the Fluorometer or Clarion ALP or equivalent.

(5) Drugs - No positive results on drug residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade A PMO as amended.

c. Aseptically Processed Mix:

(1) Temperature - None.

(2) Bacterial limits - No growth by test specified in Section VI.

(3) Drugs - No positive results on drug residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade A PMO as amended.

*Not applicable to cultured products.
**Not applicable to bulk shipped heat-treated milk products.

2. No process or manipulation other than pasteurization, ultra pasteurization or aseptic processing, freezing, processing methods integral therewith, and appropriate refrigeration (freezing) shall be applied to mix and frozen desserts for the purpose of removing or deactivating microorganisms: Provided, that in the bulk shipment of cream, skim milk, or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 125°F but less than 161°F for separation purposes is permitted when the resulting bulk shipments of cream, skim milk, and/or lowfat milk are labeled heat-treated.

B. SANITATION OF FROZEN DESSERT PLANTS

1. Floors - Construction: The floors of all rooms in which frozen desserts, or their ingredients are processed, handled or stored, including cold storage rooms, or in which containers, equipment and utensils are washed or stored shall be constructed of concrete or other equally impervious and easily cleaned material and shall be kept in good repair. Floors in all areas in which frozen desserts or their ingredients are processed or in which containers, equipment and utensils are washed shall be properly sloped and equipped with trapped drains.

2. Walls and Ceilings - Construction: Walls and ceilings of room in which frozen desserts or their ingredients are processed, handled, or stored, or in which containers, utensils, and equipment are washed shall have a smooth, water resistant, washable, light-colored surface in good repair.

3. Doors and Windows: Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather. Outside openings shall be protected against the entrance of insects by tight-fitting, self-closing doors, closed windows, screening, effective air curtains or other means.

4. Lighting and Ventilation:

a. All rooms in which frozen desserts or their ingredients are handled, processed, or stored, and/or in which containers, equipment, and utensils are washed shall be well lighted and ventilated. At least twenty foot candles of light are needed in working areas. Dry storage and cold storage rooms need at least five foot candles of light.

b. Pressurized ventilating systems shall have a filtered air intake.

5. Separate Rooms:

a. There shall be separate rooms for:

(1) The pasteurizing, processing, cooling, freezing and packaging of mix and frozen desserts.

(2) Cleaning and sanitizing facilities for tank trucks in plants receiving mix or milk products in such tanks.

(3) Receiving cans of mix in plants receiving such cans.

b. Rooms in which mix or frozen desserts are handled, processed, or stored, or in which containers, utensils, and equipment are washed or stored shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

c. Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged mix and frozen desserts.

6. Toilet-Sewage Disposal Facilities:

Every frozen desserts plant shall be provided with toilet facilities conforming with state and local plumbing laws, regulations and codes. Toilet rooms shall not open directly into any room in which frozen desserts, their ingredients, equipment, or containers are processed, handled or stored. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in wastewater system approved by the Department. A sign directing employees to wash their hands before returning to work shall be posted in all toilet rooms used by employees.

7. Water Supply:

a. Water for frozen dessert plant purposes shall be from a supply properly located, protected and operated, and shall be easily accessible, adequate and of a safe, sanitary quality.

b. Samples for bacteriological testing of individual water supplies shall be taken by the Department upon the initial approval of the physical structure, each six months thereafter, and when any repair or alteration of the water supply system has been made. Examinations shall be conducted in an official laboratory, and records maintained.

8. Hand-washing Facilities: Convenient hand-washing facilities shall be provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or approved hand drying devices. Hand-washing facilities shall be kept in a clean condition and in good repair.

9. Frozen Dessert Plant Cleanliness: All rooms in which frozen desserts are handled, processed, frozen or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, freezing, packaging and bulk milk product storage rooms.

10. Sanitary Piping:

a. All sanitary piping, fittings and connections which are exposed to frozen desserts, or from which liquids may drip, drain or be drawn into frozen desserts, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized frozen desserts shall be conducted from one piece of equipment to another only through sanitary piping.

b. All sanitary piping, connections and fittings shall consist of:

(1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(3) Heat resistant glass; or

(4) Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent, 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, may be used for gaskets, sealing applications and for short flexible take down jumpers or connections where flexibility is required for essential or functional reasons.

11. Construction and Repair of Containers and Equipment:

a. All multi-use containers and equipment with which frozen desserts or their ingredients come into contact shall be smooth, impervious, corrosion-resistant, and of non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which frozen desserts come in contact shall be nontoxic and shall have been manufactured, packaged, transported and handled in a sanitary manner.

b. All frozen dessert contact surfaces of multi-use containers and equipment shall consist of:

(1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(3) Heat resistant glass; or

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

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, Center for Food Safety and Applied Nutrition, United States Public Health Service/Food and Drug Administration, Department of Health and Human Services.

12. Cleaning and Sanitizing of Containers and Equipment:

a. The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling, freezing and storage of frozen desserts shall be effectively cleaned after each use, at least daily, and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed mix beyond the final heat treatment process shall be sterilized before any aseptically processed mix is packaged and shall be re-sterilized whenever any unsterile product has contaminated it.

b. Storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two hours, except that permission may be granted by the Department for storage of pasteurized mix longer than seventy-two hours, provided necessary plant quality controls are in place. Storage tanks which are used to store raw milk, mix or heat treated milk products longer than twenty-four hours shall be equipped with a seven-day temperature recording device.

c. A temperature recording device, complying with the specifications in Appendix H, FDA Grade A PMO as amended, or a recording device which has been reviewed by FDA and found to provide sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the Department shall be installed in the return solution or other appropriate areas to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions.

d. Recording charts shall be identified, dated and retained for three months. The Department shall review the recording charts during each inspection.

13. Storage of Cleaned Containers and Equipment: After cleaning, all multi-use frozen dessert containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

14. Storage and Handling of Single-Service Containers, Utensils and Materials: Covers, caps, parchment papers, wrappers, can liners, and single-service sticks, spoons and containers for frozen desserts or their ingredients shall be purchased and stored only in sanitary containers; wrappings or cartons shall be kept therein in a clean, dry place until used, and shall be handled in a sanitary manner.

15. Protection from Contamination

a. Frozen dessert plant operations, equipment and facilities shall be located and conducted to prevent any contamination of frozen dessert products, ingredients, equipment, containers and utensils. All frozen desserts or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than mix or frozen desserts in the plant shall be performed to preclude the contamination of such frozen desserts. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of frozen desserts or ingredients of such frozen desserts or the product-contact surfaces of all equipment, containers or utensils.

b. Frozen desserts in broken and open containers may after delivery be returned to the plant for inspection but shall not be used for making frozen desserts.

c. Whenever air under pressure is used for the agitation or movement of frozen desserts or other ingredients, or is directed at frozen dessert contact surfaces or other ingredients, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H, FDA Grade A PMO as amended. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with frozen desserts, it shall be of culinary quality and shall comply with the applicable standards of Appendix H, FDA Grade A PMO as amended.

16. Pasteurization-Aseptic Processing:

a. All mix shall be pasteurized or aseptically processed as described in Section I of this Regulation.

b. To insure that pasteurization temperature and time will be applied to every particle of mix, the system design, public health controls and testing shall comply with Section 7. Item 16p of the FDA Grade A PMO as amended.

17. Cooling:

a. All milk and fluid milk products received at frozen dessert plants for use in frozen desserts shall be cooled immediately in approved equipment to 45°F or less and maintained at that temperature until pasteurized. All pasteurized mix shall be cooled immediately in approved equipment to 45°F or less and maintained at that temperature until frozen.

b. All mix which is not frozen at the plant at which it was pasteurized shall be transported to the place of manufacturing or freezing in a sanitary manner and maintained at a temperature of 45°F or less until processed. Every room or tank in which milk products or mix are stored shall be equipped with an accurate thermometer, which shall comply with the specifications of Appendix H, FDA Grade A PMO as amended.

c. Recirculated cooling agents (water or glycol) which are used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such cooling agents shall be tested semiannually and shall comply with the bacteriological standards of Appendix G, FDA Grade A PMO as amended. Samples shall be taken by the Department and

examination shall be conducted in an official laboratory. Recirculated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, and other chemical additives, when used in recirculating systems, shall be nontoxic under conditions of use.

18. Packaging:

a. Packaging, cutting, molding, dipping, and other preparation of frozen desserts or their ingredients shall be done in a sanitary manner using approved equipment.

b. Filling equipment for frozen desserts shall have drip defectors on the filler valve to prevent condensate from entering the product or container. Shielding shall be provided over conveyors for cartons, lids, caps and filled containers until they are closed to prevent water condensate or other contamination from entering the product.

c. The product contact surface of the container, including the pouring lip for mix containers, shall be covered by the closure/lid.

d. Hand capping/packaging is not an acceptable practice. Hand capping/packaging may be approved only if suitable mechanical equipment for the capping/packaging of specific containers is not available or is not practical for use. If hand capping is approved, a Department approved procedure will be established which will eliminate all possibility of contamination.

19. Ingredients

a. All raw milk and milk products used in the manufacture of frozen desserts shall be from a Grade A domestic source as defined in the FDA Grade A Pasteurized Milk Ordinance as amended or from other supplies acceptable to the Department. All mix and frozen dessert ingredients shall be clean, have a fresh wholesome flavor and odor and a normal appearance, be of satisfactory quality and shall be processed in an approved, sanitary manner.

b. The only ingredients which may be added after pasteurization are those flavoring and coloring ingredients which are:

(1) Subjected to prior heat treatment sufficient to destroy pathogenic microorganisms.

(2) Of 0.85% water activity or less,

(3) Of pH less than 4.7,

(4) Roasted nuts (added at the freezer),

(5) Contain high alcohol content,

(6) Bacterial cultures,

(7) Fruits and vegetables added at the freezer, or

(8) Subjected to any other process which will assure that the ingredient is free of pathogenic organisms.

20. Personnel - Cleanliness: Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. Employees shall not resume work after visiting the toilet room without thoroughly washing their hands. All persons while engaged in the processing, pasteurization, freezing, handling, storage or transportation of mix or frozen desserts, containers, equipment and utensils shall wear clean outer garments. All persons while engaged in the processing of mix and frozen desserts shall wear adequate hair covering and shall not use tobacco.

21. Vehicles: All vehicles used for the transportation of frozen desserts or their ingredients shall be so constructed and operated as to protect their contents from the sun and from contamination. Such vehicles shall be kept clean and no substance capable of contaminating mix or frozen desserts or their ingredients shall be transported therewith in such manner as to permit contamination. The name of the distributor shall be prominently displayed on the vehicles.

22. Surroundings:

a. Frozen dessert plants shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents, or otherwise constitute a nuisance.

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

SECTION VIII. FROZEN DESSERTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Frozen desserts from points beyond the limits of routine inspection by the Department may be sold in South Carolina if they are manufactured under provisions substantially equivalent to the requirements of this Regulation; provided, that the Department shall be satisfied that the agency having jurisdiction over the manufacture of these products is properly enforcing such provisions.

SECTION IX. PLANS FOR CONSTRUCTION AND RECONSTRUCTION

Properly prepared plans for all frozen dessert plants regulated under this Regulation which are hereafter constructed, reconstructed or extensively altered shall be submitted to the Department for written approval before work is begun.

SECTION X. PERSONNEL HEALTH

No person affected with any disease capable of being transmitted to others through the contamination of food shall work at any frozen desserts plant in any capacity which brings them into direct contact with finished products, such as pasteurized or aseptically processed mix or frozen desserts, or which brings them into direct contact with associated pasteurized or aseptically processed mix and frozen dessert product-contact surfaces.

SECTION XI. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED:

When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of frozen desserts, or their ingredients, the Department is authorized to require any or all of the following measures:

A. The immediate exclusion of that person from handling frozen desserts, or their ingredients;

B. The immediate exclusion of the frozen desserts concerned from distribution and use;

C. Adequate medical and bacteriological examination of the person, of his associates, and of his and their body discharges.

SECTION XII. RECALLS

Each frozen desserts manufacturer should develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator 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 frozen desserts manufacturer, 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 frozen desserts manufacturer to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The frozen desserts manufacturer shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XIII. PENALTIES:

Violations of this regulation shall be punishable in accordance with S.C. Code Ann. Section 44-1-150 (1976 as amended). Each day of continued violation shall be a separate offense.

SECTION XIV. REPEAL AND DATE OF EFFECT:

All previous amendments of this regulation are hereby repealed; this regulation shall be in full force and effect immediately upon adoption and its publication, as provided by law.

SECTION XV. SEVERABILITY CLAUSE:

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

Fiscal Impact Statement:

The Department estimates there will be no new costs imposed on the State or its political subdivisions by this regulation.

Statement of Need and Reasonableness:

The Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Ann. Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION:

Purpose: These amendments will bring the Regulation in compliance with the latest Frozen Dessert guidelines of the United States Public Health Service, Food and Drug Administration and assure consumers that the latest sanitation requirements are being met by the dairy industry; these amendments will incorporate these requirements into South Carolina's regulation. Amendments will also insure that the regulation complies with the requirements of the South Carolina Administrative Procedures Act, is compatible with R.61-34.1, Pasteurized Milk and Milk Products, and will strengthen the Department's enforcement capability.

Legal Authority: The legal authority for R.61-36 is S.C. Code Ann. Sections 44-1-140 *et seq*., 44-1-140(11); 1-23-10; -110 (1976, as amended).

Plan for Implementation: The amendments will take effect upon approval by the General Assembly and publication in the *State Register*. These latest requirements have already been implemented by the Department under the authority of the FDA. The regulated community will be provided copies of the regulation.

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

This amendment will ensure that consumers are receiving safe, high quality frozen dairy foods and frozen desserts, and will bring the regulation into compliance with the latest requirements set forth by the United States Food and Drug Administration (FDA) regarding bottled water manufacturing sanitation practices.

DETERMINATION OF COSTS AND BENEFITS: There are no anticipated new costs associated with the implementation of this regulation. There will be a benefit to South Carolina's environment and the health of its citizens by ensuring that consumers are receiving safe, high quality frozen dairy foods and frozen desserts.

UNCERTAINTIES OF ESTIMATES: None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: The proposed regulation will ensure that consumers are receiving safe, high quality frozen dairy foods and frozen desserts.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: Not implementing the regulation will cause a decrease in the sanitary standards in frozen dessert and frozen dairy food manufacturing and processing facilities; this decrease in sanitary standards could have a detrimental effect on the health of South Carolina's citizens and visitors.

Statement of Rationale Pursuant to S.C. Code Section 1-23-120:

The determination to revise this regulation was in response to changes in requirements set forth by the United States Food and Drug Administration (FDA) and assure consumers that the latest sanitation requirements are being met by the dairy industry.

Document No. 2856
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Ann. Sections 44-1-140(4); 1-23-10; -110 (1976, as amended)

R.61-32. *Soft Drink Bottling Plants*

Synopsis:

These amendments of R.61-32. *Soft Drink Bottling Plants,* will bring the regulation into compliance with the latest requirements set forth by the United States Food and Drug Administration (FDA) regarding bottled water manufacturing sanitation practices. These latest requirements have already been implemented by the Department under the authority of the FDA; these amendments will incorporate these requirements into South Carolina's regulation. Amendments will also ensure that the regulation complies with the requirements of the South Carolina Administrative Procedures Act, and will strengthen the Department's enforcement capability. The title of this regulation is being changed to clearly identify the regulation as being applicable to bottled water as well as soft drinks. See Discussion of Revisions below and Statements of Need and Reasonableness and Rationale herein.

Discussion of Revisions:

SECTION/REVISION

TITLE. Title of regulation changed to include bottled waters.

CONTENTS Table of Contents added.

SECTION I. Wording changed to include bottled waters as a separate product and process.

SECTION II. Wording changed to include bottled waters as a separate product and process.

SECTION III. Bottled waters added to appropriate definitions. Twenty (20) new definitions added to reflect FDA nomenclature and to further clarify the regulation.

SECTION IV.B.3. Requirement for posting handwashing signs for employees added.

SECTION IV.C. "Insanitary" changed to "unsanitary".

SECTION V.B.5.(a) Bottled waters added to this section.

SECTION V.C.1.(a) "Source" changed to "public water system".

SECTION V.C.1.(c) Bottled waters added to this section.

SECTION V.C.1.(e) Requirement for air vents to be filtered added.

SECTION V.D.1. "Source" changed to "public water system".

SECTION V.D.2 Wording "approved by the Department" added to require approval of disinfectants used.

SECTION V.D.3. Requirement for the tank being sealed when water is "delivered" is changed to read "unloaded."

SECTION V.F.3. The word "insanitary" changed to "unsanitary."

SECTION V.F.5. Bottled waters added to the section.

SECTION VII.A.4. Bottled waters added to the section.

SECTION VII.A.7 New section added to require maintaining current certification or approval within the plant.

SECTION VII.A.8. Bottled waters added to this section.

SECTION VII.A.9. New section added to require conditions and controls to prevent microbiological contamination.

SECTION VII.A.10. New section added to require germicidal treatment by ozonation, carbonation or other equivalent disinfection approved by the Department.

SECTION VII.A.11. New section added to require weekly total coliform monitoring.

SECTION VII.A.12. New section added to require sampling for chemical and radiological contaminants in source water for bottled water products.

SECTION VII.A.13. New section added to require sampling and analysis for each type of finished bottled water product.

SECTION VII.A.14. New section added to allow bottled water to be used as an ingredient in beverages.

SECTION VII.A.15. New section added to delineate the requirements for the collection of spring water.

SECTION VII.A.16. Section added to allow the addition of fluoride or minerals.

SECTION VII.D.3.(a) Language not necessary for the requirement removed.

SECTION VII.D.3.(b) Language not necessary for the requirement removed.

SECTION VII.I.1. Bottled waters added to this section.

SECTION VII.I.2. Bottled waters added to this section.

SECTION IX.A. Bottled waters added to this section.

SECTION IX.B.1. Bottled waters added to this section.

SECTION IX.C. Changes made in this section to reflect the requirements of the South Carolina Administrative Procedures Act.

SECTION IX.D.1. Wording added to allow revocation of the permit for "the interference with the health authority in the performance of duty."

SECTION IX.D.4. Wording added to reflect the requirements of the South Carolina Administrative Procedures Act.

SECTION IX.F. Wording added to reflect the requirements of the South Carolina Administrative Procedures Act.

SECTION IX.H. Bottled waters added to this section.

SECTION IX.L. New section added to establish requirements for out-of-state imports.

SECTION IX.M. New section added to establish requirements for out-of-country imports.

SECTION IX.N. New section added to require established procedures for initiating and performing a product recall when necessary.

Instructions: Replace R.61-32 in its entirety by this amendment:

Text:

R.61-32. Soft Drink And Water Bottling Plants

CONTENTS:

SECTION I. PURPOSE

This regulation sets forth minimum health standards, procedures and practices to ensure that soft drinks and bottled waters~~,~~ are manufactured in South Carolina in a safe and wholesome manner.

SECTION II. SCOPE

This regulation shall apply to all persons in South Carolina who manufacture or bottle soft drinks and bottled waters~~,~~ sold for human consumption in South Carolina.

SECTION III. DEFINITIONS

ADEQUATE - shall mean substantial compliance with acceptable health standards, procedures and practices.

ADULTERATED or ADULTERATION - the presence or addition of any harmful or unwholesome substance, article, object, or other ingredients which may dilute or lower the quality of the beverage involved or any substance which is prohibited by law or regulation in a soft drink or bottled water.

APPROVED - acceptable to the Department based on a determination as to conformance with applicable standards and good public health practice.

APPROVED LABORATORY - a laboratory approved by the Department or certified by the U.S. Environmental Protection Agency (EPA), or certified (accredited) by a third-party organization acceptable to the Department.

APPROVED SOURCE - when used in reference to a bottled water plant's product water or water used in the plant's operations, means the source of the water whether it be from a spring, artesian well, drilled well, public or community water system, or any other source that has been inspected and the water sampled, analyzed, and found of a safe and sanitary quality with or without treatment, and approved by the Department in accordance with Regulation 61-58, State Primary Drinking Water Regulations.

ARTESIAN WATER - bottled water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to the Department that the water level stands at some height above the top of the aquifer.

BOTTLED WATER - water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water."

BOTTLING - filling, capping, packaging or enclosing in containers.

BOTTLING PLANT - any establishment involved in the manufacturing or packaging of soft drinks and bottled waters.

BULK WATER - source water collected at an approved site remote from the bottling plant and transported to the bottling plant for further processing and bottling.

CODE OF FEDERAL REGULATION (CFR) - a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

CONTAINER - any material used for the packaging of soft drinks and bottled waters, whether of glass, plastic, metal, paper or any combination thereof.

DEMINERALIZED WATER - bottled water which is produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia and specified by the U. S. Food and Drug Administration (FDA) in 21 CFR Section 165.110.

DEIONIZED WATER - bottled water that has been produced by a process of deionization and that meets the definition of "purified water" in the United States Pharmacopoeia and specified by the FDA in 21 CFR Section 165.110.

DEPARTMENT - the South Carolina Department of Health and Environmental Control acting through its authorized representatives.

DISTILLED WATER - bottled water which has been produced by a process of distillation and meets the definition of "purified water" in the United States Pharmacopoeia and specified by FDA in 21 CFR Section 165.110.

DRINKING WATER - water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.

EASILY CLEANABLE - surfaces that are readily accessible and made of such materials and finishes and fabricated in such a way that residue may be effectively removed by normal cleaning methods.

EMPLOYEE - any person in a bottling plant engaged in the mixing of syrups, filling of containers, or any other capacity which brings them into contact with ingredients, containers, or equipment used in the manufacturing and packaging of soft drinks and bottled waters.

EQUIPMENT - all machinery, utensils, conveyors, containers, cases, and other articles used in the manufacturing of soft drinks and bottled waters.

FOOD - raw materials and ingredients.

FOOD-CONTACT SURFACE - the surface of any object coming into direct contact with ingredients and finished products during storage and manufacture. This shall include any surface upon which the product routinely may drip, drain, or be drawn into, as part of normal processing.

GROUND WATER - water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. Ground water must not be under the direct influence of surface water.

MICROORGANISMS - mean yeast, molds, bacteria and viruses and include, but are not limited to, species having public health significance.

MINERAL WATER - bottled water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.

NATURAL WATER - bottled spring, mineral, artesian, or well water which is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation or equivalent disinfection process).

PERSON - any individual, plant operator, partnership, company, corporation, trustee, association, or a public or private entity.

PEST - any animals or insects including, but not limited to, birds, rodents, flies and larvae.

PURIFIED WATER - bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.

REMODELED - any enlarging, replacing of floors, walls or ceilings, or changing in any respect, the structure at which a soft drink or water bottling plant is housed; provided, however, this shall not apply to repainting or refinishing of floors or walls.

REVERSE OSMOSIS WATER – bottled water that is produced by a process of reverse osmosis and that meets the definition of "purified water" in the United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.

SANITIZE - to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance.

SHALL - the item or condition discussed is mandatory.

SHOULD or MAY - the item or condition discussed is preferred but not mandatory.

SOFT DRINK - any nonalcoholic flavored carbonated beverage, soda or soda water, fruit juice, fruit drink, nonalcoholic still beverage, and seltzer or club soda.

SPARKLING BOTTLED WATER - bottled water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at the emergence from the source. Manufacturers may add carbonation to previously noncarbonated bottled water products and label such water appropriately (e.g. sparkling spring water).

SPRING WATER – bottled water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must comply with the FDA standard of identity in 21 CFR 165.110.

STANDARD OF IDENTITY - the FDA Standard of Identity for bottled water as set forth in 21 CFR 165.110.

STANDARD OF QUALITY - the FDA Standards of Quality for bottled as set forth in 21 CFR165.110.

STERILE WATER – bottled water that meets the requirements under "Sterility Tests" <71> in the current United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.

UNDESIRABLE MICROORGANISMS - those microorganisms which are considered to be of public health significance, which subject food to decomposition, which indicate that food is contaminated with filth, or which otherwise may cause food to be adulterated.

WELL WATER – bottled water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.

SECTION IV. PERSONNEL

A. DISEASE CONTROL

Any 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 by which may contribute to the reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations expected to result in such contamination, until the condition is corrected. All personnel shall be instructed to report such health conditions to their supervisors.

B. CLEANLINESS

All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. Methods for maintaining cleanliness to prevent food contamination include, but are not limited to:

1. Wearing outer garments suitable for the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

2. Maintaining adequate personal cleanliness.

3. Washing hands thoroughly (and sanitizing, if necessary, to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. Signs shall be posted reminding employees to wash their hands before returning to work.

4. Removing all insecure jewelry or other objects which might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it should be covered by material that can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

5. Maintaining gloves used in food handling in an intact, clean, and sanitary condition. These gloves should be of an impermeable material.

6. Where appropriate, wearing in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.

7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

C. EDUCATION AND TRAINING

Personnel responsible for identifying sanitation failures or food contamination should have a background in education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food protection principles, and should be informed of the danger of poor personal hygiene and unsanitary practices.

D. SUPERVISION

Responsibility for ensuring compliance by all personnel with all requirements of this section shall be clearly assigned to competent supervisory personnel.

SECTION V. GROUNDS, BUILDINGS AND FACILITIES

A. GROUNDS

The grounds around a bottling plant under the control of the operator shall be kept in such condition to protect against the contamination of its products. The methods for adequate maintenance of grounds include, but are not limited to:

1. Properly storing equipment, removing litter and waste, and cutting weeds or grass in the immediate vicinity of plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

3. Adequately draining areas that may contribute to the contamination of food by seepage, foot-borne filth, or providing a breeding place for pests.

4. Operating waste treatment and disposal systems in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

B. BUILDING CONSTRUCTION AND DESIGN

Bottling plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes and to prevent drip and condensation from fixtures, ducts and pipes from contaminating foods, food-contact surfaces or food containers. Sufficient space shall be provided for the placement of equipment and storage of materials as deemed necessary for the proper maintenance of sanitary operations and production of safe food. Bottling plants shall meet, but not be limited to, the following:

1. REQUIRED ROOMS

(a) Whenever ingredients are mixed, a separate room (commonly called a syrup or blend room) or separate area of the filling room shall be provided for this purpose. This room or separate area of the filling room shall be used only for mixing ingredients and storage of mixed batches.

(b) A separate room shall be provided for filling and sealing containers (commonly called a filling or bottling room). This room shall contain only necessary filling, sealing, electronic inspection, coding and labeling equipment. Only the exit end of the bottle washing machine shall open into this room through a tight-fitting wall. If approved by the Department, the mixing of ingredients and storage of mixed batches can be conducted in this room.

2. FLOORS

(a) The floors of the syrup and filling rooms shall be constructed of concrete or equally impervious, easily cleanable material, and shall be kept clean, in good repair, and properly sloped to trapped drains to prevent pools of standing water after flushing. Integral coved juncture bases should be provided in these areas.

(b) The floors of storage, packaging and accessory rooms shall be easily cleanable, and be kept clean and in good repair at all times.

3. WALLS AND CEILINGS

(a) The walls and ceilings in the syrup and filling rooms shall be smooth, washable, light colored, and shall be kept clean and in good repair at all times. Lay-in ceiling tile panels may be used if they are designed to be easily removable for cleaning and replacement, as needed.

(b) The walls and ceilings of storage, packaging and accessory rooms or areas shall be of sound construction and kept clean and in good repair at all times.

4. LIGHTING

(a) Adequate lighting shall be provided in all areas of the plant. A minimum of 20 foot-candles of light should be provided in all working areas, and a minimum of 10 foot-candles in all storage areas.

(b) Adequate protection from glass breakage and falling debris shall be provided for all light bulbs and fixtures located over exposed food or unsealed containers in any step of preparation.

5. VENTILATION

(a) Adequate ventilation or control equipment shall be provided to minimize odors, vapors and moisture and to keep excessive carbon dioxide, ozone, and other processing gases, from accumulating in areas where soft drinks and bottled waters are manufactured.

(b) Pressurized ventilating systems shall have a filtered air intake.

(c) Fans and other air-moving equipment shall be located and operated in a manner minimizing the potential for contaminating food and unsealed containers.

6. DOORS AND WINDOWS

(a) All openings into the syrup and filling rooms shall be adequately protected against the entrance of dust and insects by tight-fitting, self-closing doors, closed windows, screening, air curtains, vinyl or rubber strip curtains, or by other means approved by the Department.

(b) Screens for windows, doors, skylights, transoms, intake and exhaust air ducts, and other openings into the syrup and filling rooms shall be tight-fitting and free of breaks. Screening materials shall not be less than sixteen mesh to the inch.

(c) Openings for conveyor lines into the filling room shall be as small as possible.

(d) Solid doors for the syrup and filling rooms shall be outward opening unless accompanied by self-closing, outward-opening screen doors.

C. SANITARY FACILITIES AND CONTROLS

Each bottling plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:

1. WATER SUPPLY

(a) The water supply shall be from a public water system approved by the Department.

(b) The design, operation and maintenance of water purification systems used to further treat potable water shall be approved by the Department. They shall not be operated beyond their rated capacity and shall be maintained in a clean, sanitary condition at all times. This shall include dispensed water vending machines.

(c) Potable running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of soft drinks and bottled waters, for the cleaning of equipment, utensils, and containers, and for employee sanitary facilities.

(d) Carbonated water shall be conveyed in approved stainless steel or equal food-grade piping and not in piping of galvanized iron, lead, zinc, or other deleterious materials.

(e) All water storage and cooling tanks shall be of noncorrosive material, properly covered, air vents properly filtered, clean, free from dust both inside and outside, and the inlet and outlet so arranged as to prevent contamination during filling and emptying.

D. TRANSPORTATION OF BULK WATER.

1. Bulk water shall be from a public water system approved by the Department.

2. The means and methods of transporting bulk water shall be approved by the Department. Bulk tanks, hoses, pumps and connections used for loading, transporting and unloading water shall be sanitized. Source water for transport shall be treated with an effective disinfectant approved by the Department at an approved concentration prior to being transported.

3. Tank filling and delivery hose connections shall be cleaned and sanitized on a regular basis. The tank shall be sealed at all times except when being filled, being cleaned and sanitized and when the water is being unloaded. A record of such cleaning and sanitizing shall be maintained with the vehicle and shall be available upon request by the Department. Pumps, hoses, connections and fittings shall be capped and protected from contamination when not in use. The tank manhole shall not be used as a means of filling the tank. To prevent collapse of the tank during delivery of bulk water, the manhole may be opened but shall be provided with an air filter to prevent contamination.

4. All surfaces which come into contact with water during storage prior to transport, shall be of smooth, impervious, nonabsorbent, corrosion resistant and nontoxic material such as stainless steel of the American Iron and Steel Institute 300 Series, or equally corrosion resistant, nontoxic material. All water contact surfaces shall be free of substances which may render the water hazardous to health or which may adversely affect the flavor, color, turbidity, odor, radiological, microbiological or chemical quality of the water.

5. Bulk water transport is intended to move source water from one area to another for the purpose of treatment, packaging and human consumption. Such water shall not be dispensed directly to consumers from a bulk water transport tank or indirectly through some other vending device unless otherwise approved by the Department. In case of an emergency, such as a drinking water shortage or outage, or a contaminated water supply, treated water may be dispensed directly from a properly sanitized water transport tank.

E. DISPOSAL OF WASTES.

1. All liquid wastes shall be disposed of by connection to a public sewer or as approved by the Department.

2. Rubbish, refuse, and garbage shall be so handled, stored and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces and water supplies.

F. PLUMBING.

Plumbing shall meet all applicable state and local plumbing laws, ordinances and regulations, and shall be sized, installed and maintained to:

1. Carry sufficient quantities of water to required locations throughout the bottling plant.

2. Properly convey sewage and liquid disposable waste from the bottling plant.

3. Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an unsanitary condition.

4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

5. Prevent backflow or back-siphonage from, or cross-connection between, piping systems discharging wastewater or sewage and piping systems carrying water for soft drink and bottled water manufacturing. This shall include adequate backflow and back-siphonage protection for water lines used to transport detergents, sanitizers, lubricants, etc.

G. TOILET FACILITIES.

1. Toilet facilities shall be approved by the Department, shall be adequate, conveniently located, accessible to employees at all times, and shall conform to applicable building and plumbing codes.

2. Toilet room floors shall be easily cleanable. Toilet room floors should be properly sloped to trapped drains.

3. Toilet room walls and ceilings shall be of sound construction. Toilet room walls shall be smooth and washable to at least a wainscot height.

4. Toilet rooms shall not open directly into the syrup or filling rooms.

5. Toilet room doors shall be self-closing.

6. Toilet rooms shall be adequately ventilated. Toilet room windows opened for ventilation shall be properly screened.

7. Toilet rooms shall be kept clean, in good repair and free of insects at all times.

8. Approved hand-washing signs shall be posted in each toilet room used by production employees.

9. Toilet tissue, soap, individual towels and trash receptacles shall be provided.

H. DRESSING ROOMS AND LOCKER AREAS.

1. If employees routinely change clothes within the bottling plant, rooms or areas shall be designated and used for that purpose and shall be kept clean and in good repair.

2. Adequate lockers or other suitable facilities shall be provided and used for the orderly storage of employee clothing and other belongings and shall be kept clean. Personnel lockers shall not be located in the syrup or filling rooms.

I. HAND-WASHING FACILITIES.

1. An adequate number of lavatories, convenient to toilet rooms and production areas, shall be provided.

2. Each lavatory shall be provided with hot and cold running water, soap and approved sanitary towels, or other approved hand-drying devices. If disposable towels are used, easily cleanable waste receptacles shall be conveniently located near the hand washing facilities.

J. SANITARY OPERATIONS.

1. GENERAL MAINTENANCE

Buildings, fixtures, and other physical facilities of the bottling plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the bottling plant. These materials shall be identified, used only in such manner and under conditions as will be safe for their intended uses, and stored in an approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.

2. ANIMAL AND VERMIN CONTROL

No animals or birds shall be allowed in any area of the bottling plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or

packaging materials with illegal residues. Insecticides and rodenticides shall be properly labeled and stored in a approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.

SECTION VI. EQUIPMENT AND UTENSILS

A. All bottling plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained and kept clean and in good repair. The design, construction and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal and glass fragments, contaminated water, or any other contaminants.

B. All equipment shall be so installed and maintained to facilitate the cleaning of the equipment and all adjacent spaces.

C. All food-contact surfaces shall be corrosion-resistant when in contact with food and shall be made of nontoxic materials and designed to withstand the environment of their intended use and any corrosive action by the food, cleaning compounds and sanitizing agents. Seams on food-contact surfaces shall be smoothly bonded.

D. All equipment shall be designed to prevent food-contact surfaces from being contaminated by clothing or personal contact.

E. Mixing and storage tanks shall be provided with approved tight-fitting covers which shall be kept closed when in use, except when blending is being conducted.

F. All equipment shall be constructed so that drip or condensation from fixtures, ducts, pipes, etc., does not contaminate food, food-contact surfaces or food-packaging materials.

G. All equipment that is in the manufacturing or food-handling areas and that does not come in contact with food shall be so constructed that it can be kept in a clean condition.

H. Approved washable covers shall be provided over exposed containers prior to filling and between filling and sealing in all areas where contamination is reasonable possible.

SECTION VII. PRODUCTION AND PROCESS CONTROLS

A. PROCESS CONTROLS.

1. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of food shall be conducted in accordance with adequate sanitation principles. During delivery of bulk ingredients in tanks, to prevent collapse of the tank, the manhole may be opened, but shall be provided with an air filter to prevent contamination.

2. Appropriate quality control operators should be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the bottling plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.

3. Chemical, microbiological, or extraneous material testing procedures shall be used, where necessary, to identify sanitation failures or possible food contamination. All food that has become adulterated shall be rejected, or if permissible, treated or processed to eliminate the contamination.

4. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into soft drinks and bottled waters and shall be stored under conditions that will protect against contamination and minimize deterioration.

5. Raw materials and other ingredients shall be properly labeled and stored in containers designed and constructed so as to protect against contamination.

6. Raw materials and ingredients shall be kept at such temperature and relative humidity to prevent the food from becoming adulterated.

7. The bottler shall maintain in the plant a current certification or notification of approval from the Department which shall constitute approval of the water source and which shall be available for inspection, and a copy of which shall be made available to consumers upon request.

8. Soft drink and bottled water products shall not be stored, transported, processed or bottled through equipment or lines used for any non-food product.

9. Soft drink and bottled water production, including transporting, processing, packaging, and storage shall be conducted under such conditions and controls as are necessary to minimize the potential for microbiological contamination of the finished product.

10. Bottled water shall be subject to effective germicidal treatment by ozonation or carbonation at a minimum of three volumes of carbon dioxide or other equivalent disinfection approved by the Department.

11. Weekly in-house total coliform monitoring on finished product of each bottled water product type and quarterly rinse/swab tests on bottled water containers (incoming as well as those immediately from the washer) and closures shall be performed in-house or by an approved laboratory as stipulated in 21 CFR Section 129.80. For microbiological contaminants (total coliform), analyze a representative sample from a batch or segment of a continuous production run for each bottled water product type produced by the plant.

12. Samples of source water shall be taken and analyzed by the bottled water plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every four years for radiological contaminants. Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants.

13. For chemical, physical, and radiological contaminants, a representative sample from a batch or segment of continuous production run for each type of finished bottled water product produced by the plant shall be analyzed annually to assure that the product(s) complies with current FDA standards.

14. Bottled water may be used as an ingredient in beverages (e.g. diluted juices, flavored bottled waters).

15. Spring water shall be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified and such identification shall be maintained in the company's records. Spring water collected with the use of an external force shall be from the same underground striation as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is

collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request to the Department, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the borehole.

16. Fluoride may be optionally added to bottled water within the limitations established in 21 CFR Section 165.110. Firms may manufacture nonstandardized bottled water products with ingredients such as minerals for flavor. The common usual name of the resultant product must reflect these additions.

B. CLEANING AND SANITIZING OF EQUIPMENT AND UTENSILS

All utensils and food-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Non food-contact surfaces of equipment used in the operation of bottling plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles and other debris. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and food-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruptions during which such utensils and food-contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the food-contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. All cleaning and sanitizing agents shall be free of undesirable microorganisms, shall be safe and adequate under the conditions of use, shall have labels which properly identify the contents, and shall be properly stored. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment. All cleaned and sanitized equipment and utensils shall be transported and stored to assure complete drainage and stored in a manner that protects the food-contact surfaces from contamination.

C. APPROVED METHODS OF SANITIZATION.

1. Hot water may be used if the cleaned surfaces to be sanitized are in contact with water at a temperature not less than 170ºF. for a period of not less than two minutes. In treating pipelines and fillers, the water issuing from the outlet must be a minimum of 170ºF. for a least two minutes.

2. Chlorine may be used if the cleaned surfaces to be sanitized are in contact with a solution containing not less than fifty parts per million of available chlorine as a hypochlorite and at a temperature of at least 75ºF. for not less than one minute or to an equivalent chlorine concentration/time period process approved by the Department.

3. Other methods of sanitization may be used if approved by the Department.

D. RETURNABLE CONTAINER CLEANING.

1. All returnable containers shall be adequately, mechanically washed and sanitized prior to filling. Unless the containers are sealed after washing, they shall be washed immediately prior to filling. Hand cleaning of containers is prohibited except as a preliminary to subsequent mechanical washing.

2. METAL AND GLASS CONTAINERS

(a) All metal and glass containers shall be exposed to a minimum 3% alkali solution of which not less than 60% is caustic soda (sodium hydroxide) by an approved automatic mechanical method for a period of not less than five minutes at a temperature of not less than 130ºF., or to an equivalent cleaning and sanitizing process approved by the Department.

(b) Containers shall be rinsed of all caustic soda with potable water.

3. POLYCARBONATE CONTAINERS

(a) Polycarbonate containers shall be cleaned with approved non-caustic detergents at their required concentrations by an approved mechanical method.

(b) An approved sanitizing rinse consisting of chlorine, bromine, iodine, quaternary ammonia or ozonated water at the proper approved temperature/time/concentration must follow the cleaning cycle.

4. A permanent record of key operating parameters of the container washer should be maintained. These records or logs should include, but not limited to wash temperatures, concentrations of cleaners, concentrations of sanitizers, lack of carryover of cleaners or caustic in bottles, and maintenance on the washer. Tests on cleaner/sanitizer concentrations and carryover should be carried out at start-up and regularly thereafter throughout the shift. All maintenance on washer should be recorded, such as cleaning or aligning spray jets. All records shall be kept on file at least two years for regulatory inspection. Each washer shall be equipped with an indicating thermometer.

E. SINGLE-SERVICE CONTAINERS.

1. Single-service containers shall be manufactured from food-grade materials that do not impart odors or tastes to the product nor contaminate the product with microorganisms, toxic or injurious substances.

2. Single-service containers shall be packaged and stored in a manner approved by the Department prior to filling.

3. Unless otherwise approved by the Department, all single-service containers shall be inverted and rinsed with potable water, treated by filtered compressed air or vacuumed to remove dust prior to filling.

F. INSPECTION OF RETURNABLE CONTAINERS.

1. BOTTLES

(a) All empty bottles shall be visually inspected immediately after the final rinse of the washing operation for defects, chips, foreign objects, and unclean product contact surfaces as the bottles pass on a conveyor before a well-illuminated background at a speed slow enough for the inspector to achieve high efficiency. Bottles used exclusively for bottled water coolers do not have to pass before a well-illuminated background, but should be visually inspected prior to reuse.

(b) Dirty bottles shall be removed from the production line and either destroyed or rewashed. Defective bottles shall be removed from the production line and destroyed. When inspectors break bottles for cullet, adequate protection shall be provided for exposed bottles in the immediate are to prevent glass fragments from entering them.

(c) Electronic inspection devices can be used in addition to visual inspection; however, electronic inspection devices shall not be substituted for visual inspection of returnable bottles without the approval of the Department. Inspectors shall have good eyesight, with or without corrective lenses, and shall be rotated to noninspection work as often as is necessary to maintain high efficiency.

(d) Returnable bottles shall not be used where their condition or design may prevent proper inspection of the contents thereof.

2. METAL CANISTERS

(a) All metal canisters shall be visually inspected immediately after the final rinse of the washing operation for the presence of foreign objects or unclean product contact surfaces.

(b) Unclean canisters shall be either immediately returned to the washer or removed to the storage area for unclean canisters.

G. CONTAINER CLOSURES.

1. Container closures shall be manufactured from food-grade materials which do not impart odors or tastes to the product nor contaminate the product with microorganisms, toxic or injurious substances.

2. Container closures shall be received by the bottling plant in an undamaged package sealed by the manufacturer.

3. All container closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination. Closures which have been touched on the inner side by the operator, as may occur while adjusting equipment, shall be discarded.

4. Container closures not used during the period of processing operations shall be resealed in their original container or stored in an approved tightly covered container.

5. Only new container closures shall be used.

H. FILLING AND SEALING.

1. Containers shall be filled and sealed with approved mechanical equipment. Manual filling and sealing shall be prohibited, except when otherwise approved by the Department for package sizes in which mechanical sealing equipment is not yet readily available.

2. Filling equipment which fills glass containers under pressure should be provided with an adequate shield to protect against broken glass entering unsealed containers. Whenever a glass bottle breaks while being filled or sealed, the machinery involved shall be stopped and all broken glass shall be removed from parts which touch the opening of bottles or which contact the product. This shall be performed in such a manner to protect against transferring broken glass into nearby bottles which have exposed openings.

3. No person or his clothing shall come in contact with any portion of the container or equipment which might result in contamination of the product.

4. The contents of all imperfectly sealed containers shall be discarded.

I. INGREDIENTS AND LABELING.

1. All soft drinks and bottled waters shall be prepared with approved ingredients that meet all applicable ingredient regulations as defined by the United States Food and Drug Administration.

2. All soft drink and bottled water labeling shall conform to applicable federal and state labeling laws.

SECTION VIII. EXAMINATION AND CONDEMNATION OF UNWHOLESOME OR CONTAMINATED RAW MATERIALS OR FINISHED PRODUCT.

A. Samples of ingredients, drinks, and other substances shall be taken and examined by the Department as often as may be necessary for the detection of unwholesomeness or adulteration.

B. The Department may condemn and forbid the sale of, or cause to be removed and destroyed, any ingredients or products which are unwholesome or adulterated.

SECTION IX. ENFORCEMENT PROCEDURES

A. PERMITS

It shall be unlawful for any person to manufacture soft drinks or bottled waters in South Carolina without a valid permit issued by the Department for the specific bottling plant. Permits are not transferable.

B. ISSUANCE OF PERMITS

1. Any person desiring to manufacture soft drinks or bottled waters in South Carolina shall make written application for a permit on the appropriate application form provided by the Department. This form shall include name and address of bottling plant's owner, location and type of facility and products to be manufactured, applicant's signature and such other information deemed necessary by the Department to determine compliance with this regulation.

2. A permit is valid as long as the bottling plant continues in operation under the same ownership or until the permit is revoked or suspended.

3. Any person whose application for a permit is denied under this regulation may request that a hearing be held as required by law.

C. SUSPENSION OF PERMIT

1. Permits may be suspended temporarily by the Department for repeated violation, for total number of violations, or for interference with the Department in the performance of its duty. Prior to permit suspension, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be suspended and that the permit shall be suspended at the end of the 15 days following service of such notice unless a written request for a hearing is filed with the Department by the permit holder within such 15-day period. If no written request is filed within 15 days, the permit is suspended and bottling operations shall immediately cease. If the hearing upholds the finds of the Department, the permit shall be suspended until the reasons for the suspension have been corrected.

2. The Department may without warning, notice, or hearing suspend the permit to operate a bottling plant when it is determined that the operation of the bottling plant constitutes an imminent hazard to public health. Following immediate permit suspension, all bottling operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended, and that an opportunity for a hearing will be provided if a written request for a hearing is filed with the Department by the permit holder within 15 days. If no written request for a hearing is filed within 15 days, the suspension is sustained. During the hearing process, the permit shall remain suspended unless the imminent health hazard has been corrected.

3. Hearings on suspension of permits as provided for in this regulation shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, Sections 1-23-310 et seq., 1976 Code of Laws of South Carolina as amended, and applicable regulations.

D. REVOCATION OF PERMIT.

1. The permit may be revoked for failure to correct deficiencies within prescribed time limits or for repeated violations of any of the requirements of this regulation, or for the interference with the health authority in the performance of duty.

2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit shall be revoked at the end of the 15 days following service of such notice unless a written request is filed with the Department by the permit holder within such 15-day period.

3. Any person whose permit is revoked shall not be eligible to apply for repermitting within one 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 bottling plants permit for the second time, shall not be granted another permit.

4. Hearings on revocation of permits as provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, SC Code Ann. 1-23-310 et seq. (1976, as amended) and applicable regulations.

E. SERVICE OF NOTICES

A notice provided for in this regulation is properly served when it is delivered to the permit holder, manager or other duly authorized representative, or when it is sent by registered or certified mail, return receipt requested and delivery restricted to the addressee, to the last known address of the bottling plant's permit holder.

F. HEARINGS

All hearings provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, SC Code Ann. 1-23-310 et seq. (1976, as amended) and applicable regulations.

G. INSPECTIONS

Inspections of bottling plants shall be performed as frequently as deemed necessary to insure compliance with this regulation.

H. ACCESS

Representatives of the Department, after proper identification, shall be permitted to enter any bottling plant at any reasonable time for the purpose of making inspections to determine compliance with this regulation. The representatives shall be permitted to examine the records of the establishment to ascertain information relative to the purchasing, receiving, and use of such food products or other supplies used in the manufacturing of soft drinks and bottled waters. It shall be unlawful for any representatives of the Department who, in an official capacity, obtain any information under the provisions of this regulation which is entitled to protection as a trade secret (including information as to quantity, quality, source or disposition of soft drink~~s~~ or bottled water products, or results of inspections or tests thereof) to use such information to their own advantage or to reveal it to any unauthorized person.

I. REPORT OF INSPECTIONS

When an inspection of a bottling plant is conducted, a copy of the completed inspection report form shall be furnished to the permit holder, manager or other duly authorized representative.

J. SUBMISSION OF PLANS

When a bottling plant is constructed or extensively remodeled and when an existing structure is converted for use as a bottling plant, properly prepared plans and specifications for such construction, remodeling, or conversion should be submitted to the Department for review and approval before construction, remodeling, or conversion. The plans and specifications should indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the make and model number of proposed fixed equipment and facilities. The Department shall approve the plans and specifications if they meet the requirements of this regulation. In the absence of plan approval, issuance of the bottling plant permit shall be determined by compliance with all applicable requirements of this regulation.

K. RECIPROCITY

Upon receiving from any person, entity, or any regulatory agency outside this state, a report of a possible violation of this regulation by a permit holder, the Department may conduct such inspection or investigation as it deems appropriate. Upon receiving information that soft drinks or bottled waters manufactured or bottled outside this state and introduced into this state may have been manufactured in violation of applicable state or federal law or not in conformance with prevailing and applicable standards and good public health practices, the Department may notify appropriate regulatory authorities located outside this state and request that such authorities take appropriate action.

L. OUT-OF-STATE IMPORTS

Due to additional FDA laboratory testing requirements for bottled water products, out-of-state water bottlers should submit the following to the Department: (a) a certification signed by the applicable regulatory agency with jurisdiction over the bottling in the state of origin stating that the plant(s) is permitted or licensed as required, the source water supply meets all EPA public drinking water requirements, and is operated and maintained in a sanitary manner based on previous plant inspection(s); (b) the name, address, and phone number(s) of all plant(s) manufacturing bottled products for sale in South Carolina; (c) a copy of the latest finished bottled water product water analyses (total coliform, inorganic, organic, radiological); and (d) the location(s) where the product(s) may be sampled in South Carolina.

M. OUT-OF-COUNTRY IMPORTS

For bottled water products imported from outside the United States, permission should be obtained from the Department prior to initiating the importation of bottled water products into South Carolina. This should include a certification signed by the applicable regulatory agency in the country of origin with jurisdiction over the bottling that (a) describes the requirements of said country for the source, bottling facility, treatment, bottling practices, and finished products; (b) states the date of the last officially authorized inspection by the applicable regulatory agency or acceptable third-party inspection organization and review of said source, facility, treatment, bottling practices, and final products; (c) certifies that said source, facility, treatment, bottling practices, and finished products meet the standards of the country of origin except those that are in conflict with U.S. State and Federal laws and regulations; and (d) where the product(s) may be sampled in South Carolina.

N. RECALL

Each bottling plant operator shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to

any product for which the operator 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 bottling supplier, 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 bottling supplier to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The bottling supplier shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

O. ENFORCEMENT PROVISIONS

This regulation is issued under the authority of South Carolina Code Ann. Section 44-1-140 (1976, as amended) and shall be enforced by the Department.

P. PENALTIES

Violation of this regulation shall be punishable in accordance with South Carolina Code Ann. Section 44-1-150 (1976, as amended).

Fiscal Impact Statement:

The Department estimates there will be no new costs imposed on the State or its political subdivisions by this regulation.

Statement of Need and Reasonableness:

The Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Ann. Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION:

Purpose: These amendments will bring the regulation into compliance with the latest requirements set forth by the United States Food and Drug Administration (FDA) regarding bottled water manufacturing sanitation practices. These latest requirements have already been implemented by the Department under the authority of the FDA; these amendments will incorporate these requirements into South Carolina's regulation. Amendments will also ensure that the regulation complies with the requirements of the South Carolina Administrative Procedures Act, and will strengthen the Department's enforcement capability. The title of this regulation is being changed to clearly identify the regulation as being applicable to bottled water as well as soft drinks.

Legal Authority: The legal authority for R.61-32 is S.C. Code Ann. Section 44-1-140(4) et seq. (1976, as amended).

Plan for Implementation: The amendments will take effect upon approval by the General Assembly and publication in the *State Register*. These latest requirements have already been implemented by the Department under the authority of the FDA. The regulated community will be provided copies of the regulation.

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

The regulation will ensure that consumers are receiving safe, high quality soft drink and bottled water products, and will bring the regulation into compliance with the latest requirements set forth by the United States Food and Drug Administration (FDA) regarding bottled water manufacturing sanitation practices.

DETERMINATION OF COSTS AND BENEFITS: There are no anticipated new costs associated with the implementation of this regulation. There will be a benefit to South Carolina's environment and the health of its citizens by ensuring that consumers are receiving safe, high quality soft drink and bottled water products.

UNCERTAINTIES OF ESTIMATES: None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: The regulation will ensure that consumers are receiving safe, high quality soft drink and bottled water products.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: Not implementing the regulation will cause a decrease in the sanitary standards in soft drink bottling plants and water bottling facilities; this decrease in sanitary standards could have a detrimental effect on the health of South Carolina's citizens and visitors.

Statement of Rationale Pursuant to S.C. Code Section 1-23-120:

The determination to revise this regulation was in response to changes in requirements set forth by the United States Food and Drug Administration (FDA) regarding bottled water manufacturing sanitation practices.

Document No. 2859
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: S.C. Code Ann. § 44-7-265 (1976, as amended)

R.61-108, *Standards For Licensing Freestanding or Mobile Technology*.

Synopsis:

The S.C. Code Of Laws (Section 44-7-265) establishes requirements for the promulgation of regulations for freestanding or mobile technology that will include at a minimum: 1) standards for the maintenance and operation of freestanding or mobile technology to ensure the safe and effective treatment of persons served; 2) a description of the professional qualifications necessary for personnel to operate the equipment and interpret the test results; 3) minimum staffing requirements to ensure the safe operation of the equipment and interpret the test results; and 4) that all freestanding or mobile technology must be in conformance with professional organizational standards. Promulgation of this regulation satisfies a legislative mandate requiring the Department to develop regulations to set standards for the licensing and inspection of freestanding or mobile technology. See Discussion below and Statements of Need and Reasonableness and Rationale herein.

Discussion of New Regulation

SECTION 100 includes definitions, references, and licensing requirements. Section 103 addresses licensing fees.

SECTION 200 addresses methods used in enforcing regulations, i.e., investigations, inspections, and consultations.

SECTION 300 references the types of enforcement actions that may be taken by the Department, the classifications of violations, range of penalty amounts, and the appeal process.

SECTION 400 includes requirements that the agency maintain policies and procedures that include descriptions of how the standards in this regulation will be achieved.

SECTION 500 addresses general staff requirements including staff training, qualifications, and numbers to comply with applicable federal, state, and local laws and in accordance with professional organizational standards; on-site manager, medical director, medical staff, staff health status.

SECTION 600 provides reporting requirements to the Department.

SECTION 700 addresses patient record content and maintenance.

SECTION 800 provides requirements for care, treatment, procedures, and services to patients.

SECTION 900 includes patient rights and assurances.

SECTION 1000 addresses medication management.

SECTION 1100 addresses emergency procedures/disaster preparedness.

SECTION 1200 includes fire prevention, i.e., arrangements for fire department response/protection, tests and inspections, fire response training, and fire drills.

SECTION 1300 addresses equipment maintenance.

SECTION 1400 addresses infection control including staff practices which promote the prevention of the spread of infectious, contagious disease, vaccinations, sterilization procedures, and tuberculin skin testing, per Centers for Disease Control and Prevention (CDC) and the Department's TB Control requirements, the handling of infectious waste, housekeeping, and clean/soiled linen.

SECTION 1500 addresses the quality improvement program.

SECTION 1600 addresses design and construction.

SECTION 1700 addresses fire protection equipment and systems.

SECTION 1800 addresses mobile units.

SECTION 1900 includes a severability clause that indicates that if a court of competent jurisdiction determines that part of the regulation is invalid or otherwise unenforceable then the remainder of the regulation will not be affected and will still be in force.

SECTION 2000 includes "general" that refers to any conditions that have not been addressed in the regulation.

Instructions:

Add R.61-108 to Chapter 61 regulations.

Text:

R.61-108 - STANDARDS FOR LICENSING FREESTANDING OR MOBILE TECHNOLOGY

CONTENTS:

SECTION 100 - DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions

For the purpose of these standards, the following definitions shall apply:

A. Administering Medication. The direct application of a single dose of a medication to the body of a patient by injection, ingestion, or any other means.

B. Advanced Practice Registered Nurse. An individual who has official recognition to practice as an advanced practice registered nurse by the S.C. State Board of Nursing.

C. Anesthesiologist. A physician who has completed a residency in anesthesiology.

D. Anesthesiologist's Assistant. An individual currently authorized as such by the S.C. Board of Medical Examiners.

E. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious (moderate) or deep sedation.

F. Cardiac Catheterization. The passage of a small catheter, usually through a blood vessel into chambers of the heart, under roentgenologic control, permitting the securing of blood samples, determination of intracardiac pressure, and detection of cardiac anomalies.

G. Certified Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a certified registered nurse anesthetist by the S.C. State Board of Nursing.

H. Computerized Tomography (CT). The recording of internal body images in which an emergent X-ray beam is measured by a scintillation counter. The electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube.

I. Conduction Anesthesia. The administration of anesthetic agents to interrupt nerve impulses without loss of consciousness. Major conduction blocks include regional nerve blocks (epidural, caudal, and spinal anesthesia). Minor conduction blocks include local infiltration, local nerve blocks, and nerve blocks by direct pressure and refrigeration.

J. Conscious (Moderate) Sedation. The administration of drugs to obtund or reduce the intensity of pain and awareness without the loss of defensive reflexes.

K. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the S.C. Controlled Substances Act.

L. Consultation. A visit by individuals authorized by the Department to provide information to the licensee to enable better compliance with these regulations.

M. Department. The S.C. Department of Health and Environmental Control (DHEC).

N. Direct Care Staff Member. An individual who provides care, treatment, and/or services or performs procedures for a patient.

O. Existing Equipment. Equipment that was in operation prior to the promulgation of this regulation. The licensing standards governing new equipment apply if and when existing equipment is not continuously operated and licensed under this regulation.

P. Freestanding or Mobile Technology. Medical equipment which is to be used for diagnosis or treatment and is owned or operated by a person, other than a health care facility (as defined in S.C. Code Ann. § 44-7-130 (1976, as amended)), for which the total cost is in excess of that prescribed by R.61-15 and for which specific standards or criteria are prescribed in the State Health Plan.

Q. Gamma Knife. Stereotactic radiosurgery by which intracranial lesions are treated with high dose, high energy photons, i.e., a non-invasive procedure utilizing narrow bands of radiant energy that are directed at a treatment target in the head.

R. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, physician's assistant, or advanced practice registered nurse or by a registered nurse, pursuant to standing orders approved by a physician, as evidenced by the physician's signature in accordance with facility policy.

S. Host/Host Hospital. An acute care facility or other entity that leases or otherwise arranges for the provision of services of a mobile technology unit.

T. Ionized Radiation. Radiation that causes a neutral atom or molecule to acquire a positive or negative charge.

U. Inspection. A visit by an authorized individual(s) for the purpose of determining compliance with this regulation.

V. Investigation. A visit by an authorized individual(s) for the purpose of determining the validity of allegations received by the Department relating to this regulation.

W. Initial License. A license granted for new equipment.

X. Legally Authorized Health Care Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures, and/or services to patients. Examples of individuals who may be authorized by law to provide specific medical care, treatment, procedures, and/or services within the lawful scope of practice may include, but are not limited to, advanced practice registered nurses, radiological technicians, and physician's assistants.

Y. Legend Drug.

1. A drug required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only."

2. A drug required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only;

3. Any drug products designated by the S.C. Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

Z. License. A certificate issued by the Department to freestanding or mobile technology that authorizes equipment operation subject to the provisions of this regulation.

AA. Licensed Nurse. An individual authorized by the S.C. State Board of Nursing to practice as a registered nurse or licensed practical nurse.

BB. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, and/or services and with whom rests the ultimate responsibility for compliance with this regulation.

CC. Magnetic Resonance Imaging (MRI). A diagnostic procedure used to create cross-sectional images of the body by the use of magnetic fields and radio frequency fields. It can also show certain biochemical activity and is non-invasive.

DD. Monitoring. The observation of a patient using instruments to measure, display, and/or record (continuously or intermittently) the values of certain physiologic variables such as pulse, blood pressure, oxygen saturation, and respiration.

EE. New Equipment. Equipment that is:

1. Being licensed for the first time;

2. Providing a different service that requires a change in the type of license;

3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered the license and the equipment has not been continuously operated.

FF. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this State and the federal government.

GG. On-Site Manager. The individual designated by the licensee to have the authority and responsibility to manage/operate the equipment. This person, or an individual designated to act in his/her absence, is the main contact with Department personnel.

HH. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

II. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

JJ. Physician's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

KK. Positron Emission Tomography (PET). A procedure that allows the study of metabolic processes, such as oxygen consumption and utilization of glucose and fatty acids, by capturing images of cellular activity or metabolism by tracking the movement of radioactive tracers throughout the body.

LL. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

MM. Quality Improvement Program. The process used to examine methods and practices of providing care, treatment, procedures, and/or services, identify the ways to improve performance, and take actions that result in higher quality of care, treatment, procedures, and/or services for patients.

NN. Radiation Therapist. A person, other than an individual licensed to practice within the lawful scope of practice of medicine in this State, who applies radiation to humans for therapeutic purposes.

OO. Radiation Therapy. The use of a stream of high-energy particles or waves such as X-rays, gamma rays, and alpha and beta particles to destroy or damage cancer cells.

PP. Radiographer. A person, other than an individual licensed to practice, medicine, dentistry, podiatry, chiropractic, or osteopathy in this State, who applies radiation to humans for diagnostic purposes, including, but not limited to, mammography, cardiovascular-interventional technology, and computed tomography.

QQ. Radiologic Technologist. A person who is a limited practice radiographer, radiographer, podiatric limited practice radiographer, limited chest radiographer, radiation therapist, or nuclear medicine technologist certified by the American Registry of Radiologic Technologists or who is certified by the S.C. Radiation Quality Standards Association (SCRQSA) or who has obtained a certificate acceptable to the SCRQSA.

RR. Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a registered nurse anesthetist by the S.C. State Board of Nursing.

SS. Repeat Violation. The recurrence of any violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

TT. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator or person with a health care power of attorney or other durable power of attorney.

UU. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

VV. Staff Member. An individual who is 18 years or older and is a compensated employee on either a full or part-time basis.

WW. Suspension of License. An action by the Department requiring a licensee to cease operation for a period of time until such time as the Department rescinds that restriction.

XX. Vendor. A person who owns and/or operates mobile technology and contracts with acute care hospitals or other hosts for the purpose of providing diagnostic or therapeutic services.

YY. Volunteer. An individual who performs tasks at the direction of the on-site manager or his or her designee without compensation.

102. References

The following publications/standards are referenced in this regulation:

A. Departmental:

1. R.61-4, *Controlled Substances*;

2. R.61-15, *Certification of Need for Health Facilities and Services*;

3. R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*;

4. R.61-20, *Communicable Diseases*;

5. R.61-63, *Radioactive Materials*;

6. R.61-64, *X-Rays, (Title B)*;

7. R.61-105, *Infectious Waste Management*;

8. *Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*;

9. Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities;

10. South Carolina Health Plan.

B. Non-Departmental:

1. Bloodborne Pathogens Standards, Occupational Safety and Health Act (OSHA) of 1970;

2. Centers for Disease Control and Prevention (CDC);

3. *Health Insurance Portability and Accountability Act of 1996 (HIPAA);*

4. National Fire Protection Association (NFPA);

5. Environmental Protection Agency (EPA);

6. Federal Food and Drug Administration (FDA).

103. License Requirements (II)

A. Compliance. An initial license shall not be issued to an owner/operator who has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed equipment is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity/freestanding or mobile technology licensed by the Department makes application for another facility/activity/freestanding or mobile technology or increase in licensed capacity of a facility, the currently licensed facility/activity/freestanding or mobile technology shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility/activity/freestanding or mobile technology.

B. A copy of the licensing standards shall be maintained by the licensee and accessible to all staff members.

C. No licensee who has been issued a license for a particular type of equipment shall establish new care, treatment, procedures, and/or services without first obtaining authorization from the Department. (I)

D. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place near the licensed equipment.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety or the well-being of any patient.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. Equipment that is licensed pursuant to this regulation and is acquired by a licensed health care facility through purchase, contract, lease, or assuming/obtaining possession, shall be included as a part of the health care facility's license, and the original equipment license shall become null and void.

5. A license shall be effective for specified equipment at a specific location(s) for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

6. Equipment owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, e.g., interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

7. Multiple types of equipment on the same premises may be licensed separately even though owned by the same entity.

E. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant's oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be

signed by the owner(s) of the equipment if an individual or partnership; in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the type of equipment, including the year, model of equipment, all equipment upgrades, location of the equipment for which the license is sought and of the owner in the event his or her address is different from that of the location of the equipment, and the names of the persons in control of the equipment. A copy of the nonapplicability, exemption, or Certificate of Need shall be included as part of the initial application. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or limited partnerships shall be registered with the S.C. Office of the Secretary of State.

F. Licensing Fees. The initial and annual license fee shall be $600.00. Such fees shall be made payable by check or money order to the Department and are not refundable. The Department may charge an additional amount, if necessary, to cover the cost of inspection or investigation.

G. Late Fee. Failure to submit a renewal application or fee after the license expiration date may result in a late fee of 25% of the licensing fee amount, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action.

H. License Renewal. To renew a license an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure period.

I. Registered Equipment. Licensees utilizing equipment that is required to be registered by the Department's Bureau of Radiological Health shall not be licensed until such equipment is properly registered.

J. Change of License.

1. A licensee shall request issuance of a new or amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership of equipment;

b. Change of types of equipment as shown on the license;

c. Change of equipment location from one geographic site to another.

2. Changes in address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

3. Replacement of equipment shall be accomplished by letter from the licensee.

K. A freestanding or mobile technology license shall not be required for, nor shall such a license be issued to, equipment operated by the federal government.

L. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised and provided the standard is not specifically required by statute.

SECTION 200 - ENFORCING REGULATIONS

201. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation in order to enforce this regulation.

202. Inspections/Investigations

A. An inspection shall be conducted prior to initial licensing of equipment and subsequent inspections conducted as deemed appropriate by the Department. Regulatory related accreditations may be considered in determining the appropriateness of Department inspections.

B. All equipment and those areas of the location that impact treatment/procedures provided by the equipment are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records that are pertinent to the operation of equipment and have the authority to require the licensee to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations, and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (II)

D. A licensee found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the on-site manager and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar);

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by S.C. Code Ann. §§ 44-7-310 and -315 (1976, as amended).

203. Consultations

Consultations may be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 300 - ENFORCEMENT ACTIONS

301. General

When the Department determines that a licensee is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such equipment, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, or revoke its license.

302. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the patients for whom the equipment is used or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of patients for whom equipment is used. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations "(I)" or "(II)", placed within sections of this regulation indicate that those standards are considered Class I or II violations if they are not met. Failure to meet standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the licensee to correct cited violations; behavior of the licensee that reflects negatively on the licensee's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the Department may invoke S.C. Code Ann. § 44-7-320(C) (1976, as amended), to determine the dollar amount or may utilize the following schedule:

Frequency of violation of standard within a 36-month period:

MONETARY PENALTY ACTIONS

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500 - 1,500	$ 300 - 800	$100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	7,500	5,000	2,000 - 5,000
6th and more	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed pursuant to the Administrative Procedures Act, S.C. Code Ann. § 1-23-310 (1976, as amended).

SECTION 400 - POLICIES AND PROCEDURES

401. General (II)

Policies and procedures addressing each section of this regulation regarding care, treatment, procedures, and/or services, rights, and the operation of the equipment shall be developed and implemented, and revised as required in order to accurately reflect actual operation. The licensee shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible at all times, either by hard copy or electronically.

SECTION 500 - STAFF

501. General (II)

A. Appropriate staffing in sufficient numbers and training shall be provided to operate equipment in a manner that shall safely and effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise. Such staffing numbers and training shall:

1. Meet the recommendations of the equipment manufacturers;

2. Adhere to current professional organizational standards;

3. Comply with all local, state, and federal laws.

B. Additional staff members shall be provided if it is determined by the Department that the staff on duty is inadequate to effectively and safely operate the equipment.

C. All staff members operating and/or maintaining equipment shall be assigned duties and responsibilities in accordance with the individual's capability. Such duties shall be in writing and be reviewed on an annual basis by the staff member and supervisor.

D. There shall be accurate current information maintained regarding all staff members who operate and/or maintain equipment to include at least an address, phone number, and health and personal/work/ training background. For those staff members who are licensed/certified, a copy of the license/certificate shall be available for review.

E. Staff members who operate and/or maintain equipment shall not have a prior conviction or have pled no contest (nolo contendere) within the last 10 years for child or adult abuse, neglect, exploitation, or mistreatment, or for sexual assault or assault with a deadly weapon. The licensee may take certain considerations into account regarding criminal records when making hiring decisions, i.e., discretion may be exercised regarding convictions/nolo contendere pleas occurring more than 10 years ago and may determine that an applicant, who would otherwise be disqualified, could be hired. (I)

502. On-Site Manager (II)

A. Licensees shall have an on-site manager who shall be capable of meeting the responsibilities of operating and/or maintaining the equipment to ensure that it is in compliance with these regulations and shall demonstrate adequate knowledge of these regulations

B. A staff member shall be designated by name or position, in writing, to act in the absence of the on-site manager.

C. Mobile units shall maintain a list of individuals approved by the licensee to be the on-site manager(s) on a day-to-day basis.

503. Medical Director (II)

A. There shall be a medical director who shall be a physician who is responsible for the quality of medical equipment services provided to patients.

B. The on-site manager and medical director may be the same person.

504. Medical Staff (I)

A. Physicians and other legally authorized health care providers performing treatment/procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such treatment/procedures.

B. Privileges for each medical staff member to perform treatment/procedures and anesthesia shall be in accordance with criteria that the medical staff has established and approved.

C. There shall be a roster of medical staff having treatment/procedures and anesthesia privileges, specifying the privileges and limitations of each and a current listing of all types of treatment/procedures offered.

505. Qualifications (I)

A. Those persons who practice within the lawful scope of their practice utilizing ionizing radiation such as cardiac catheterization (fluoroscopy) shall be appropriately qualified in accordance with R.61-63 and R.61-64.

B. Those individuals providing the following services shall have the following qualifications:

1. Magnetic Resonance Imaging (MRI).

a. Physicians responsible for reviewing all indications for examinations, specifying the use and dosage of contrast agents, etc. shall be certified in radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada with documented evidence of MRI training and meet the guidelines of the American College of Radiology Standard for Continuing Medical Education.

b. Individuals conducting MRI's shall be licensed nurses or Radiologic Technologists with documented evidence of appropriate MRI training.

2. Cardiac Catheterization.

a. Any physician performing cardiac catheterization shall have:

(1) Board certification in internal medicine and the subspecialty of cardiovascular disease or be board-eligible in the subspecialty of cardiovascular disease and be examined for certification within two years of initial eligibility;

(2) Completed current training in cardiac catheterization;

(3) Met the experience requirements of the American Board of Internal Medicine.

b. All direct care personnel in the cardiac catheterization laboratory shall be certified in basic cardiac life support (BCLS), with at least one staff member/volunteer with a current certification in Advanced Cardiac Life Support (ACLS) whenever patients are present.

3. Anesthesia Services (If Provided)

a. Anesthesia shall be administered only by:

(1) An anesthesiologist;

(2) A physician, other than an anesthesiologist, or dentist or podiatrist who is qualified to administer anesthesia pursuant to the S.C. Code of Laws;

(3) A certified registered nurse anesthetist;

(4) A registered nurse anesthetist;

(5) An anesthesiologist's assistant.

506. Inservice Training (II)

A. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, and/or services delineated in Sections 501.A and 800.

B. The following training shall be provided by appropriate resources, e.g., licensed or registered persons, video tapes, books, etc., to all staff members as appropriate to their job duties and responsibilities prior to patient contact and at a frequency determined by the policies and procedures but at least annually:

1. Cause, effect, transmission, prevention, and elimination of infections, to include standard precautions, management and care of persons with contagious and/or communicable disease, e.g., hepatitis, tuberculosis, HIV infection;

2. OSHA standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within 24 hours of the employee's first day on the job (see Section 1100);

5. Fire response training within 24 hours of the employee's first day on the job (see Section 1203);

6. Aseptic techniques, such as handwashing, disinfecting, the handling and storage of equipment and supplies, and, if applicable, scrubbing practices, proper gowning and masking, dressing care techniques, and sterilizing techniques.

C. A staff member with a valid cardio-pulmonary resuscitation certification shall be on duty whenever patients are present.

D. All newly hired staff members shall receive orientation regarding the organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

507. Health Status (I)

A. All staff members who have contact with patients shall have, within 12 months prior to initial patient contact, a health assessment as defined in Section 101.R.

B. The health assessment shall include tuberculin screening as described in Section 1404.

C. If a staff member is working at multiple locations operated by the same licensee, copies of records for tuberculin screening and the pre-employment health assessment shall be acceptable at each location. (II)

SECTION 600 - REPORTING

601. Incidents/Accidents (II)

A. A record of each incident and/or accident occurring in the equipment location area involving patients or staff members shall be retained.

1. Serious incidents/accidents and/or medical conditions as defined below and any illness resulting in death or inpatient hospitalization shall be reported via telephone to the next-of-kin or responsible party immediately and in writing to the Department's Division of Health Licensing within 10 days of the occurrence.

2. Serious medical conditions shall be considered as, but not limited to: major permanent loss of function, hemolytic transfusion reaction involving administration of blood or blood products, a procedure on the wrong patient or wrong body part, fractures of major limbs or joints, severe burns, lacerations, or hematomas, and actual or suspected abuse or mistreatment of patients.

B. Reports made to the Division of Health Licensing shall contain at a minimum: facility name, patient age and sex, date of incident/accident, location, extent/type of injury, and means of treatment, e.g., hospitalization.

C. Significant medication errors and significant adverse medication reactions that require intervention shall be reported immediately to the patient or next-of-kin or responsible party, prescriber, supervising staff member, and administrator. Significant medication errors and significant adverse medication reactions include events that are unintended and undesirable, as well as unexpected effects of prescribed medications or of medication errors that:

1. Require discontinuing a medication or modifying the dose;

2. Require hospitalization;

3. Result in disability;

4. Require treatment with a prescription medication;

5. Result in cognitive deterioration or impairment;

6. Are life-threatening;

7. Result in death.

D. Changes in the patient's condition, to the extent that serious health concerns are evident, e.g., heart attack, shall be reported immediately to the attending physician, the next-of-kin or responsible party, and the on-site manager. (I)

602. Fire/Disasters (II)

The Department's Office of Fire and Life Safety and the Division of Health Licensing shall be notified immediately via telephone or facsimile regarding any fire occurring at the equipment location and followed by a complete written report to include fire department reports, if any, submitted within a time period determined by the policies and procedures, but not to exceed 10 days from the occurrence of the fire.

603. Communicable Diseases (I)

All cases of diseases that are required to be reported to the appropriate county health department shall be reported in accordance with R.61-20.

604. On-site Manager Change

The Department's Division of Health Licensing shall be notified in writing by the licensee of freestanding technology within 10 days of any change in on-site manager. The notice shall include at a minimum the name of the newly appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

605. Joint Annual Report

Licensees, if required by the Department's Planning and Certificate of Need Division to submit a "Joint Annual Report," shall complete and return this report within the time period specified by that Division.

606. Accounting of Controlled Substances and Devices (I)

In accordance with R.61-4, any licensee whose licensed equipment is housed in a facility registered with the Department's Bureau of Drug Control shall report any theft or significant loss of controlled substances to the Bureau of Drug Control upon discovery of the loss/theft. Pursuant to S.C. Code Ann. § 40-43-91 (1976, as amended), any licensee whose licensed equipment is housed in a facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of controlled substances or devices within thirty working days of the discovery of the loss/theft to the S.C. Board of Pharmacy.

607. Equipment Change

The Department's Division of Health Licensing shall be notified in writing by the licensee within 10 days of any change, upgrade and/or replacement of licensed equipment.

608. Equipment Location Closure

A. Prior to the permanent closure of a business where equipment is licensed, the Department's Division of Health Licensing shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the Division of Health Licensing shall be notified of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Division of Health Licensing.

B. When a business where equipment is licensed temporarily closes, the Division of Health Licensing shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but is not limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current standards to the equipment prior to its usage. If the location is closed for a period longer than one year, and there is a desire to re-open, the licensee shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application.

SECTION 700 - PATIENT RECORDS

701. Content (II)

A. An organized record shall be initiated and maintained for each patient. The record shall contain: sufficient documented information to identify the patient; the person responsible for each patient; the description of the diagnosis and the care, treatment, procedures, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, and/or services provided. All entries shall be indelibly written, signed by the author, and dated.

B. Specific entries/documentation shall include at a minimum:

1. Consultations by physicians or other legally authorized health care providers;

2. Orders and recommendations for all care, treatment, procedures, and/or services from physicians or other legally authorized health care providers, completed prior to, or at the time of patient arrival, and subsequently, as warranted;

3. Care, treatment, procedures, and/or services provided;

4. Record of administration of each dose of medication and procedures followed if an error is made;

5. Special procedures and preventive measures performed, e.g., isolation for symptoms of tuberculosis;

6. Notes of observation during recovery, to include vital signs pre- and post-treatment/procedure;

7. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining post-treatment/procedure emergency care;

8. Special information, e.g., allergies, etc.

9. Signed informed consent for treatment as required by HIPAA and, if applicable, consent for participation in research;

10. If applicable, anesthesia records of pertinent pre-treatment/procedure reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note.

11. Treatment/procedure report (dictated or written into the record immediately after treatment/ procedure) to include at least:

a. Description of findings;

b. Techniques utilized to perform treatment/procedure;

c. Specimens removed, if applicable;

d. Primary physician and assistants.

12. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated.

C. Except as required by law, patient records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, e.g., interpretations of imaging technology and video tapes without the medium itself.

702. Record Maintenance

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary, to include, at a minimum, the diagnosis, care, treatment, procedures, and/or services provided, and medication administration record, shall accompany the patient to the receiving facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The licensee shall have a written policy designating the persons allowed to access confidential patient information. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's responsible party. (II)

D. Records generated by organizations or individuals with whom the licensee contracts for care, treatment, procedures, and/or services shall be maintained at the equipment location. Appropriate information shall be provided to assure continuity of care.

E. The licensee shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of an equipment location for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department's Division of Health Licensing, in writing, describing these arrangements and the location of the records.

G. Records of patients shall be retained for at least six years following the discharge of the patient. Records of minors shall be retained until after the expiration of the period of election following achievement of majority as prescribed by statute. Other documents required by this regulation, e.g., fire drills, shall be retained at least 12 months or until the next Division of Health Licensing inspection.

H. Patient records are the property of the licensee; the original record shall not be removed without court order. (II)

SECTION 800 - CARE/TREATMENT/PROCEDURES/SERVICES

801. General (I)

A. Care, treatment, procedures, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized health care providers, and precautions shall be taken for patients with special conditions, e.g., pacemakers, pregnancy, Alzheimer's disease, etc., and/or for those who may be susceptible to deleterious effects as a result of the treatment.

B. If a patient or potential patient has a communicable disease, a physician or other legally authorized health care provider shall insure that adequate care can be provided to prevent the spread of the disease and that the staff

members are adequately trained and qualified to manage the patient, or transfer the patient to an appropriate facility, if necessary.

C. When the licensee engages a source to provide services normally provided by the staff, e.g., staffing, training, equipment maintenance, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, procedures, and/or services, confidentiality, and rights. (II)

D. The licensee shall comply with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, and/or services, and protection.

E. A current listing of all types of treatment and procedures offered shall be available. A chronological record of all treatment and procedures performed shall be maintained that shall include patient identification, pre-treatment/procedure diagnosis, type of treatment/procedure performed, type of anesthesia utilized (if applicable), and any unusual occurrence.

802. Anesthesia Services (If Provided) (I)

A. Anesthesia shall be administered only by those individuals indicated in Section 505.B.3.a.

B. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative/procedure supervision by the nursing staff who shall then attend the patient until he or she has regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

803. Licensees Utilizing Ionizing Radiation (II)

All equipment where ionizing radiation is utilized shall be in compliance with those professional organizational standards specified in R.61-63 and R.61-64.

804. Laboratory Services (II)

A. Laboratory services required in connection with the treatment/procedure to be performed shall be provided or arrangements made to obtain such services.

B. Should tests be conducted that involve human specimens by utilizing any laboratory equipment such as finger-stick glucose, hemoglobin, monitoring devices, etc., for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of health, a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program shall be obtained through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

D. A pathologist shall examine all tissue specimens except for those types of specimens that the medical staff has determined and documented do not require examination.

805. Adverse Conditions (I)

Should a patient experience any adverse condition or complication during or after the performance of the treatment/procedure, he or she shall remain at the equipment location until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care beyond the capability of the equipment or staff shall be transferred to an appropriate facility.

806. Patient Instruction (If applicable) (I)

Written instructions shall be issued to all patients upon discharge and shall include at a minimum the following:

A. Signs and symptoms of possible complications;

B. Telephone number at the location of the equipment or the attending physician or other knowledgeable professional staff member, should any complication occur or questions arise;

C. An emergency telephone number should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care;

D. Limitations regarding activities, foods, etc.;

E. Date for follow-up or return visit, if applicable.

SECTION 900 - RIGHTS AND ASSURANCES

901. General (II)

A. The licensee shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, and/or services, patient rights and protections, discrimination, and privacy and disclosure requirements, e.g., S.C. Code Ann. § 44-81-10 (1976, as amended).

B. The licensee shall develop and post in a conspicuous place in a public area a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department's Division of Health Licensing and a provision prohibiting retaliation should the grievance right be exercised.

C. Care, treatment, procedures, and/or services provided, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

D. Patients shall be permitted to use a telephone and allowed privacy when making calls.

E. Adequate safeguards shall be provided for protection and storage of patients' personal belongings.

F. Patient rights shall be guaranteed, prominently displayed, and, the patient shall be informed of these rights, to include, at a minimum:

1. The care, treatment, procedures, and/or services to be provided;

2. Informed consent for care, treatment, procedures, and/or services;

3. Respect for the patient's property;

4. Freedom from mental and physical abuse and exploitation;

5. Privacy while being treated and while receiving care;

6. Respect and dignity in receiving care, treatment, procedures, and/or services;

7. Refusal of treatment. The patient shall be informed of the consequences of refusal of the treatment/procedure, and the reason shall be reported to the physician and documented in the patient record;

8. Refusal of experimental treatment and drugs;

9. Confidentiality and privacy of records.

G. Except in emergencies, documentation regarding informed consent shall be properly executed prior to the treatment/procedure.

SECTION 1000 - MEDICATION MANAGEMENT

1001. General (I)

A. Medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations, to include the securing, storing, and administering of medications, medical supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. Non-legend medications may be retained and labeled as stock for administration as ordered by a physician or other legally authorized health care provider.

C. If controlled substances are to be used, a controlled substances registration from the Department's Bureau of Drug Control and a controlled substance registration from the Federal Drug Enforcement Administration (DEA) shall be obtained. The registration(s) shall be displayed in a conspicuous location.

D. Upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit or cart of lifesaving medicines and equipment shall be maintained for the use of physicians or other legally authorized health care providers in treating the emergency needs of patients.

1. The kit/cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The emergency medication kit/cart shall display the following information:

a. "For Emergency Use Only";

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit/cart is opened, it shall be restocked and resealed within a reasonable time to prevent risk of harm to a patient.

4. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained for a period of two years or until the Department's Division of Health Licensing's next inspection, whichever is longer.

E. Medications shall not be expired.

F. Applicable reference materials published within the previous year shall be available in order to provide staff members with adequate information concerning medications.

1002. Medication Orders (I)

A. Medications, to include oxygen, shall be administered to patients only upon orders of a physician or other legally authorized health care provider.

B. All orders (including verbal) shall be received only by licensed nurses or other legally authorized health care providers and shall be authenticated and dated by a physician or other legally authorized health care provider pursuant to policies and procedures, but no later than 72 hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other legally authorized health care provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

1003. Administering Medication (I)

Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided identification of the individual's initials is located within the record.

1004. Pharmacy Services (I)

Licensees that maintain stocks of legend medications and biologicals for patient use shall obtain and maintain a valid, current, applicable pharmacy permit, displayed in a conspicuous location, from the S.C. Board of Pharmacy and have a consultant pharmacist on-call during operating hours.

1005. Medication Containers (I)

Medications for each patient shall be dispensed from their original container(s), including unit dose systems. There shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration except by direction of a physician or other legally authorized health care provider.

1006. Medication Storage (I)

A. Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage and shall be locked when not under direct observation by a licensed health care provider. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

C. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U.S. Pharmacopeia (36 - 46 degrees F.). Food and drinks and laboratory specimens shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

D. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications;

3. Separately from food.

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department's Division of Health Licensing.

1007. Disposition of Medications (I)

A. Medications shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When noncontrolled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the name of the individual performing the destruction and a witness. The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4.

B. Destruction records shall be retained by the facility for at least two years or until the Department's Division of Health Licensing's next inspection.

SECTION 1100 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1101. Emergency Services (I)

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital.

B. The licensee shall make arrangements for obtaining blood and blood products to meet emergency situations.

1102. Disaster Preparedness (II)

The licensee shall establish plans, based on equipment and staff capabilities, to meet its responsibilities for providing emergency care.

1103. Emergency Call Numbers (I)

Although the equipment may be in a location that has access to "911," emergency call data shall be immediately available and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance

service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

SECTION 1200 - FIRE PREVENTION

1201. Arrangements for Fire Department Response/Protection (I)

A. Each licensee shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, i.e., fire plan and evacuation plan.

B. When equipment is located outside a service area or range of a public fire department, the licensee shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department.

1202. Tests and Inspections (I)

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. Fire alarm systems shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

1203. Fire Response Training (I)

A. Each staff member shall receive training within 24 hours of his or her first day on the job and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;

2. Reporting a fire;

3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;

5. Methods of fire containment;

6. Specific responsibilities, tasks, or duties of each staff member.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures in case of fire or other emergencies, shall be established and posted in conspicuous public areas.

1204. Fire Drills (I)

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained, indicating the date, time, shift, description, and evaluation of the drill and the names of staff members directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, the provisions of the statute or regulation shall be complied with and shall supersede the requirements of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1203 above.

SECTION 1300 - EQUIPMENT MAINTENANCE

1301. General (II)

Equipment utilized for providing treatment/procedures, including its component parts, shall be properly maintained to perform the functions for which it is designed.

1302. Equipment (II)

A. Equipment used in the provision of care, treatment, procedures, and/or services shall meet appropriate specifications and calibrations and shall be monitored and operated in accordance with the manufacturer's guidelines and with local, state, and federal laws. Records shall be maintained to indicate all testing and maintenance.

B. If equipment for the administration of anesthesia is utilized, it shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit audible and visual alarms should the proportion of oxygen fall below a safe level. (I)

2. A record of the inspections made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department's Division of Health Licensing inspection.

1303. Preventive Maintenance of Life Support Equipment (II)

A. A written preventive maintenance program shall be developed and implemented for all life support equipment, to include, but not be limited to:

1. Patient monitoring equipment;

2. Isolated electrical systems;

3. Patient ground systems;

4. Medical gas systems.

B. This equipment shall be calibrated, if applicable, and/or tested at periodic intervals, but not less than annually, to insure proper operation. After repairs and/or alterations are made to any equipment or system, thorough testing for proper operation shall be accomplished prior to returning it to service. (I)

C. Records shall be maintained on all life support equipment to indicate its history of testing and maintenance.

SECTION 1400 - INFECTION CONTROL AND ENVIRONMENT

1401. Staff Practices (I)

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) *Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee*; the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61-105; and other applicable federal, state, and local laws and regulations.

1402. Vaccinations (I)

A. Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case the decision shall be documented.

2. Each staff member who elects vaccination shall have completed the initial dose of the three-dose series within 30 days of employment.

B. Influenza. All direct care staff shall have an annual influenza vaccination unless contraindicated or offered and declined. In either case the decision shall be documented.

C. MMR and Varicella. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered and declined. In either case the decision shall be documented. Immunity to mumps is recommended.

1403. Sterilization (If applicable) (I)

A. If applicable, sterilizing equipment of the appropriate type shall be available and of adequate capacity to properly sterilize instruments and treatment/procedure room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly; periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

B. The dates of sterilization and expiration shall be marked on all supplies sterilized or licensees may utilize "event-related" methodologies for determining sterile integrity in lieu of "time-related" methods provided there is an established policy and procedure.

C. Provisions shall be made for appropriate storage and distribution of sterile supplies and equipment pursuant to policies and procedures.

D. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use, shall be accomplished. A method of monitoring disinfectant performance shall be employed. Disinfectants, e.g., glutraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer's instructions and shall include, at a minimum, a record of readings/testings and change dates of the disinfectant solution. Disinfectants must bear the U.S. Environmental Protection Agency (EPA) registration number and be approved by EPA or FDA for the particular use.

1404. Tuberculin Screening (I)

A. Tuberculin screening, utilizing a two-step intradermal (Mantoux) method of five tuberculin units of stabilized purified protein derivative (PPD), is a procedure recommended by the CDC Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities to establish baseline status. The two-step procedure involves one initial tuberculin skin test with a negative result, followed 7-21 days later by a second test. A licensed nurse may perform the tuberculin screening.

B. Testing Procedures.

1. Direct care staff members shall have a two-step tuberculin skin test within three months prior to patient contact. If there is a documented negative tuberculin skin test (at least single-step) within the previous 12 months, the individual shall be required to have only one tuberculin skin test to establish a baseline status. If two-step testing is indicated, it is acceptable for staff and volunteers who are asymptomatic for TB to begin patient contact after completion of the first skin test with a documented negative result.

2. Individuals with negative test results from the initial two-step procedure shall be required to have an annual one-step skin test.

C. Positive Reactions/Exposure.

1. Individuals with tuberculin skin test reactions of 10mm or more of induration and known human immunodeficiency virus (HIV)-positive individuals with tuberculin skin test reactions of 5mm or more of induration shall be referred to a physician or other legally authorized health care provider for appropriate evaluation.

2. All persons who are known or suspected to have tuberculosis (TB) shall be evaluated by a physician or other legally authorized health care provider. These individuals shall not be allowed to return to work until they have been declared non-contagious.

3. Patients with symptoms of TB shall be isolated and/or treated or referred as necessary by a physician or other legally authorized health care provider, and documented in the patient record.

4. Individuals who have a prior history of TB shall be required to have a chest radiograph and certification within one month prior to employment by a physician or other legally authorized health care provider that they are not contagious.

5. If an individual who was previously documented as skin test negative has an exposure to a documented case of TB, the local county health department or the Department's TB Control Division shall be contacted immediately for consultation.

6. An individual with TB infection who remains asymptomatic shall not be required to have a chest radiograph but shall have an annual documented assessment by a physician or other legally authorized health care provider for symptoms suggestive of TB, e.g., cough, weight loss, night sweats, fever, etc.

D. Treatment.

1. Preventive treatment of individuals who are new positive reactors is recommended unless specifically contraindicated.

2. Individuals who complete treatment either for disease or infection are exempt from further treatment unless they develop symptoms of TB.

1405. Housekeeping (II)

The equipment location shall be neat, uncluttered, clean, and free of vermin and offensive odors; housekeeping shall at a minimum include:

A. Cleaning each specific area;

B. Cleaning treatment/procedure rooms in accordance with established written procedures.

1406. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be segregated, stored, and disposed of in a manner compliant with *Infectious Waste Management* R.61-105, OSHA Bloodborne Pathogens Standard, and the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*.

1407. Clean/Soiled Linen (II)

A. A supply of clean, sanitary linen shall be available at all times and not stored with other items. In order to prevent the contamination of clean linen by dust or other airborne particles or organisms, it shall be stored and transported in a sanitary manner, i.e., enclosed and covered. Linen storage rooms shall be used only for the storage of linen.

B. Soiled linen.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing;

2. Soiled linen shall be kept in enclosed/covered containers.

SECTION 1500 - QUALITY IMPROVEMENT PROGRAM

1501. General (II)

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, procedures, and/or services provided.

B. The quality improvement program, as a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is systematically, objectively, and regularly accomplished at a frequency as determined by policies and procedures to ensure that policies and procedures and this regulation are met, but not less than every three months;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

5. At least every three months, review an established percentage of patient records to verify the accuracy and integrity of the system and take corrective action as needed;

6. Establish a systematic method of obtaining feedback from patients and other interested persons, e.g., family members and peer organizations, as expressed by the level of satisfaction with care, treatment, procedures, and/or services received.

SECTION 1600 - DESIGN AND CONSTRUCTION

1601. General (II)

The building in which equipment is utilized shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

1602. Local and State Codes and Standards (II)

Buildings and mobile units shall meet requirements for "Business Occupancy," and shall comply with State Fire Marshal regulations and pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No equipment shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the building in which it is housed.

SECTION 1700 - FIRE PROTECTION EQUIPMENT AND SYSTEMS

1701. Firefighting Equipment (I)

Firefighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the State Fire Marshal.

1702. Flammable Liquids (I)

The storage and handling of flammable liquids shall be in accordance with NFPA 30 and 99.

1703. Gases (I)

A. Gases, i.e., flammable and nonflammable, shall be handled and stored in accordance with the provisions of NFPA 99 and 101.

B. Installation, maintenance, and testing of piped gas systems shall meet the provisions of NFPA 99.

C. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously and placed on oxygen cylinders. All cylinders shall be properly secured in place.

1704. Furnishings/Equipment (I)

A. The physical plant shall be maintained free of fire hazards and impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted at the equipment location except as permitted by the State Fire Marshal Regulations.

C. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with NFPA 701, *Standard Methods of Fire Tests for Flame-Resistant Textiles and Films*.

EXCEPTION: Window blinds require no flame treatments or documentation thereof.

SECTION 1800 - MOBILE UNITS

1801. Care/Services

A. All mobile units, e.g., self-contained vans or tractor trailers, that transport equipment from one host site to another, shall meet the current standards of this regulation and of the local, state, and federal Departments of Transportation for the permitting and safe operation of the vehicle. Such compliance includes approval by the Federal Food and Drug Administration (FDA) for the provision of diagnostic or therapeutic services in the mobile unit.

B. A mobile cardiac catheterization laboratory shall only provide services on the campus of a host hospital that has emergency medical and intensive coronary care services.

C. A procedure shall not be performed on a patient in a mobile cardiac catheterization laboratory if any of the following are present:

1. Recent myocardial infarction (within 10 days or less);

2. Uncontrolled arrhythmias;

3. Severe uncontrolled congestive heart failure;

4. Current hospitalization with highly unstable angina;

5. The patient is under 18 years of age.

SECTION 1900 - SEVERABILITY

1901. General

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2000 - GENERAL

2001. General

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

Fiscal Impact Statement:

There will be no cost to the state and its political subdivisions. Cost of implementation will be me by the licensing fees imposed by this regulation. There will be costs to the regulated community. See Statement of Need and Reasonableness below.

Statement of Need and Reasonableness:

This statement was determined by staff analysis pursuant to S.C. Code, Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-108, *Standards For Licensing Freestanding or Mobile Technology*.

Purpose of Regulation: Promulgation of this regulation satisfies a legislative mandate requiring the Department to develop regulations to set standards for the licensing and inspection of freestanding or mobile technology.

Legal Authority: S.C. Code Ann. § 44-7-265 (1976, as amended).

Plan for Implementation: The regulation will take effect upon publication in the *State Register* following approval by the S.C. General Assembly. The regulation will be implemented by providing the regulated community with copies of the regulation and enforced through inspections by the Department.

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

This regulation is needed and reasonable because its development will satisfy a legislative mandate pursuant to S.C. Code Ann. § 44-7-265 (1976, as amended).

This regulation is needed and reasonable because it will promote health by providing standards for freestanding or mobile technology, thereby reducing the likelihood of adverse outcomes as a result of unsafe, inadequate equipment and procedures.

DETERMINATION OF COSTS AND BENEFITS: There will be no cost to the state and its political subdivisions. There will be minimal costs to the regulated community in that there shall be a licensing fee in an attempt to recover increased licensing inspection/investigation operational costs.

UNCERTAINTIES OF ESTIMATES: None

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: There will be no effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE NEW REGULATION IS NOT IMPLEMENTED: There will be an adverse effect on the public health if the regulation is not implemented, since the implementation of uniform, comprehensive standards for freestanding or mobile technology based on effective established procedures and practices would not be realized, thus denying the public these protections thereby increasing the potential that the public may be harmed. In addition, failure to implement will deny compliance to the statutory mandate for DHEC to promulgate these standards.

Statement of Rationale:

Since the S.C. Code Ann. § 44-7-265 (1976, as amended) requires the promulgation of standards for freestanding or mobile technology, initiation of the process to develop such standards is appropriate.

Document No. 2843
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CHAPTER 126
Statutory Authority: 1976 Code Section 44-6-90

126-425. Recipient Utilization

Synopsis:

This amendment defines the parameters of the DHHS Medicaid recipient restricted card process, including the factors that will be considered in making a determination for restriction, the rights and conditions for recipients before and during their restriction, and the recipient's selection of a Medicaid provider. The amendments also define the services that are governed and not governed by the restricted card process.

Instructions: Please replace the existing regulation, 126-425. Recipient Utilization, with the new text.

Text:

SUBARTICLE 2

PROGRAM INTEGRITY

126-425. Recipient Utilization

A.Definitions.

(1) The Division of Program Integrity of the South Carolina Department of Health and Human Services (DHHS) is designed to safeguard against unnecessary, harmful, wasteful, and uncoordinated utilization of services by Medicaid eligible recipients and health care providers.

(2) Medicaid Recipient--an individual who has been determined to be eligible for health services as described in the State Plan under Title XIX and Title XXI of the Social Security Act, as amended.

(3) Recipient Profile--a comprehensive statistical and utilization profile of a Medicaid recipient who has deviated from predefined thresholds, standards of medical care, and other criteria for the purposes of analysis and review.

(4) Misutilization ("misuse")—overuse, underuse, harmful, wasteful, and uncoordinated use of Medicaid services or improper or incorrect use of services provided under the Medicaid Program, whether intentional or unintentional.

(5) Restriction ("restricted")—The limitation of a Medicaid recipient to Medicaid services provided by a designated primary physician practitioner, pharmacy, hospital, or mental health provider for other than emergency health care. A restriction may be to more than one provider. A designated primary physician practitioner may make referrals to other health care providers, which will not be affected by the restriction designation.

(6) Provider--an individual, partnership, corporation, association, or institution that is eligible to provide medical assistance to a recipient pursuant to the State Medical Assistance Plan in accordance with Title XIX and Title XXI of the Social Security Act, as amended. A provider must be licensed, as applicable, under State law, is in good standing with applicable professional review boards, has not had a license revoked or suspended, and has not been convicted of fraud in any legal jurisdiction.

(7) Practitioner--a physician or other health care professional licensed under State law to practice his or her profession, is in good standing with applicable professional review boards, has not had a license revoked or suspended, and has not been convicted of fraud in any legal jurisdiction.

(8) Treatment Pathway - is the most appropriate medical condition specific treatment protocol. Treatment pathways have been researched and approved by professional associations, provide desired outcomes, include definitive evaluation and re-evaluation plateaus, offer a coordinated health team approach to care, eliminate duplication of costly services, and reduce errors.

(9) Medically Reasonable and Necessary ("medically necessary") – means procedures, treatments, medications or supplies ordered by a physician, dentist, chiropractor, mental health care provider, or other approved, licensed health care practitioner to identify or treat an illness or injury. Procedures, treatments, medications or supplies must be administered in accordance with recognized and acceptable medical and/or surgical discipline at the time the patient receives the service and in the least costly setting required by the patient's condition. All services administered must be in compliance with the patient's diagnosis, standards of care, and not for the patient's convenience. The fact that physician prescribed a service or supply does not deem it medically necessary.

B. Recipient Policies.

(1) The services that are governed by this program are as follows:

(a) All medical services rendered by a Medicaid provider for non-emergency services;

(b) Recipients' use of Medicaid services;

(2) Services that are not governed by this program are as follows:

(a) Emergency services which are necessary to prevent death or serious impairment of the health of a recipient;

(b) Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services;

(3) Recipient profiles shall be reviewed to identify potential utilization or compliance issues.

(4) Providers shall refer suspected misusers of Medicaid services to the DHHS.

(5) Recipients identified as suspected misusers of Medicaid services will be notified in writing that he/she will be restricted subject to paragraph A (5). The period of restriction shall be in accordance with 42 CFR 431.54(e). DHHS shall monitor restricted recipients' utilization patterns.

(6) The factors to be considered in making a determination whether to implement a restriction shall include all or some of the following:

(a) Medical factors;

(b) Patient utilization history;

(c) The degree of aberrancy;

(d) Any history of prior misutilization;

(e) Utilization patterns inconsistent with their peers;

(f) Utilization patterns inconsistent with treatment pathways;

(g) Evidence of abusive, duplicative, and wasteful utilization practices;

(h) Evidence of drug-seeking behaviors;

(i) Evidence of utilization patterns that could cause harm to the recipient;

(j) The degree of compliance with medical advice and treatment pathways;

(k) Evidence that a recipient's medical outcomes and health status may be improved by following treatment pathways and coordinated care.

(7) Rights and conditions of recipient during restriction period.

(a) Recipients will be notified by mail of a pending restriction or action subject to 42 CFR 431.206 through 42 CFR 431.214.

(b) Recipients are given freedom of choice of their primary providers. If a recipient does not select a primary provider, DHHS may select one for the recipient.

(c) A Recipient will be released from restriction upon DHHS determination that the recipient's service utilization patterns are in compliance with treatment pathways and consistent with their medical needs.

(8) Fair Hearing--any Medicaid recipient who has been notified in writing by DHHS or its designee of a pending restriction due to misutilization of Medicaid services may exercise his/her right to a fair hearing. Notice will be given pursuant to 42 CFR 431, Subpart E and the Fair Hearing will be conducted pursuant to R 126-150 et seq. and 42 CFR 431, Subpart E.

Fiscal Impact Statement:

The Department of Health and Human Services estimates that no additional costs will be incurred as a result of the promulgation of these regulations, and no additional state funding is requested.

Statement of Rationale:

For information contact George Burnett, Esquire, Department of Health and Human Services, P. O. Box 8206, Columbia, South Carolina 29202-8206.

Summary of Assessment Report:

Not applicable.

Document No. 2870
DEPARTMENT OF LABOR, LICENSING AND REGULATION
DIVISION OF LABOR
CHAPTER 71
Statutory Authority: 1976 Code Section 41-15-210

Regulation 71, Article I, Subarticle 3 - Recording and Reporting Occupational Injuries and Illnesses

Synopsis:
The purpose of the amendment is to revise the regulation to delete the two provisions concerning musculoskeletal disorders (MSDs). This amendment is required by the United States Department of Labor 29 CFR 1904.37 "State Recordkeeping Regulations."

Instructions:

SCRR 71-300 to 311 remains the same
SCRR 71-312 Delete, Reserved
SCRR 71-313 to 328 remains the same
SCRR 71-329 (a) and (b)(1) through (7)(v) remains the same.
SCRR 71-329 paragraph (b)(7)(vi) replace with the following amendment
SCRR 71-329 paragraph (b)(8) through (10) remains the same.
SCRR 71-330 to 346 remains the same

Statement of Rationale:

There was no scientific or technical basis relied upon in developing the regulation.

Text:

SCRR 71-312 Recording criteria for cases involving work-related musculoskeletal disorders. [Reserved]

SCRR 71-329 Forms.
(b) (7) (vi) Other illnesses, if the employee voluntarily requests that his or her name not be entered on the log.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Document No. 2911
DEPARTMENT OF LABOR, LICENSING AND REGULATION
CHAPTER 71
Statutory Authority: 1976 Code Section 41-15-210
Article I, Subarticle 6
Occupational Safety and Health Standards

The South Carolina Department of Labor, Licensing and Regulation, Division of Labor, Office of Occupational Safety and Health, hereby promulgates the following changes to South Carolina Regulations:

In Subarticle 6 (General Industry):
Removal of Subpart I, Section 1910.139 Respiratory Protection for M. Tuberculosis as amended in FEDERAL REGISTER, Volume 68, Number 250, pages 75776 – 75780, dated December 31, 2003.

In Subarticle 6 (General Industry):
Retention of Subpart N, Section 1910.178 (m)(12) of the Powered Industrial Truck Standard including its subordinate paragraphs (m)(12)(i) through (m)(12)(iii). As a result of the significant percentage of deaths and injuries attributed to falls from personnel lifting that have occurred per year in South Carolina, SCOSHA has decided not to adopt the change made by the United States Department of Labor but to retain 1910.178 (m)(12). Paragraph (m)(12) of §1910.178, as it was published in May 1971, reads as follows:

Whenever a truck is equipped with vertical only, or vertical and horizontal controls elevatable with the lifting carriage or forks for lifting personnel, the following additional precautions ***shall be taken*** for the protection of personnel being elevated.

(i) Use of a safety platform firmly secured to the lifting carriage and/or forks.

(ii) Means ***shall be provided*** whereby personnel on the platform can shut off power to the truck.

(iii) Such protection from falling objects as indicated necessary by the operating conditions ***shall be provided***.

In Subarticle 6 (General Industry):
Minimum standard for Commercial Diving Operations shall be 1910.401 – 402 with addition of Appendix C to Subpart T as amended in FEDERAL REGISTER, Volume 69, Number 31, pages 7351 – 7366, dated February 17, 2004.

Copies of these final regulation changes can be obtained or reviewed at the South Carolina Department of Labor, Licensing and Regulation during normal business hours by contacting the Office of Public Information at (803) 896-4380.

Document No. 2891
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF MEDICAL EXAMINERS
CHAPTER 81
Statutory Authority: 1976 Code Section 40-47-20, 40-1-70

81-95 Continued Competency

Synopsis:

The South Carolina Board of Medical Examiners is adopting a new Regulation, 81-95, to establish continued competency options for licensed physicians in this state.

Instructions:

81-95 Continued Competency - Insert in its entirety as published below.

Statement of Rationale:

There was no scientific or technical basis relied upon in the development of this regulation.

Text:

81-95. Continued Competency

The continued professional competency of physicians holding a permanent license shall be assured in the following manner:

A. For renewal of a permanent license initially issued during a biennial renewal period, compliance with all educational, examination, and other requirements for the issuance of a permanent license shall be deemed sufficient for the first renewal period following initial licensure.

B. For renewal of an active permanent license biennially, documented evidence of at least one of following options during the renewal period:

1. forty (40) hours of Category I continuing medical education sponsored by the American Medical Association, American Osteopathic Association, or other organization approved by the Board as having acceptable standards for courses it sponsors, at least thirty (30) hours of which are directly related to the licensee's practice area; or

2. certification of added qualifications or recertification after examination by a national specialty board recognized by the American Board of Medical Specialties or American Osteopathic Association or other approved specialty board certification; or

3. completion of a residency program or fellowship in medicine in the United States or Canada approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association; or

4. passage of the Special Purpose Examination (SPEX) or Comprehensive Osteopathic Medical Variable Purpose Examination (COMVEX); or

5. successful completion of a clinical skills assessment program approved by the Board, such as the Institute for Physician Evaluation (IPE), the Post-Licensure Assessment System (PLAS), or the Colorado Personalized Education Program (CPEP).

C. For reinstatement of a permanent license from lapsed or inactive status of less than four years, documented evidence of at least one of the following options within the preceding two years:

1. forty (40) hours of Category I continuing medical education sponsored by the American Medical Association, American Osteopathic Association, or other organization approved by the Board as having acceptable standards for courses it sponsors, at least thirty (30) hours of which are directly related to the licensee's practice area; or

2. certification of added qualifications or recertification after examination by a national specialty board recognized by the American Board of Medical Specialties or American Osteopathic Association or other approved specialty board certification; or

3. completion of a residency program or fellowship in medicine in the United States or Canada approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association; or

4. passage of the Special Purpose Examination (SPEX) or Comprehensive Osteopathic Medical Variable Purpose Examination (COMVEX); or

5. successful completion of a clinical skills assessment program approved by the Board, such as the Institute for Physician Evaluation (IPE), the Post-Licensure Assessment System (PLAS), or the Colorado Personalized Education Program (CPEP).

D. For reinstatement of a permanent license from lapsed or inactive status of four years or more, documented evidence of at least one of the following options:

1. certification of added qualifications or recertification after examination by a national specialty board recognized by the American Board of Medical Specialties or American Osteopathic Association or other approved specialty board certification; or

2. completion of a residency program or fellowship in medicine in the United States or Canada approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association; or

3. passage of the Special Purpose Examination (SPEX) or Comprehensive Osteopathic Medical Variable Purpose Examination (COMVEX); or

4. successful completion of a clinical skills assessment program approved by the Board, such as the Institute for Physician Evaluation (IPE), the Post-Licensure Assessment System (PLAS), or the Colorado Personalized Education Program (CPEP).

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Resubmitted February 4, 2004

Document No. 2860
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF MEDICAL EXAMINERS
CHAPTER 81
Chapter Statutory Authority: 1976 Code Sections 40-47-20 and 40-47-80.

Regulation 81-70 Requirements for Limited License.

Synopsis:

The State Board of Medical Examiners is amending Regulations 81-70 and 81-90 by changing “associate” to “assistant” professor so as to permit licensure for employment of certain academic faculty at the rank of assistant professor or greater at medical schools in South Carolina. Additionally, 81-70 is itemized and the text is clarified.

Instructions:

81-70 Replace with the following amendment.
81-90(A)(3)(c) Replace with the following amendment
81-90(H)(3) Replace with the following amendment

Statement of Rationale:

There was no scientific or technical basis relied upon in developing the regulation. Furthermore, these amendments offer medical schools in this State a larger pool of academic faculty members. Associate professors are more difficult to attract from current positions because of their tenure of ten to fifteen years experience required to be an associate professor. Assistant professors are required to have two to four years experience. The change from "associate" to "assistant" professor permits certain academic faculty at the rank of assistant professor or greater at medical schools in South Carolina to receive credit for postgraduate training for the academic appointment for licensure purposes.

Text:

81-70. Requirements for Limited License.

A. Interns, residents and other physicians (M.D., D.O.) approved for limited practice situations may apply for a Limited License if they do not meet the requirements for a Permanent License. An applicant for a Limited License must write the Board to request an application stating: Mailing address, type of training, and name of hospital or institution, and intended plans after expiration of Limited License.

B. Applicants must furnish to the Board a copy of a position contract or submit a recommendation letter for a training program from the institution. Applicants who practice before they are approved are subject to a late fee of $25 and charges of violation of the Medical Practice Laws and Regulations.

C. Limited Licenses are issued only for medical training or limited practice approved by the Board. A Limited License will entitle the holder to apply for individual controlled substance registration through DHEC for a training program or any practice that is approved by the Board. Each Limited License is for one fiscal year or part thereof. Renewal may be considered upon approval of the Board.

D. An applicant must be a graduate of an approved medical school located in the United States or Canada; graduates of a medical school located outside the United States or Canada may be considered on an individual basis.

E. Section VI of the Limited License application is to be completed by the dean of the applicant's medical school or as approved by the Board.

F. Graduates of medical schools located outside of the United States or Canada must complete Section VI of the Limited License application and present approved copies of a medical diploma from schools approved by the Board. If the diploma is not in English, an approved translation must be provided. Graduates of medical schools located outside of the United States or Canada must also (1) document successful completion of a Fifth Pathway program, or (2) furnish copies of current ECFMG certificate and documentation of all post-graduate training completed in the United States. All copies must be initialed by the physician in charge of the applicant's program.

G. The Fifth Pathway or ECFMG certificate requirement may be waived if the applicant has a full-time academic faculty appointment at the rank of assistant professor or greater in an A.C.G.M.E. accredited medical school in the United States.

H. Physicians remaining in South Carolina after the expiration of their Limited License may apply for a Permanent License by written examination or by endorsement at least 90 days before their Limited License expires annually on June 30th. No parts of a Limited License application shall be applied to an application for examination or endorsement. Each application is filed separately. The fee for each Limited License is $150.

81-90 (A) (3) . Requirements For Permanent License.

(c) Notwithstanding 81-90 A(3)(a) or (b), the ECFMG or Fifth Pathway requirement may be waived at the discretion of the Board if the applicant is to have full time academic faculty appointment at the rank of assistant professor or greater at a medical school in South Carolina.

81-90 (H)

(3) The Board has the discretion of accepting a full time academic appointment at the rate of assistant professor or greater in a medical or osteopathic school in the United States as a substitute for, and in lieu of postgraduate training. Each year of this academic appointment may be credited as one year of postgraduate training for purposes of the Board's postgraduate training requirements.

Fiscal Impact Statement:

There will be no additional cost incurred by the State or any political subdivision.

Document No. 2898
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF NURSING
CHAPTER 91
Statutory Authority: 1976 Code Sections 40-1-70 and 40-33-270

Synopsis:

The State Board of Nursing is amending Regulations 91-13.d. and 91-15.d. to allow the nurse licensure examination to be repeated every forty-five (45) days instead of every three months, as currently provided. This change is consistent with a recent change in the testing procedure of the National Council of State Boards of Nursing, which administers the National Council Licensure Examination (NCLEX).

Instructions:

91-13.d. Replace as indicated below
91-15.d. Replace as indicated below

Statement of Rationale:

There was no scientific or technical basis relied upon in the development of this regulation.

Text:

91-13.d. An applicant who does not pass the first licensure examination may repeat the examination but not more frequently than once in any forty-five day period. If the applicant does not pass the examination within one year of graduation, the applicant must provide evidence of further study satisfactory to the Board prior to reexamination. The applicant shall comply with application procedures established by the National Council Licensure Examination and the Board. Applications for licensure are valid for one (1) year. Failure to attain licensure during this period will require the submission of another application with the prescribed fee.

91-15.d. An applicant who does not pass the first licensure examination may repeat the examination but not more frequently than once every forty-five days. If the applicant does not pass the examination within one year of graduation, the applicant must provide evidence of further study satisfactory to the Board prior to reexamination. The applicant shall comply with application procedures established by the National Council Licensure Examination and the Board. Applications for licensure are valid for one (1) year. Failure to attain licensure during this period will require the submission of another application with the prescribed fee.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Document No. 2845
DEPARTMENT OF LABOR, LICENSING, AND REGULATION
SOUTH CAROLINA OCCUPATIONAL HEALTH AND SAFETY REVIEW BOARD
CHAPTER 127
Statutory Authority: 1976 Code Section 41-15-610(a)

R.127-1.6 Failure to Appear

Synopsis:

The Occupational Health and Safety Review Board is amending Regulation 127-1.6 to reflect social and economic changes since its promulgation.

Instructions:

R.127-1.6 Failure to Appear
In the last sentence of 127-1.6, replace "One Hundred ($100) dollars" with "Three Hundred Fifty ($350) dollars."

Text:

127-1.6. Failure to Appear.

The failure of a protesting party to appear at a hearing shall be deemed a withdrawal of the Notice of Protest and a waiver of all rights except the right to be served with a copy of the order of the Board or of the Board member to whom the matter has been assigned. If a party requesting a change in abatement dates fails to appear, such failure shall be an abandonment of the request. Upon a showing of good cause, the Board or Board member to whom the matter has been assigned may grant requests for reinstatement filed within ten (10) days after the scheduled hearing. In such cases, the hearing may be rescheduled. If the matter is not reinstated, the protesting party in default may be taxed with the costs of the hearing in the amount of Three Hundred Fifty ($350) dollars.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions.

Statement of Rationale:

There were no scientific or technical basis relied upon in developing the regulation. Furthermore, the State of South Carolina, through the Occupational Safety and Health Review Board and the Department of Labor, Licensing and Regulation, incurs significant costs in providing administrative review hearings at the request of employers who contest OSHA citations. It is appropriate for the taxpayer to bear the costs of providing due process to an employer. It is not appropriate for the taxpayer to bear the costs of abuse of the administrative review system by employers who request hearings and then fail to appear to state their objections to the citation. The proposed figure of Three Hundred Fifty ($350) dollars was chosen to reflect the actual costs of issuing hearing notices, attendance by a hearing officer and a court reporter, and preparation and attendance by a state attorney and compliance officer witness. The figure was also chosen as a deterrent figure to encourage employers to withdraw their protests before these expenses are incurred if they do not intend to appear for hearing on their objections to a citation.

Document No. 2885
DEPARTMENT OF NATURAL RESOURCES
CHAPTER 123
Statutory Authority: 1976 Code Sections 50-11-105, 50-11-310, 50-11-520, 50-11-530, 50-11-2200 and 50-11-2210

Synopsis:

These regulations amend Chapter 123-40 and 123-51 in order to set seasons, bag limits and methods of hunting and taking of wildlife on existing and additional Wildlife Management Areas. These regulations add Chapter 123-54 Chronic Wasting Disease import regulations.

Instructions:

Amend Regulations 123-40 and 123-51 to establish changes and include additional WMA's. Establish regulation 123-54 Chronic Wasting Disease import regulations.

HUNTING IN WILDLIFE MANAGEMENT AREAS

123-40. Wildlife Management Area Regulations.

1.1 The following regulations amend South Carolina Department of Natural Resources regulation Numbers 123-40.

1.2. The regulations governing hunting including prescribed schedules and seasons, methods of hunting and taking wildlife, and bag limits for Wildlife Management Areas are as follows:

(D) Game Zone 4

Fairforest, Enoree, Carlisle, Broad River, Dutchman, Wateree and Worth Mountain WMA's (add "Worth Mountain")

No more than 5 bucks total may be taken during all seasons combined, regardless of method (archery, muzzleloader, gun). Worth Mountain WMA Quality Deer Management Area: Bucks must have a minimum 4 points on one side or a minimum 12-inch antler spread.

Draper WMA

Small Game	Sat. after Thanksgiving, 2nd	10 per day
Quail	Sat. in Dec.,1st and 2nd Wed. in Jan. Sunrise until 4:00 pm.	

(E) Broad River Waterfowl Management Area (Remove "Enoree River")

(V) Sand Hills State Forest WMA

Hunting by the general public closed during scheduled field trials on the Sand Hills State Forest Special Field Trial Area. Hunting allowed during permitted field trials on the Sand Hills State Forest Special Field Trial Area in compliance with R.123-96. No man-drives allowed. No buckshot allowed.

(UU) Wee Tee WMA

Deer		Total 8 deer per season
Archery	Oct. 1 through 2nd Sat. in Oct.	2 deer per day, either-sex, hogs no limit.
Muzzle Loader	Open Mon. following archery Season for one week	2 deer per day, either-sex, hogs no limit.
Still Gun Hunts	First Mon.-Sat. in Sept.	2 per day, buck only, hogs no limit.
	Sept. 15 through last Sat. in Sept.	2 deer per day, either-sex, hogs no limit.
	First Mon-Sat. in Nov.	2 deer per day, either-sex, hogs no limit.
	Mon-Sat. week of Thanksgiving.	2 deer per day, either-sex, hogs no limit.
	First Mon. in Dec. through Jan. 1.	2 deer per day, either-sex, hogs no limit.
Small Game No open season for fox hunting.	No hunting before Sept. 1 or after Mar. 1; otherwise Game Zone 9 seasons apply. Dogs allowed during small game gun season only. Closed during scheduled deer and hog hunt periods.	Game Zone 9 bag limits except Quail – 8 per day

DEER

4.1 On WMA lands with designated check stations, all deer bagged must be checked at a check station. Deer bagged too late for reporting one day must be reported the following day. Unless otherwise specified by the department, only bucks (male deer) may be taken on all WMA lands. Male deer must have antlers visible two (2) inches above the hairline to be legally bagged on "bucks only" hunts. Male deer with visible antlers of less than two (2) inches above the hairline must be taken only on either-sex days or pursuant to permits issued by the department. A point is any projection at least one inch long and longer than wide at some location at least one inch from the tip of the projection. Antler spread is the greatest outside measurement (main beam or points) on a plane perpendicular to the skull. On WMA lands, man drives for deer are permitted between 10:00 a.m. and 2:00 p.m. only, except that no man drives may be conducted on days designated by the department for taking deer of either sex. On WMA lands, drivers participating in man drives are prohibited from carrying or using weapons. On WMA lands, in Game Zones 1, 2 and 4, man drives will be permitted on the last four (4) scheduled either-sex days. A man drive is defined as an organized hunting technique involving two (2) or more individuals whereby an attempt is made to drive game animals from cover or habitat for the purpose of shooting, killing, or moving such animals toward other hunters.

10.16 Category II Designated Waterfowl Areas include Biedler Impoundment, Lake Cunningham, Russell Creek, Monticello Reservoir, Parr Reservoir, Duncan Creek, Dunaway, Dungannon, Enoree River, Moultrie, Hatchery, Hickory Top, Hickory Top Greentree Reservoir, Turtle Island, Little Pee Dee River Complex (including Ervin Dargan, Horace Tilghman), Great Pee Dee River, Oak Lea, Potato Creek Hatchery, Samson Island Unit (Bear Island), Tyger River, and Marsh Waterfowl Management Areas. Hunting on Category II Designated Waterfowl Areas is in accordance with scheduled dates and times.
(add "Hickory Top Greentree Reservoir")

DESIGNATED WATERFOWL AREAS

Hickory Top Greentree Reservoir Closed to waterfowl hunting

123-51. Turkey Hunting Rules and Seasons

1. Total limit of 5 turkey statewide per person, 2 per day gobblers only, unless otherwise specified. Total statewide and county bag limits include turkeys harvested on Wildlife Management Areas (WMAs). Small unnamed WMAs in counties indicated are open for turkey hunting. Turkey seasons and limits on DNR-owned lands and Wildlife Management Area lands are as follows:

AREA	DATES	LIMIT	Other Restrictions
Sand Hills State Forest WMA	April 1 – May 1	2	(delete Wed-Sat. only)
Donnelley WMA	April 1 – May 1	1	Hunting by public draw only
Santee Cooper WMA	April 1 – May 1	1	Hunting by public draw only
Edisto WMA	April 1 – May 1	2	Wed. Only
Wee Tee	April 1 – May 1	2	Wed. and Sat. Only
Statewide Youth Hunt Day	Sat. before April 1	2	Youth Only

2. The following Regulations apply to all Wildlife Management Area lands.

a. During the spring turkey hunting season no game animal may be taken except turkey gobblers (bearded birds). During the fall turkey season (if scheduled) both gobblers and hens may be taken.

b. Shotguns, muzzleloader shotguns, or bows and arrows are permitted, all other weapons and methods of taking are prohibited including rifles, pistols, hard jacketed bullets, buckshot and slugs.

c. Turkeys may not be hunted with dogs.

d. Live decoys are prohibited.

e. It is unlawful to hunt turkeys on Sundays on Wildlife Management Area lands and on private lands within Game Zones 1 and 2. (delete zone 4)

123-54. Chronic Wasting Disease Carcass Importation Regulations

Section 1. Definitions.

1. "Cervid" means a member of the family Cervidae.
2. "Chronic wasting disease (CWD)" means a fatal neurological disease of cervids belonging to a group of diseases called transmissible spongiform encephalopathies.
3. "Clean" means having no meat or other tissues attached to the carcass part.
4. "Infected state" means a state of the United States or province of Canada that has a known case of chronic wasting disease.
5. "Importation" means the transportation of a cervid carcass or carcass part into this State.
6. "Whole" means the entire carcass whether eviscerated or not, prior to the carcass being processed.

Section 2. Prohibition on the Importation and Possession of a Whole Cervid Carcass or Carcass Part from an Infected State.

1. No person may import or possess a whole cervid carcass or carcass part from an infected state unless the carcass or part has been converted as specified in subsections (2) or (3) of this section.
2. A person may import a cervid carcass or a carcass part from an infected state if:
   (a) Quarters or other portions of meat have no part of the spinal column or head attached; or
   (b) Meat has been boned out.
3. A person may import or possess the following inedible parts of a cervid carcass from an infected state:
   (a) Antlers;
   (b) Antlers that are attached to a clean skull plate;
   (c) A clean skull;
   (d) Clean upper canine teeth;
   (e) A finished taxidermy product; or
   (f) The hide.

Section 3. Penalty

The penalty for a violation of this regulation shall be as provided in Section 50-1-130.

Fiscal Impact Statement:

This amendment of Regulation 123.40 will result in increased public hunting opportunities that should generate additional State revenue through license sales. In addition, the local economy should benefit from sales of hunting supplies, food and overnight accommodations. Sales taxes on these items will also directly benefit government.

There is no cost associated with the implementation of Regulation 123-54. The regulation is for the purpose of protecting the State's white-tailed deer resource from CWD. The economics associated with deer hunting in South Carolina are approximately $200 million in annual retail sales. CWD has caused significant impact to the economics associated with deer hunting in states where the disease has been detected. If CWD is introduced into South Carolina significant economic damage could result.

Statement of Rational:

Rationale for the formulation of these regulations is based on over 60 years of experience by SCDNR in establishing public hunting areas. New areas are evaluated on location, size, current wildlife presence, access and recreation use potential. Contractual agreements with the landowners provide guidelines for the use and management of the property. Wildlife Management Area agreements are on file with the Wildlife Management Section of the Department of Natural Resources, Room 267, Dennis Building, 1000 Assembly Street, Columbia.

Document No. 2883
DEPARTMENT OF TRANSPORTATION
CHAPTER 63
Statutory Authority: 1976 Code Section 57-25-170

63-338 Specific Information Service Signing

Synopsis:

The South Carolina Department of Transportation proposes to amend 63-338 to provide for a bid solicitation and selection process at intersections where the number of qualifying businesses exceeds the available spaces on the service panel and to delete the requirement that an attraction must have public telephones to qualify for participation on an Attraction service panel.

Section-by-Section Discussion:

SECTION CITATION:	EXPLANATION OF CHANGE:
63-338 D	Subsection 5, which provides for a potential increase in the number of business signs displayed on a single panel, is deleted and the other subsections renumbered. This change is made to conform with federal requirements which will not allow the increase.
63-338 E(5)-(7)	Subsections 5-7 are amended to provide for a bid solicitation and selection process at intersections where the number of qualifying businesses exceeds the available spaces on the service panel.
63-338 (I)(e) (2)	Subsection is amended to delete the reference to hiking and picnicking under Amusement Parks because those activities are covered under Recreational Areas. The reference to the SCMUTCD publication is deleted because that publication is obsolete. The requirement that public telephones be available at a zoological or botanical park is deleted to conform with federal guidelines.
63-338	In Subsections (C) and (I) of the proposed regulation, changes are proposed to correct scriveners errors in the existing regulations.

Instructions: Replace the existing Code of Laws Section 63-338 with the following text:

Text:

63-338. Specific Information Service Signing.

A. Introduction. The South Carolina Department of Transportation has developed this program for the installation of specific service panels and business signs on fully controlled access highways.

B. Purpose. The purpose of this program is:

(1) To provide motorists with business identification and directional information for essential motorist services and for eligible attractions;
(2) To eliminate illegal outdoor advertising signs as required by the South Carolina Highway Advertising Control Act. 57-25-110, et seq.

C. Definitions

(1) Department is the South Carolina Department of Transportation or its authorized agents.
(2) A Specific Service Panel is an official sign, rectangular in shape, located within the highway right-of-way and carrying legend for one (1) (or a combination of up to three (3)) of the following services: gas, food, lodging, camping, or attraction along with directional information and space for one (1) to six (6) individual business signs.
(3) A Business Sign is a separately attached sign, rectangular in shape, mounted on the specific service panel to show the brand or trademark and name, or both, of a qualified motorist service available at or near the next interchange.
(4) A Ramp Panel is an official sign, rectangular in shape, located along an exit ramp and carrying legend for one (1) (or a combination of up to three (3)) of the following services: gas, food, lodging, camping or attraction together with directional information and space for one (1) to six (6) individual business signs of the same design as business signs, but smaller.
(5) A Trailblazer Panel is an official sign, rectangular in shape, located on the right of way of a highway with directional arrows and space for one (1) to four (4) individual signs of the same design as business signs, but smaller.

(6) A Business is an individual business that provides gas, food, lodging, camping or attraction services to motorists.

(7) Continuous Operation is the unremitting availability of motorist services within a prescribed number of hours.

(8) Rest Room Facilities are separate facilities for men and women, to include sink and toilet, and available to all motorists at no charge.

(9) Drinking Water is a water fountain and/or cups of water provide to all motorists at no charge.

(10) Public Telephone is a coin operated telephone available to all motorists. Private or business phones may be allowed if the business is unable to obtain a coin operated telephone so long as its use is provided to motorists.

D. Specific Service Panels

(1) A specific service panel bearing one (1) to six (6) separately attached business signs may be erected on fully controlled access highways between the previous interchange and the exit direction sign where space permits.

(2)The specific service panel nearest to the interchange should be erected no closer than 1600 feet to the beginning of exit ramp taper of the approaching interchange with at least 800 foot spacing between the information panels. The specific service panel should be located longitudinally so as to take advantage of natural terrain and have the least impact on the scenic environment.

(3) The number of business signs that may be displayed on specific service panels shall be limited to six (6) each for Gas, Food, Lodging, Camping, and Attractions at any interchange.

(4) A combination panel is a specific service panel that may display a maximum of three (3) specific services. The total number of business signs on a combination panel shall be limited to six (6).

(5) The size of specific service panels should be adequate to accommodate the number of business signs to be erected, using the required legend height and spacing in accordance with the latest Department specifications.

(6) For double exit interchanges the specific service panel shall consist of two sections, one for each exit. The top or left section shall display the business signs for the first exit and the lower or right section shall display the business signs for the second exit. Where participation for one exit is less than three (3) businesses for a service, the specific service panel may be arranged to allow for four (4) to six (6) business signs to be displayed for the other exit. No more than six (6) business signs shall be displayed for any service at an interchange.

(7) The background color of a specific service panel shall be blue with white reflectorized border. The words gas, food, lodging, camping or attraction and directional information shall be white reflectorized legend mounted on the blue panel.

(8) Specific service panels shall not be erected at any interchange with another controlled access facility; nor shall they be erected at any interchange where there is no entrance ramp at the interchange or at another reasonably convenient interchange by which the motorist may proceed in the desired direction of travel without undue indirection or use of poor connecting roads.

(9) No more than one specific service panel for gas, food, lodging, camping or attraction shall be erected in each direction approaching an interchange.

(10) A maximum of four (4) specific service panels may be erected in each direction approaching an interchange.

(11) Attraction signing shall not be used for facilities that have the primary purpose of retail sales.

E. Business Signs - Main Roadway

(1) Business signs separately attached on a specific service panel shall show the brand or trademark and name, or both, of the gas, food, lodging, camping or attraction facility located at or conveniently accessible from an interchange. Nationally, regionally or locally known commercial symbols or trademarks shall be used when applicable. The brand or trademark identification symbol used shall be reproduced with the colors and general shape consistent with customary use. Any messages, trademarks or brand symbols which interfere with, imitate or resemble an official traffic control device will not be permitted.

(2) Each business sign on a specific service panel shall be contained in a rectangular background area. Any business sign that does not display a nationally, regionally or locally known symbol or trademark shall display the business name in legend that contrasts effectively with the background.

(3) If a food business is only open six (6) days a week, it will be required to incorporate into the design of its business signs a message indicating what day the business is closed. This message shall be legend that says "CLOSED" followed by the day of week the business is closed. The color of the legend shall contrast effectively with the background of the business sign.

(4) Only one business sign may be shown in each direction of travel for each service provided by a business, even though the business may be accessible from more than one interchange. Signing will be provided at the interchange closest to the business, as determined by the Department.

(5) Where the number of fully qualifying gas, food, lodging, camping or attraction businesses exceeds the available spaces on the specific service panel, the Department. will solicit bids from all of the qualified businesses. Bid solicitation and selection will be governed by the Department's policies and procedures.

F. Ramp Panels

(1) When the Department determines that any participating business is not visible from the terminal or decision point of a ramp which permits traffic to proceed in more than one direction on the crossroad, a ramp panel shall be placed on the exit ramp or at its terminus.

(2) Ramp signs shall not be erected for businesses not displaying business signs on a specific service panel.

(3) A ramp combination panel is a ramp panel that may display a maximum of three (3) specific services. The total number of ramp business signs on a ramp combination panel shall be limited to six (6).

(4) Ramp panels will be of an appropriate size to display the required number of ramp business signs.

(5) The background color of a ramp panel shall be blue with white reflectorized border. The words gas, food, lodging, camping or attraction and directional information shall be in white reflectorized legend mounted on the blue panel.

G. Trailblazer Panels

(1) When the Department determines that the route to a business requires a direction change, it is questionable as to which roadway to follow, or when additional guidance is needed, a trailblazer panel may be placed along a crossroad up to 500 feet prior to any required turn.

(2) Trailblazer panels will be of an appropriate size to display the required number of trailblazer business signs.

(3) The background color of a trailblazer panel shall be blue with white reflectorized border. White reflectorized directional arrows shall be mounted on the blue panel as needed for proper guidance.

(4) Trailblazer panels shall not be erected for businesses not displaying business signs on a special service panel and a ramp panel.

(5) A trailblazer panel may contain various types of services on a single panel.

(6) When space along the right-of-way limits the number of signs or panels that can be erected, all other Department signing shall take priority over trailblazer panels.

H. Business Signs – Ramp and Trailblazer

(1) Ramp and trailblazer business signs shall be of the same design as business signs, but smaller.

(2) Each business sign mounted on a ramp panel and trailblazer panel shall be contained in a rectangular background area. Any business sign which does not display a nationally, regionally or locally known symbol or trademark shall display the business name legend which contrasts effectively with the background.

(3) If a food business is only open six (6) days a week, it will be required to incorporate into the design of its business signs a message indicating what day the business is closed. This message shall say "CLOSED" followed by the day of week the business is closed. The color of the legend shall contrast effectively with the background of the business sign.

I. Criteria

(1) A business located at or conveniently accessible from an interchange on a fully controlled access highway shall be eligible to have its business sign placed on a specific service panel, a ramp panel, and on a trailblazer panel (but in accordance with Section F(1) and G(1)) if it meets the following conditions:

(a) Gas:
1. Located within three (3) miles of the interchange;
2. Vehicle services shall include fuel, oil and water;
3. Continuous operation at least sixteen (16) hours per day, seven (7) days a week;
4. Rest room facilities;
5. Drinking water;
6. Public telephone;

(b) Food:
1. Located within three (3) miles of the interchange;
2. Maintain a "Grade A" rating as defined by the South Carolina Department of Health and Environmental Control;
3. Continuous operation at least twelve (12) hours a day, six (6) days a week;
4. Rest room facilities;
5. Public telephone;
6. Indoor seating capacity for at least twenty (20) persons and/or drive-thru service;

(c) Lodging:
1. Located within three (3) miles of the interchange;
2. Permit to operate by the South Carolina Department of Health and Environmental Control;
3. Continuous operation, twelve (12) months per year;
4. At least ten (10) lodging rooms;
5. Public telephone;

(d) Camping:
1. Located within six (6) miles of the interchange;
2. Permit to operate by the South Carolina Department of Health and Environmental Control;
3. Modern sanitary facilities including restrooms and showers;
4. Drinking water;
5. Overnight accommodations for all types of travel trailers, tents and camping vehicles;
6. Adequate parking accommodations for at least ten (10) camping vehicles;
7. Continuous operation, seven (7) days a week;
8. If operated on a seasonal basis, signs will be removed;
9. Public telephone.

(e) Attraction:
1. Located within fifteen (15) miles of the interchange;
2. Be an activity or location that is one of the following:

(i) Amusement Park: a permanent area, open to the general public, whose principle activities include boating, entertainment rides, swimming, etc.;

(ii) Arena: an auditorium, civic or convention center, racetrack, sports complex, or stadium having a minimum seating capacity of 5,000;

(iii) College or University Facilities: an institution that is approved by a nationally recognized accreditation agency, has an enrollment of at least 500 fulltime students, and grants degrees;

(iv) Commerce Park: a group of commercial manufacturing or research facilities;

(v) Cultural Center: a facility for cultural events;

(vi) Facility Tour Location: a facility such as a factory, institution, or plant which conducts daily or weekly public tours on regular scheduled basis year-round;

(vii) Fairground: a tract of land where fairs or exhibitions are held and which has permanent buildings including, but not limited to, bandstands, exhibition halls, livestock exhibition pens, etc.;

(viii) Historical Site or District: a structure or area listed on the national or state historical register and recognized by the Department as a historic attraction or location. Historic districts shall provide the

public with a single, central location, such as a self-service kiosk or welcome center, where motorists can obtain information regarding the district;

(ix) Recreational Area: a recreational attraction recognized by the Department including, but not limited to, bicycling, boating, fishing, hiking, picnicking, or rafting;

(x) Natural Phenomenon: a naturally occurring area which is of outstanding interest to the general public, such as a waterfall or a cavern;

(xi) Visitor Information Center: visitor information centers other than those operated by the South Carolina Department of Parks, Recreation and Tourism must meet the criteria outlined by the Department;

(xii) Zoological/Botanical Park: a facility in which living animals or plants are kept and exhibited to the public;

3. Maintain regular hours for that type of establishment;
4. Public restrooms;
5. Adequate parking accommodations.

(2) Where space is available on an existing gas, food or lodging specific service panel, distances for participation may be extended to a total of six (6) miles from the interchange. Extension of distances will be at the sole discretion of the Department and will be measured as described in Section I (3). In all instances, businesses meeting all of the provisions of Section I will be given first priority.

(3) In determining distances from the interchange, roadway mileages are to be used, measured from the off-ramp terminal (where the off-ramp intersects the crossing road or frontage road) nearest to the business under consideration. The measurement shall begin where the left edge of the off-ramp pavement intersects the near edge of the crossing road pavement. If the off-ramp terminal is channelized, the measurement shall begin at the intersection portion of the terminal nearest to the business under consideration.

(a) For gas, food, lodging, and attractions the measurement will terminate at the main entrance of the building where payment is received for services rendered.

(b) For camping facilities, the distance will be measured to the registration office on the property of the camping facility.

J. Installation and Maintenance

(1) The cost to the business for participation in the specific service signing program shall be determined by the Department based on each business sign installed. Fees will include yearly renewal and installation or removal of signs.

(2) All business signs will be furnished to the Department by the business at no cost to the Department and shall be manufactured to the standard specifications and approved design of the Department. Business signs not meeting the specifications shall not be used.

(3) The Department shall be responsible for all required installation, routine maintenance, removal and placement of business signs upon the specific service and ramp panels.

(4) The Department shall not be responsible for any damage, deterioration or loss of any business sign. The business shall be responsible for furnishing replacement business signs to the Department.

K. General Provisions

(1) Upon application to participate in the specific service signing program, a business shall give written assurance of its conformity with all applicable laws concerning the provision of public accommodations without regard to race, religion, color or national origin.

(2) If a business, at any time, fails to comply with applicable laws or these rules and regulations, the Department will take the necessary actions to remove the business signs and disqualify that business from further participation in the program, except when a business closing is due to damages sustained by fire, accident or similar causes and when the Department is notified in writing within ten (10) days of such closing. In such cases the business sign shall be removed or covered until the business is re-opened.

(3) Any business that maintains any form of illegal outdoor advertising as determined by the South Carolina Highway Advertising Control Act shall be ineligible to participate in this program until such illegal advertising devices are removed.

(4) The Department reserves the right to cover or remove any or all business signs during maintenance or construction operations or for research studies, or whenever deemed by the Department to be in the best interest

of the Department or the traveling public without advance notice. The Department reserves the right to terminate the program or any portion thereof by furnishing the business written notice of such intent not less than thirty (30) calendar days prior to such action.

(5) The Department will prescribe the format and content of standard application and agreement forms to be used in the administration of this program.

(6) After a business has received approval of its application for participation in the program, an agreement, in accordance with these regulations, will be entered into between the Department and the business. Designs for the business signs should be submitted, if required, for approval as soon as possible upon application

Fiscal Impact Statement:

The Department of Transportation estimates that the competitive bid process proposed in these regulations will increase the annual logo program revenues by $175,000 to $450,000.

Statement of Rational

This change in the regulations is necessary, because the demand for space on these signs often exceeds the availability of space. The use of a bid solicitation and selection process will allow SCDOT to assign spaces on service panels based on a competitive system. The deletion of the requirement for public telephones is based on recent announcements by telephone companies in the state that the number of pay phones in the state is being drastically reduced because of the expanded use of cell phone technology.