Regulation Development Annual Report
Fiscal Year 2018

June 30, 2018
In accordance with the South Carolina Administrative Procedures Act, the Department of Health and Environmental Control (“DHEC” or “Department”) promulgates new regulations and amends and repeals existing regulations as necessary to execute policy passed by the South Carolina General Assembly. S.C. Code Sections 1-23-10 et seq. If a statute does not require accompanying regulation(s) and is self-executing, the Department generally refrains from promulgating a regulation. Furthermore, the Department does not promulgate regulations that conflict with or exceed its authority as enumerated in governing law.

The Department’s promulgation year follows the legislative fiscal year. The following regulatory activities occurred from July 1, 2017, through June 30, 2018.

- **New Regulation Added**: 1
- **Amendments to Existing Regulations**: 4
- **Pending New Regulation, and Amendments and Repeals of Existing Regulations**: 17 (1 New, 11 Amendments, 5 Repeals)
The following DHEC regulations took legal effect during the 2018 fiscal year upon publication in the *South Carolina State Register*. This includes four (4) amendments to existing regulations and one (1) new regulation. Provided below is a summary of the changes made, the effective date, the publication details, and a link to the official text for each regulation.

**South Carolina Stroke Care System**  
**Health Regulation**  

**Summary:**  
Executes the requirements of the Stroke System of Care Act of 2011, S.C. Code Sections 44-61-610 et seq.  
Establishes a process of application and recognition of acute care hospitals seeking recognition as stroke centers.  
Establishes a statewide stroke registry for collection and analysis of stroke care by acute care hospitals.  
Adopts a nationally recognized and standardized stroke-triage assessment tool.

**Effective Date:**  
May 25, 2018

**Publication:**  
*State Register* Document No. 4760 (Volume 42, Issue 5)

**Link to Final Regulation:**  
www.scstatehouse.gov/regs/4760.docx
Minimun Standards for Licensing Hospitals and Institutional General Infirmaries
Health Regulation

Summary:
Allows dietitians to prescribe diets and other dietary services.


Incorporates existing inspection and construction fees.

Incorporates new safe haven requirements.

Effective Date: May 25, 2018

Publication: State Register Document No. 4740 (Volume 42, Issue 5)

Link to Final Regulation: www.scstatehouse.gov/regs/4740.docx

Air Pollution Control Regulations and Standards
Environmental Affairs

Summary:
Adoption of federal amendments promulgated from January 1, 2016, to December 31, 2016, for:

R.61-62.1, Definitions and General Requirements
R.61-62.5, Standard No. 7, Prevention of Significant Deterioration
R.61-62.60, South Carolina Designated Facility Plan and New Source Performance Standards
R.61-62.61, National Emission Standards for Hazardous Air Pollutants (NESHAP)
R.61-62.63, National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories
R.61-62.70, Title V Operating Permit Program

Addition of R.61-62.97, Cross-State Air Pollution (CSAPR) Trading Program incorporating EPA’s CSAPR trading program for South Carolina in 40 CFR Part 97 for NOX (Annual) and SO2 (Annual). This regulation addresses mandatory transport and regional haze SIP infrastructure elements pursuant to 42 U.S.C. Sections 7410 and 7491.
Adoption of federal regulatory updates for:
- Clarifying and correcting Parts II, V, VII, and XII.
- Enabling specific licensees to install and service generally licensed devices.
- Enabling individuals receiving security-related information to protect it from public disclosure.

Effective Date: February 23, 2018

Publication: State Register Document No. 4791 (Volume 42, Issue 2)

Link to Final Regulation: www.scstatehouse.gov/regs/4791.docx

Standards for Licensing Hospices
Health Regulation

Summary:
Incorporates 2017 Act No. 61, which comprises changes to the Hospice Licensure Act, S.C. Code Sections 44-71-10 et seq. to:
- Require registration of multiple locations.
- Update requirements for medication disposal.
- Expand Joint Annual Report requirements to outpatient hospices.
Effective Date: June 22, 2018

Publication: State Register Document No. 4800 (Volume 42, Issue 6)

Link to Regulation: www.scstatehouse.gov/regs/4800.docx
At the close of the 2018 fiscal year, the Department had seventeen pending regulatory developments, including new regulations, and amendments and repeals of existing regulations. Most of these will continue to the 2019 fiscal year. All of the below entries require General Assembly review, unless noted otherwise, due to compliance with federal law.

For status updates on the below proposed actions, visit DHEC’s Regulation Development Monthly Update webpage at:

http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/

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**Standards for Licensing Crisis Stabilization Unit Facilities**

**Health Regulation**

**R.61-125**

**Summary:**
Add new regulation R.61-125 to establish licensure and regulatory requirements for Crisis Stabilization Unit Facilities, which provide a short-term residential program offering psychiatric stabilization services and brief, intensive crisis services to individuals eighteen years of age or older, twenty-four hours a day, seven days a week.

**Current Phase:**
Notice of Final Regulation (Pending)

Submitted to legislature March 2018.

Will be resubmitted for 2019 legislative session.

**Link to Pending Regulation:** [www.scstatehouse.gov/regs/4809.docx](http://www.scstatehouse.gov/regs/4809.docx)
Amendments to Existing Regulations

Administrative Procedures (DHEC Coastal Division)

Summary:
Clarifies the review process to allow sufficient time for affected landowners to understand the Department's methodology in setting jurisdictional lines and erosion rates, and bring any substantiating evidence to the attention of the Office of Ocean and Coastal Resource Management for a staff determination.

Current Phase:
Notice of Final Regulation (Pending)
Submitted to legislature March 2018.

The Department will not resubmit this amendment for legislative review because the Beachfront Management Reform Act (Act No. 173) addressed the above-mentioned issues.

Link to Pending Regulation: www.scstatehouse.gov/regs/4810.docx

Vital Statistics

Summary:
Amend R.61-19 to clarify that the State Registrar may (at his or her discretion) allow other documents to be used for amendment of birth records; increase instances in which names may be administratively added to a birth record; and update the fee schedule.

Current Phase:
Notice of Drafting published June 22, 2018
Retail Food Establishments
Environmental Affairs

**Summary:**

Amend and include inspection fees currently appearing in R.61-37, *Retail Food Establishment Inspection Fees*, which is pending repeal (see page 13). Revise the fee scale based on a process (risk) level or type of establishment and increase fees last updated approximately eighteen years ago.

**Current Phase:**
Notice of Drafting published April 27, 2018

Onsite Wastewater Systems
Environmental Affairs

**Summary:**
Amend R.61-56 to add new system standards; clarify and amend definitions; and clarify and update selected sections.


**Current Phase:**
Notice of Drafting published April 27, 2018

Air Pollution Control Regulations and Standards
Environmental Affairs

**Summary:**
Amend R.61-62.1, *Definitions and General Requirements*, to expand and improve consistency in language regarding general and registration permits, and update public participation procedures.

Amend R.61-62.5, Standard No. 5.2, *Control of Oxides of Nitrogen (NOx)*, to update applicability and exemptions.


Amend R.61-62.70, *Title V Operating Permit Program*, to update public participation procedures.

**Current Phase:** Notice of Proposed Regulation published June 22, 2018

**Link to Proposed Regulation:** www.scstatehouse.gov/regs/4815.docx

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**Air Pollution Control Regulations and Standards**

**Environmental Affairs**

**Summary:**
Adopt federal amendments promulgated from January 1, 2017, to December 31, 2017, for:

- R.61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*


Repeal R.61-62.96, *Nitrogen Oxides (NOx) and Sulfur Dioxide (SO2) Budget Trading Program*, as its requirements have sunsetted and R.61-62.97, *Cross-State Air Pollution Rule (CSAPR) Trading Program*, replaces these requirements.

Exempt from General Assembly review.

**Current Phase:** Notice of Proposed Regulation published June 22, 2018

**Link to Proposed Regulation:** www.scstatehouse.gov/regs/4814.docx
Summary:
Amend R.61-79 to adopt the federal “Hazardous Waste Generator Improvements Rule,” which will:

Reorganize the hazardous waste generator regulations to improve their usability by the regulated community;

Provide a better understanding of how the Resource Conservation and Recovery Act hazardous waste generator regulatory program works;

Address gaps in existing regulations to strengthen environmental protections;

Provide greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner; and

Make technical corrections to address inadvertent errors and remove obsolete references to programs that no longer exist.

Current Phase: Notice of Drafting published April 27, 2018

Exempt from General Assembly review.

Summary:
Amend R.61-79 to adopt the federal “Imports and Exports of Hazardous Waste Rule,” which will:

Make existing export and import-related requirements more consistent with the current import-export requirements for shipments between members of the Organization for Economic Cooperation and Development;

Enable electronic submittal to the EPA of all export and import-related documents; and

Enable electronic validation of consent in the Automated Export System for export shipments subject to Resource Conservation and Recovery Act export consent requirements prior to exit.

Current Phase: Notice of Drafting published April 27, 2018
Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies
Public Health

Summary:
Amend R.61-80 to address storage and usage provisions of the regulation by including a maximum length of time for storage of blood samples; and

Amend to allow for expanding testing to include other congenital disorders or metabolic diseases, while ensuring all testing procedures are in compliance with applicable standards.

Current Phase: Notice of Drafting published June 22, 2018

Standards for Licensing Facilities That Treat Individuals for Psychoactive Substance Abuse or Dependence
Health Regulation

Summary:
Amend R.61-93 for provisions relating to staffing, accident and incident reporting, emergency preparedness, construction, and licensure requirements for facilities that treat individuals for psychoactive substance abuse or dependence.

Current Phase: Notice of Drafting published June 22, 2018

South Carolina Immunization Registry
Public Health

Summary:
Amend R.61-120 to allow DHEC to provide specific Healthcare Effectiveness Data and Information Set ("HEDIS") data from the South Carolina Immunization Registry ("Registry") to health plans; and
Amend to detail the availability and use of a new patient portal, clarify patient consent for the new patient portal, and revise the regulation to conform with updates and improvements to the Registry and advancements in public health practice.

**Current Phase:** Notice of Drafting published April 27, 2018
Repeals of Existing Regulations

Retail Food Establishment Inspection Fees
Environmental Affairs

Summary:
Repeal R.61-37, as amendments to R.61-25, Retail Food Establishments, will incorporate an amended fee scale and fee increase (see page 8). The fee scale currently appears in R.61-37.

Current Phase: Notice of Drafting published April 27, 2018

Septic Tank Site Evaluation Fees
Environmental Affairs

Summary:
Repeal R.61-55, as amendments to R.61-56, Onsite Wastewater Systems, will incorporate amended definitions, a fee increase, a new expedited permitting process, and service application fees (see page 8). These provisions currently appear in R.61-55.

Current Phase: Notice of Drafting published April 27, 2018

License to Construct or Clean Onsite Wastewater Sewage Treatment and Disposal Systems and Self-Contained Toilets
Environmental Affairs

Summary:
Repeal R.61-56.1, as amendments to R.61-56, Onsite Wastewater Systems, will incorporate revised licensing and fee requirements for pumpers and haulers (see page 8). These fees currently appear in R.61-56.1.

Current Phase: Notice of Drafting published April 27, 2018
Licensure of Onsite Wastewater System Contractors
Environmental Affairs

Summary:
Repeal R.61-56.2, as amendments to R.61-56, Onsite Wastewater Systems, will incorporate a new tiered licensing program (see page 8). The existing licensure system appears in R.61-56.2.

Current Phase: Notice of Drafting published April 27, 2018

Requirements for State Water Pollution Control Revolving Fund Loan Assistance
Environmental Affairs

Summary:
Repeal R.61-67.1 due to the repeal of its original authorizing statute. The fund is currently effectively administered through another statute; other existing state laws and regulations; and federal laws, regulations, and grant requirements.

Current Phase: Notice of Drafting published June 22, 2018
Listed below by area of administration are all current DHEC regulations and dates of their last permanent amendments, or revisions made through errata, as of June 30, 2018.

### Chief Financial Officer

**Budgets and Financial Planning**

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-1</td>
<td>Medical and Dental Scholarship Fund</td>
<td>05/25/1974</td>
</tr>
</tbody>
</table>

### General Counsel

**General Counsel**

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-117</td>
<td>Access to Restricted Information</td>
<td>05/25/2012</td>
</tr>
</tbody>
</table>

### Environmental Affairs

**Environmental Affairs Administration**

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-30</td>
<td>Environmental Protection Fees</td>
<td>06/27/2014</td>
</tr>
<tr>
<td>61-115</td>
<td>Environmental Electronic Reporting Requirements</td>
<td>05/23/2008</td>
</tr>
</tbody>
</table>

### Air Quality

**Air Pollution Control Regulations and Standards**

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-62</td>
<td>Air Pollution Control Regulations and Standards</td>
<td></td>
</tr>
<tr>
<td>61-62.1</td>
<td>Definitions and General Requirements</td>
<td>08/25/2017</td>
</tr>
<tr>
<td>61-62.2</td>
<td>Prohibition of Open Burning</td>
<td>12/27/2013</td>
</tr>
<tr>
<td>61-62.3</td>
<td>Air Pollution Episodes</td>
<td>04/26/2013</td>
</tr>
<tr>
<td>61-62.4</td>
<td>Hazardous Air Pollution Conditions</td>
<td>09/28/2012</td>
</tr>
<tr>
<td>61-62.5</td>
<td>Air Pollution Control Standards</td>
<td></td>
</tr>
<tr>
<td>Standard No. 2</td>
<td>Ambient Air Quality Standards</td>
<td>09/23/2016</td>
</tr>
<tr>
<td>Standard No. 3</td>
<td>Waste Combustion and Reduction</td>
<td>09/23/2016</td>
</tr>
<tr>
<td>Standard No. 3.1</td>
<td>Hospital, Medical, Infectious Waste Incinerators (HMIWI)</td>
<td>09/23/2016</td>
</tr>
<tr>
<td>Standard No. 4</td>
<td>Emissions from Process Industries</td>
<td>09/23/2016</td>
</tr>
<tr>
<td>Standard No. 5</td>
<td>Volatile Organic Compounds</td>
<td>11/27/2015</td>
</tr>
<tr>
<td>Standard No. 5.1</td>
<td>Reserved</td>
<td></td>
</tr>
</tbody>
</table>
Standard No. 5.2  Control of Oxides of Nitrogen (NO\textsubscript{X})  08/25/2017
Standard No. 6  Reserved
Standard No. 7  Prevention of Significant Deterioration  08/25/2017
Standard No. 7.1  Nonattainment New Source Review  11/27/2015
Standard No. 8  Toxic Air Pollutants  06/26/2015
61-62.6  Control of Fugitive Particulate Matter  11/27/2015
61-62.7  Good Engineering Practice Stack Height  12/28/2012
61-62.60  South Carolina Designated Facility Plan and New Source Performance Standards  08/25/2017
61-62.61  National Emission Standards for Hazardous Air Pollutants (NESHAP)  08/25/2017
61-62.63  National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories  08/25/2017
61-62.68  Chemical Accident Prevention Provisions  09/24/2004
61-62.70  Title V Operating Permit Program  08/25/2017
61-62.72  Acid Rain  04/26/2013
61-86.1  Standards of Performance for Asbestos Projects  05/27/2011
61-62.96  Nitrogen Oxides (NO\textsubscript{X}) and Sulfur Dioxide (SO\textsubscript{2}) Budget Trading Program  04/26/2013
61-62.97  Cross-State Air Pollution Rule (CSAPR) Trading Program  08/25/2017
61-62.99  Nitrogen Oxides (NO\textsubscript{X}) Budget Program Requirements for Stationary Sources Not in the Trading Program  06/22/2012

Environmental Health Services
61-25  Retail Food Establishments  04/24/2015
61-29  Environmental Health Inspections and Fees  06/26/1992
61-32  Soft Drink and Water Bottling Plants  05/28/2004
61-34  Raw Milk for Human Consumption  06/26/2009
61-34.1  Pasteurized Milk and Milk Products  06/26/2015
61-36  Frozen Desserts  05/28/2004
61-37  Retail Food Establishment Inspection Fees  06/28/2002
61-54  Wholesale Commercial Ice Manufacturing  05/23/2008
61-55  Septic Tank Site Evaluation Fees  06/22/2007
61-56  Onsite Wastewater Systems  05/27/216
61-56.1  License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets  05/27/1994
61-56.2  Licensure of Onsite Wastewater System Contractors  06/26/2009
61-81  State Environmental Laboratory Certification Program  04/11/1980
## Land and Waste Management

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-33</td>
<td>Drycleaning Facility Restoration</td>
<td>05/26/2017</td>
</tr>
<tr>
<td>61-63</td>
<td>Radioactive Materials (Title A)</td>
<td>04/27/2018</td>
</tr>
<tr>
<td></td>
<td>*co-managed with Radiological Health</td>
<td></td>
</tr>
<tr>
<td>61-79</td>
<td>Hazardous Waste Management Regulations</td>
<td>05/27/2016</td>
</tr>
<tr>
<td>61-83</td>
<td>Transportation of Radioactive Waste Into or Within South Carolina</td>
<td>10/27/2006</td>
</tr>
<tr>
<td>61-92</td>
<td>Underground Storage Tank Regulations</td>
<td>08/25/2017</td>
</tr>
<tr>
<td>61-104</td>
<td>Hazardous Waste Management Location Standards</td>
<td>02/22/1991</td>
</tr>
<tr>
<td>61-105</td>
<td>Infectious Waste Management</td>
<td>06/25/2010</td>
</tr>
<tr>
<td>61-107</td>
<td>Solid Waste Management</td>
<td></td>
</tr>
<tr>
<td>61-107.2</td>
<td>Full Cost Disclosure</td>
<td>04/23/1993</td>
</tr>
<tr>
<td>61-107.3</td>
<td>Waste Tires</td>
<td>06/26/2015</td>
</tr>
<tr>
<td>61-107.4</td>
<td>Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residuals</td>
<td>06/27/2014</td>
</tr>
<tr>
<td>61-107.5</td>
<td>Collection, Temporary Storage, and Transportation of Municipal Solid Waste</td>
<td>05/28/1993</td>
</tr>
<tr>
<td>61-107.6</td>
<td>Solid Waste Processing Facilities</td>
<td>06/23/1995</td>
</tr>
<tr>
<td>61-107.7</td>
<td>Transfer of Solid Waste</td>
<td>05/28/1993</td>
</tr>
<tr>
<td>61-107.8</td>
<td>Lead-Acid Batteries</td>
<td>06/23/1995</td>
</tr>
<tr>
<td>61-107.9</td>
<td>White Goods</td>
<td>06/25/1993</td>
</tr>
<tr>
<td>61-107.10</td>
<td>Research, Development, and Demonstration Permit Criteria</td>
<td>06/25/1993</td>
</tr>
<tr>
<td>61-107.12</td>
<td>Solid Waste Incineration and Solid Waste Pyrolysis Facilities</td>
<td>06/24/2016</td>
</tr>
<tr>
<td>61-107.15</td>
<td>Land Application of Solid Waste</td>
<td>07/26/1996</td>
</tr>
<tr>
<td>61-107.17</td>
<td>Demonstration of Need</td>
<td>06/26/2009</td>
</tr>
<tr>
<td>61-107.18</td>
<td>Off-site Treatment of Contaminated Soil</td>
<td>05/25/2001</td>
</tr>
<tr>
<td>61-107.19</td>
<td>Solid Waste Landfills and Structural Fill</td>
<td>05/23/2008</td>
</tr>
<tr>
<td>61-107.279</td>
<td>Used Oil</td>
<td>06/24/2016</td>
</tr>
<tr>
<td>61-124</td>
<td>Consumer Electronic Equipment Collection and Recovery</td>
<td>02/26/2016</td>
</tr>
<tr>
<td>89-10</td>
<td>Office of the Governor – Mining Council of South Carolina</td>
<td>06/27/2003</td>
</tr>
<tr>
<td>121-8.0 - 121-8.28</td>
<td>Oil and Gas Exploration, Drilling, and Production</td>
<td>09/28/1984</td>
</tr>
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</table>

## Water

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-450</td>
<td>Permits for Construction in Navigable Waters</td>
<td>06/23/1995</td>
</tr>
</tbody>
</table>
61-9 Water Pollution Control Permits 06/27/2014
61-44 Permitting of Individual Residential Wells and Irrigation Wells 06/25/1999
61-47 Shellfish 05/26/2017
61-50 Natural Public Swimming Areas 05/27/2016
61-51 Public Swimming Pools 06/27/2014
61-58 State Primary Drinking Water Regulations 09/26/2014
61-67 Standards for Wastewater Facility Construction 06/26/2015
61-67.1 State Water Pollution Control Revolving Fund Loan Assistance 06/24/1988
61-68 Water Classification and Standards 06/27/2014
61-69 Classified Waters 06/22/2012
61-71 Well Standards 06/24/2016
61-82 Proper Closeout of Wastewater Treatment Facilities 04/11/1980
61-87 Underground Injection Control Regulations 01/25/2002
61-101 Water Quality Certification 06/23/1995
61-110 Total Maximum Daily Loads (TMDLs) for Pollutants in Water 05/27/2005
61-113 Groundwater Use and Reporting 06/23/2006
61-119 Surface Water Withdrawal, Permitting, Use, and Reporting 06/22/2012
72-1 - 72-9 Dams and Reservoirs Safety Act Regulations 07/25/1997
72-300 - 72-316 Standards for Stormwater Management and Sediment Reduction 06/28/2002

Ocean and Coastal Resource Management
30-1 Statement of Policy 06/24/2016
30-2 Applying for a Permit 06/28/2002
30-3 Public Hearings 06/25/1999
30-4 Decisions on a Permit 03/26/2004
30-5 Exceptions 06/24/2016
30-6 Appeals of Permit Decisions 04/25/2008
30-8 Enforcement 04/25/2008
30-9 Other Provisions 06/24/2016
30-10 Critical Area Boundaries 06/25/1999
30-11 General Guidelines for All Critical Areas 06/25/1999
30-12  Specific Project Standards for Tidelands and Coastal Waters  04/25/2008
30-13  Specific Project Standards for Beaches and the Beach/Dune System  06/24/2016
30-14  Administrative Procedures  04/25/2008
30-15  Activities Allowed Seaward of Baseline  06/24/2016
30-16  Documentation Requirements Before Commencing Activities Between Setback Line and Baseline  06/25/1999
30-17  Application Procedures for General Permits Pursuant to Section 48-39-290(B)(4)  06/25/1999
30-18  Beachfront Restoration Fund  06/25/1999
30-21  Beachfront Management Plan  05/28/1993

## Health Regulation

### Drug Control
61-4  Statement of Policy  06/28/2013

### Emergency Medical Services, Trauma, and Athletic Trainers
61-7  Emergency Medical Services  06/24/2016
61-96  Athletic Trainers  06/26/2015
61-116  South Carolina Trauma System  05/27/2016
61-118  South Carolina Stroke Care System  05/25/2018

### Health Facilities Licensing
61-3  The Practice of Selling and Fitting Hearing Aids  01/22/1988
61-12  Standards for Licensing Abortion Clinics  06/28/1996
61-13  Standards for Licensing Intermediate Care Facilities for Individuals with Intellectual Disabilities  05/27/2016
61-15  Certification of Need for Health Facilities and Services  05/25/2012
61-16  Minimum Standards for Licensing Hospitals and Institutional General Infirmaries  05/25/2018
61-17  Standards for Licensing Nursing Homes  03/25/2016
61-24  Licensed Midwives  06/28/2013
61-31  Health Care Cooperative Agreements  06/25/2010
61-75  Standards for Licensing Day Care Facilities for Adults  06/26/2015
61-77  Standards for Licensing Home Health Agencies  05/28/1999
61-78  Standards for Licensing Hospices  06/22/2018
61-84  Standards for Licensing Community Residential Care Facilities  09/25/2015
61-91  Ambulatory Surgical Facility  06/26/2015
<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-93</td>
<td>Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence</td>
<td>06/26/2015</td>
</tr>
<tr>
<td>61-95</td>
<td>Medicaid Nursing Home Permits</td>
<td>05/26/1989</td>
</tr>
<tr>
<td>61-97</td>
<td>Standards for Licensing Renal Dialysis Facilities</td>
<td>06/25/2010</td>
</tr>
<tr>
<td>61-102</td>
<td>Standards for Licensing Birthing Centers for Deliveries by Midwives</td>
<td>06/25/2010</td>
</tr>
<tr>
<td>61-103</td>
<td>Residential Treatment Facilities for Children and Adolescents</td>
<td>06/24/2016</td>
</tr>
<tr>
<td>61-108</td>
<td>Standards for Licensing Freestanding or Mobile Technology</td>
<td>05/28/2004</td>
</tr>
<tr>
<td>61-109</td>
<td>Standards for Permitting Body Piercing Facilities</td>
<td>05/27/2016</td>
</tr>
<tr>
<td>61-111</td>
<td>Standards for Licensing Tattoo Facilities</td>
<td>05/27/2016</td>
</tr>
<tr>
<td>61-122</td>
<td>Standards for Licensing In-home Care Providers</td>
<td>06/27/2014</td>
</tr>
<tr>
<td>61-123</td>
<td>Critical Congenital Heart Defects Screening on Newborns</td>
<td>06/27/2014</td>
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**Radiological Health**

<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>61-63</td>
<td>Radioactive Materials (Title A)*</td>
<td>04/27/2018</td>
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<tr>
<td></td>
<td>*co-managed with Land and Waste</td>
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<tr>
<td>61-64</td>
<td>X-Rays (Title B)</td>
<td>06/24/2016</td>
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<tr>
<td>61-65</td>
<td>Particle Accelerators (Title C)</td>
<td>06/26/2015</td>
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<tr>
<td>61-106</td>
<td>Tanning Facilities</td>
<td>05/23/2008</td>
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**Public Health**

**Disease Control**

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<th>No.</th>
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<tr>
<td>61-8</td>
<td>Immunization Requirements for School and Childcare Attendance</td>
<td>07/25/2014</td>
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<tr>
<td>61-20</td>
<td>Communicable Diseases</td>
<td>06/24/2016</td>
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<tr>
<td>61-21</td>
<td>Sexually Transmitted Diseases</td>
<td>06/24/2016</td>
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<tr>
<td>61-22</td>
<td>The Evaluation of School Employees for Tuberculosis</td>
<td>05/26/2017</td>
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<td>61-120</td>
<td>South Carolina Immunization Registry</td>
<td>05/24/2013</td>
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**Maternal and Child Health**

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<tr>
<td>61-80</td>
<td>Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies</td>
<td>06/27/2003</td>
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<tr>
<td>61-94</td>
<td>WIC Vendors</td>
<td>05/26/2017</td>
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<tr>
<td>61-114</td>
<td>South Carolina Birth Defects Program</td>
<td>05/23/2008</td>
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**Public Health Statistics and Information Services**

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<thead>
<tr>
<th>No.</th>
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<tbody>
<tr>
<td>61-19</td>
<td>Vital Statistics</td>
<td>06/24/2016</td>
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<tr>
<td>61-45</td>
<td>South Carolina Central Cancer Registry</td>
<td>06/26/1998</td>
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### Public Health Preparedness

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<thead>
<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>61-23</td>
<td>Control of Anthrax</td>
<td>07/01/1960</td>
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For more DHEC Regulation information, visit:

www.scdhec.gov/Agency/RegulationsAndUpdates/