



DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
FY2015 REGULATION DEVELOPMENT ANNUAL REPORT
(July 25, 2014 - June 26, 2015)

June 26, 2015

The Department of Health and Environmental Control (DHEC) promulgates regulations each fiscal year subject to the S.C. Administrative Procedures Act (APA), S.C. Code Ann. Section 1-23-10 *et seq.* The Department's regulatory activity for FY2015 addressed sixty-seven of its regulations, proposing two new regulations, fourteen regulations for repeal and fifty-one regulations for amendment. Thirty proposed regulations of the overall total were carried over from FY2014 for continuation of the APA promulgation process in FY2015.

Part I of this report describes DHEC regulations taking legal effect in FY2015 after publication in the *State Register*. Part II reports the status of the proposed regulations not taking effect this period that were tolled, permanently withdrawn or disapproved by Joint Resolution and tolled at the legislative level. The Department also issued two emergency regulations described in Part III. Part IV lists proposed regulations not yet in effect, which the Department intends to carry over to FY2016 for promulgation, amendment or repeal.

PART I

FINAL REGULATIONS

The Department repealed three regulations and amended sixteen regulations during FY2015, as follows:

DHEC Office of General Counsel

R.61-72, Procedures for Contested Cases

This Regulation was repealed by Document No. 4466 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The repeal can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4466.docx>. Adjudicatory hearings as prescribed in R.61-72 no longer occur due to the statutory creation of the Administrative Law Court ("ALC") and 1976 Code Section 44-1-60 providing for ALC review of final agency decisions. As such, R.61-72 has no legal effect and was repealed because it is no longer needed.

DHEC Environmental Affairs

Air Quality

R.61-62, Air Pollution Control Regulations and Standards

This Regulation was amended by Document No. 4465 that took effect by publication in *State Register* Volume 38 Issue 9 on September 26, 2014. These amendments did not require legislative review pursuant to 1976 S.C. Code

Section 1-23-120(H) and can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4465.docx>. R.61-62.5, Standard No. 2, *Ambient Air Quality Standards*, was amended to incorporate the U.S. Environmental Protection Agency's revision to the National Ambient Air Quality Standards for Fine Particulate Matter ("PM_{2.5}"), Sulfur Dioxide ("SO₂"), and Nitrogen Dioxide ("NO₂") set forth in 40 C.F.R. Part 50. Revisions also amend R. 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*, and R. 61-62.63, *National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Source Categories*, to incorporate by reference recent federal amendments promulgated from January 1, 2013 through December 31, 2013.

R.61-62, Air Pollution Control Regulations and Standards

This Regulation was amended by Document No. 4481 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. These amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4481.docx>. Regulations 61-62.5, Standards 1, 2, 7, 7.1, and 8, 61-62.60, and 61-62.70 were revised, and R.61-62.5 Standard 5.1 was repealed. The amendments will support the Department's goal of promoting and protecting the health of the public and the environment in a more efficient and effective manner. These amendments will expand and clarify definitions applicable to air pollution control regulations and standards; streamline permitting options; clarify reporting requirements; and provide corrections for consistency and clarification to improve the overall regulation.

Environmental Health Services

R.61-34.1, Pasteurized Milk and Milk Products

This Regulation was amended and replaced in its entirety by Document No. 4497 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4497.docx>. This Regulation was amended to ensure that consumers are receiving safe, high quality grade milk and milk products and that proper sanitation requirements are being met by the dairy industry. The Regulation governs the manufacturing of pasteurized milk and milk products in South Carolina. The amendment of R.61-34.1 will meet the current standards of the most recent edition of the United States Public Health Service, United States Food and Drug Administration (FDA) *Grade "A" Pasteurized Milk Ordinance (PMO), 2013 Revision*, inclusive of its associated documents.

Land and Waste Management

R.61-79, Hazardous Waste Management Regulations

This Regulation was amended by Document No. 4541 that took effect by publication in Volume 39 Issue 6 of the *State Register* on June 26, 2015. These amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4541.docx>. The amendments provide opportunities for the regulated community to use best demonstrated available technologies for treatment of a specific type of waste while reducing compliance costs for industry, revise the definition of solid waste, and make technical corrections and correct typographical errors. Amendments adopt the following: "Removal of Saccharin and Its Salts from the Lists of Hazardous Constituents," published on January 18, 2011, at 75 FR 78918-78926; "Academic Laboratories Generator Standards Technical Corrections," published in the Federal Register on December 20, 2010 at 75 FR 79304-79308; "Revision of the Land Disposal Treatment Standards for Carbamate Wastes," published in the Federal Register on June 13, 2011 at 76 FR 34147-34157; and "Hazardous Waste Technical Corrections and Clarifications," published in the Federal Register on May 14, 2012 at 77 FR 22229-22232.

R.61-107.3, Solid Waste Management: Waste Tires

This section of the Solid Waste Management Regulations at 61-107 was amended and replaced in its entirety by Document No. 4542. This amendment took effect by publication in Volume 39 Issue 6 of the *State Register* on June 26, 2015. The regulation revision can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4542.docx>. This amendment supports the Department's goal of promoting and protecting the health of the public and the environment by ensuring waste tires are managed properly. This

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amendment expands and clarifies definitions applicable to waste tire management; expands and clarifies the operational, permitting and registration requirements for haulers, collectors and processors of waste tires; and establishes bonding requirements for certain waste tire haulers. The amendment expands and clarifies exemptions to the regulation; clarifies reporting and record keeping; clarifies penalties for violations; and provides corrections for consistency, clarity, and formatting to improve the overall text of R.61-107.3.

Water

R.61-47, Shellfish

This Regulation was amended by Document No. 4483 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The amendments can be viewed on the S.C. Legislature Online website at:

<http://www.scstatehouse.gov/regs/4483.docx>. Amendments update R.61-47 for consistency with the latest version of the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish* (2013). The amendments include changes to certain control measures intended to limit the growth of pathogens after the harvest of shellfish, a simplification of the retagging requirements for certified reshippers, a requirement for certified shippers to receive annual training for the safe and sanitary handling of shellfish, and stylistic changes were made including corrections for spelling, clarity, readability, grammar, and codification for overall improvement of the text of the Regulation.

R.61-58, State Primary Drinking Water Regulations

This Regulation was amended by Document No. 4469 that took effect by publication in *State Register* Volume 39 Issue 6 on September 26, 2014. These amendments did not require legislative review pursuant to 1976 S.C. Code Section 1-23-120(H) and can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4469.docx>. This amendment adopts the “Revisions to the Total Coliform Rule” found in 40 CFR 141 to maintain conformity with federal regulations and will maintain the Department’s primary enforcement authority for the drinking water supervision program. Adoption of this rule is intended to offer a meaningful opportunity for greater public health protection beyond the 1989 Total Coliform Rule. Under this new rule, there is no longer a monthly maximum contaminant level (MCL) violation for total coliform detections. Instead, the revisions require systems that have an indication of coliform contamination in the distribution system to assess the problem and take corrective action.

R.61-67, Standards for Wastewater Facility Construction

This Regulation was amended by Document No. 4485 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. These amendments can be viewed on the S.C. Legislature Online website at:

<http://www.scstatehouse.gov/regs/4485.docx>. Amendments are intended to reduce unit loading flows in Appendix A of R.61-67 by 25 percent based on the knowledge of water savings fixtures and improved designs of sewer collection systems. For ease of implementation, the loading was rounded to the nearest whole number. The revisions also include having a service connection definition similar to the definition for a drinking water service connection, reducing the number of plans and other documents that need to be submitted, revisions to streamline industrial pump and haul operations and allowing issuance of a treatment plant permit coincident with a discharge permit. This revision includes a minor language change for clarification and a stylistic change to the table in Appendix A and Section 67.100.E.4.b(5) and (6). Language related to permit appeals was removed so as to ensure consistency with current law.

DHEC Public Health Regulations

Drug Control

R.61-11, Hypodermic Devices

This Regulation was repealed by Document No. 4468 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The repeal can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4468.docx>. R.61-11 was promulgated pursuant to Article 7, Title 44, Chapter 53, “Hypodermic Needles and Syringes.” The Article was repealed by 2002 Act No. 365, Section 5, effective September 26, 2002, with the exception of Section 44-53-930 addressing retail sales by pharmacists, Section 44-53-

950 excepting veterinarians and licensed durable medical equipment providers, and Section 44-53-960 outlining penalties. With repeal of the authorizing statute, R.61-11 is no longer enforceable or needed.

R.61-18, *Drugs and Devices*

This Regulation was repealed by Document No. 4468 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The repeal can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4468.docx>. R.61-18 was promulgated pursuant to Title 39, Chapter 23, “Adulterated, Misbranded or New Drugs and Devices.” This regulation is not necessary because the items it regulates are currently addressed in state statute and federal law. As such, in the interest of good government and efficiency, this regulation was repealed.

Health Facilities & Services

R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*

This Regulation was amended by Document 4461 that took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4461.docx>. This revision is limited to the Perinatal Care Services section of R.61-16 to account for evolving practices and to improve overall quality and effectiveness.

R.61-75, *Standards for Licensing Day Care Facilities for Adults*

This Regulation was amended by Document 4498, replacing R.61-75 in its entirety, and took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. These amendments can be reviewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4498.docx>. The amendments clarify regulations pertaining to facilities for adults 18 years of age or older, which offer in a group setting a program of individual and group activities and therapies that are affected by this Regulation. The revisions include the Department’s effort to improve licensing procedures, care of participants, infection control and sanitation, functional safety, emergency procedures, design and construction, fire and life safety, and overall licensing requirements for day care facilities for adults. In addition, corrections were also made for clarity and readability, grammar, references, codification and overall improvement to the text of the regulation.

R.61-84, *Standards for Licensing Community Residential Care Facilities*

This Regulation revision was amended by Document 4484, replacing R.61-84 in its entirety, and took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. These amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4484.docx>. Community residential care facilities are facilities which offer room and board and which, unlike a boarding house, provide/coordinate a degree of personal care for a period of time in excess of 24 consecutive hours for two or more persons, 18 years old or older, not related to the licensee within the third degree of consanguinity. A facility is designed to accommodate residents’ changing needs and preferences, maximize residents’ dignity, autonomy, privacy, independence, and safety, and encourage family and community involvement. The amendments include the Department’s effort to incorporate provisions relating to statutory mandates, medication management, meal service, emergency procedures, design and construction, fire and life safety, and overall licensing requirements for community residential care facilities. In addition, corrections were also made for clarity and readability, grammar, references, codification and overall improvement to the text of the regulation.

R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*

This Regulation was amended by Document No. 4471, replacing R.61-91 in its entirety, and took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4471.docx>. These revisions will support the Department’s goal of promoting and protecting the health of the public in a more efficient and effective manner. The amendments clarify and expand the definitions, particularly the definition of “same day,” revise the codes for fire and life safety and for design and construction. In addition, corrections were made for clarity and readability, grammar, references, codification and overall improvement to the text of the regulation.

R.61-93, *Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence*

This Regulation was amended by Document No. 4464 and took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4464.docx>. These amendments will provide a set of minimum licensing standards for facilities that treat individuals for psychoactive substance abuse or dependence. Psychoactive substance abuse or dependence facilities provide specialized structured psychoactive substance abuse/dependence care/treatment. Outpatient services will include narcotic and methadone treatment programs, and inpatient services–will include residential treatment and/or detoxification. The amendment revises the language regarding urine testing and removes unduly financial burden on entities involved in licensee change. In addition, stylistic changes were included for corrections for clarity and readability, grammar, references, codification and overall improvement of the text of the regulation.

R.61-96, *Athletic Trainers*

This Regulation was amended by *State Register* Document No. 4496, replacing R.61-96 in its entirety, and took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 2015. The revised regulation can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4496.docx>. These amendments are intended to ensure the highest degree of professional conduct by those engaged in offering athletic trainer services to the public and to safeguard the public's health, safety, and welfare by establishing minimum qualifications for those individuals wishing to offer athletic trainer services to the public. This amendment updates the nomenclature and license renewal notification requirements. In addition, stylistic changes were included for corrections for clarity, readability, grammar and overall improvement of the text of the regulation.

Radiological Health

R.61-63, *Radioactive Materials (Title A)*

This Regulation was amended by Document No. 4462 that took effect by publication in *State Register* Volume 38 Issue 10 on October 24, 2014. The amendments did not require legislative review pursuant to 1976 S.C. Code Section 1-23-120(H) and can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4462.docx>. These amendments incorporate federal regulations to maintain conformity and ensure compliance with federal requirements found in 10 CFR Parts 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 51, 70, and 71 and as required by Section 274 of the Atomic Energy Act of 1954. Rules adopted are as follows: Decommissioning Planning (RATS-ID 2011-1), Licenses, Certifications, and Approvals for Materials Licensees (RATS-ID 2011-2), Technical Corrections (RATS-ID 2012-3), Requirements for Distribution of Byproduct Material (RATS-ID 2012-4), Physical Protection of Byproduct Material (RATS-ID 2013-1), and Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions (RATS-ID 2013-2). These final rules were published in the Federal Register at 76 FR 35512 on June 17, 2011, 76 FR 56951 on September 15, 2011, 77 FR 39899 on July 6, 2012, 77 FR 43666 on July 25, 2012, 78 FR 16922 on March 19, 2013, and 78 FR 32310 on May 29, 2013, respectively.

R.61-65, *Particle Accelerators (Title C)*

This Regulation was amended by Document No. 4482, replacing R.61-65 in its entirety, and took effect by publication in *State Register* Volume 39 Issue 6 on June 26, 201. The amendments can be viewed on the S.C. Legislature Online website at: <http://www.scstatehouse.gov/regs/4482.docx>. General areas of this revision include: clarifying and simplifying the regulations, adding new definitions as required and deleting regulations that are no longer applicable. Specific areas include the added requirement for ventilation systems for particle accelerators that create radioactive material, clarifying required and/or accepted interlock systems, and clarifying the requirements and responsibilities of the Radiation Safety Officer. In addition, amendments include amending the fee structure in accordance with the governing statute. Also, stylistic changes were made for clarity, readability, grammar, punctuation, definitions, references, codification and overall improvement of the text of the regulation.

PART II

TOLLED, PERMANENTLY WITHDRAWN, AND JOINT RESOLUTIONS TO DISAPPROVE REGULATIONS AT THE LEGISLATIVE LEVEL

Senate Agriculture and Natural Resources Committee Request Withdraw for Change - Regulation Tolled:

State Register Document No. 4539, proposed new R.61-124, *Consumer Electronic Equipment Collection and Recovery*. Pursuant to the request of the Senate Agriculture and Natural Resources Committee by letter dated May 12, 2015, the Department intends to formally withdraw and resubmit a revised regulation in January of 2016 at which time the toll on Document No. 4539 will be lifted, and the legislative review period will resume.

Regulation Permanently Withdrawn by DHEC: *State Register* Document No. 4540, proposed amendment of R.61-7, *Emergency Medical Services*, was permanently withdrawn on May 14, 2015 by the Department due to *State Register* technical issues. The Department intends to reinitiate the APA promulgation process in FY2016 to amend this regulation.

House Medical, Military, Public and Municipal Affairs Committee Joint Resolution 3750 to Disapprove Regulation: *State Register* Document No. 4551, proposed amendment of R.61-15, *Certification of Health Facilities and Services*, was tolled pursuant to Joint Resolution 3750 to disapprove it. This Resolution was introduced in the House of Representatives on March 3, 2015, was read a third time in the House on March 6, 2015, and was sent to the Senate (House Journal-page 2). The Resolution was introduced in the Senate on March 10, 2015, was read a first time, and sent to the Committee on Medical Affairs (Senate Journal-page 15).

Senate Medical Affairs Committee Joint Resolution 811 to Disapprove Regulation: *State Register* Document No. 4538, proposed amendment of R.61-15, *Certification of Health Facilities and Services*, was tolled pursuant to Joint Resolution 811 to disapprove it. The Resolution was introduced on May 21, 2015 in the Senate, read a first time, and placed on the calendar without reference (Senate Journal-page 3).

PART III

EMERGENCY REGULATIONS

State Register Document No. 4526, Emergency Regulation for R.61-15, *Certification of Need for Health Facilities and Services* (Effective November 14, 2014 for 90 days)

To view, go to <http://www.scstatehouse.gov/regs/4526.docx>

State Register Document No. 4559, Refiling of Emergency Regulation for R.61-15, *Certification of Need for Health Facilities and Services* (Effective December 29, 2014 for 90 days)

To view, go to <http://www.scstatehouse.gov/regs/4559.docx>

PART IV

PENDING PROPOSED REGULATIONS

As of June 26, 2015, below listed are the Department's proposed regulations yet to take effect, which the Department intends to carry over into FY2016 for promulgation, amendment or repeal. Additional detail regarding the status of each proposed regulation, as well as the status of any new proposals that may be added after June 26, 2015, will be published in the monthly *DHEC Regulation Development Update* at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>. The FY2016 regulation development promulgation period runs from July 24, 2015 through June 24, 2016. The first issue of the *DHEC Regulation Development Update* for FY2016 is July 24, 2015.

Proposed Repeals

Proposed Repeal of R.61-28, *Horse Meat and Kangaroo Meat*
Proposed Repeal of R.61-38, *Fairs, Camp Meetings, and other Gatherings*
Proposed Repeal of R.61-39, *Camps*
Proposed Repeal of R.61-40, *Mobile/Manufactured Home Park*
Proposed Repeal of R.61-42, *Sanitation of Schools*
Proposed Repeal of R.61-46, *Nuisances*
Proposed Repeal of R.61-49, *Crabmeat*
Proposed Repeal of R.61-52, *Psittacine Birds*
Proposed Repeal of R.61-57, *Development of Subdivision Water Supply and Sewage Treatment/Disposal Systems*
Proposed Repeal of R.61-88, *Charges for Maternal and Child Health Services*
Proposed Repeal of R.61-89, *Charges for Family Planning Services*

Proposed New Regulations

Proposed New Regulation for the manufacturer of butter and cheese
Proposed New Regulation for Consumer Electronic Equipment Collection and Recovery

Proposed Amendments

Proposed Amendment of DHEC—Coastal Division R.30-1, *Statement of Policy*
Proposed Amendment of DHEC—Coastal Division R.30-5, *Exceptions*
Proposed Amendment of DHEC—Coastal Division R.30-9, *Other Provisions*
Proposed Amendment of DHEC—Coastal Division R.30-13, *Specific Project Standards for Beaches and Dunes*
Proposed Amendment of DHEC—Coastal Division R.30-14, *Administrative Procedures*
Proposed Amendment of DHEC—Coastal Division R.30-15, *Activities Allowed Seaward of the Baseline*
Proposed Amendment of DHEC—Coastal Division R.30-16, *Documentation Requirements Before Commencing Activities Between Setback Line and Baseline*
Proposed Amendment of DHEC—Coastal Division R.30-21, *Beachfront Management Plan*
Proposed Amendment of R.61-3, *Hearing Aids*
Proposed Amendment of R.61-7, *Emergency Medical Services*
Proposed Amendment of R.61-12, *Standards for Licensing Abortion Clinics*
Proposed Amendment of R.61-13, *Standards for Licensing Habilitation Centers for Persons with Intellectual Disability or Persons with Related Conditions*
Proposed Amendment of R.61-17, *Standards for Licensing Nursing Homes*
Proposed Amendment of R.61-19, *Vital Statistics*
Proposed Amendment of R.61-20, *Communicable Diseases*

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Proposed Amendment of R.61-21, *Sexually Transmitted Diseases*

Proposed Amendment of R.61-22, *Evaluation of School Employees for Tuberculosis*

Proposed Amendment of R.61-24, *Licensed Midwives*

Proposed Amendment of R.61-33, *Drycleaning Facility Restoration*

Proposed Amendment of R.61-50, *Natural Public Swimming Areas*

Proposed Amendment of R.61-56, *Onsite Wastewater Systems*

Proposed Amendments of R.61-62, *Air Pollution Control Regulations and Standards*

Proposed Amendment of R.61-64, *X-rays*

Proposed Amendment of R.61-71, *Well Standards*

Proposed Amendment of R.61-78, *Standards for Licensing Hospices*

Proposed Amendment of R.61-92, *Underground Storage Tanks*

Proposed Amendment of R.61-94, *WIC Vendors*

Proposed Amendment of R.61-102, *Standards for Licensing Birthing Centers for Deliveries by Midwives*

Proposed Amendment of R.61-103, *Standards for Licensing Residential Treatment Facilities for Children and Adolescents*

Proposed Amendment of R.61-105, *Infectious Waste Management Regulations*

Proposed Amendment of R.61-107.12, *Solid Waste Management: Solid Waste Incineration and Solid Waste Pyrolysis Facilities*

Proposed Amendment of R.61-107.279, *Solid Waste Management: Used Oil*

Proposed Amendment of R.61-109, *Standards for Permitting Body Piercing Facilities*

Proposed Amendment of R.61-111, *Standards for Licensing Tattoo Facilities*

Proposed Amendment of R.61-116, *South Carolina Trauma Systems*