



Regulation Development Update

May 25, 2018

DHEC produces this Regulation Development Update within one business day of publication of the South Carolina State Register (the fourth Friday of each month).

The Update reports DHEC's regulation development activity, including proposed new regulations, amendments, and repeals of existing regulations, currently pending. Each entry presents a synopsis, status, and (upon assignment by the S.C. Legislative Council) a searchable S.C. State Register Document Number. Legislative Council assigns a Document Number at the Notice of Proposed Regulation stage of the regulation [promulgation process](#). The Document Number subsequently remains with the particular regulation development activity throughout the process.

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While DHEC has made every effort to maintain the accuracy of content presented in this Regulation Development Update, it reserves the right to correct errors when discovered.

TABLE OF CONTENTS

Program Areas with No Pending Regulation Development Activity	1
Program Areas with Pending Regulation Development Activity	
Environmental Affairs	
Air Quality	2
Ocean and Coastal Resource Management	5
Environmental Health Services	7
Land and Waste Management	10
Health Regulation	
Emergency Medical Services and Trauma	12
Health Facilities Licensing	13
Radiological Health	16
Public Health	
Public Health Statistics and Information Services	17

NO PENDING REGULATION DEVELOPMENT ACTIVITY FOR:

The following program areas have no pending regulation development activities at this time.

Chief Financial Officer

Budgets and Financial Management

General Counsel

Environmental Affairs

Environmental Affairs Administration
Water

Health Regulation

Certificate of Need
Drug Control

Public Health

Disease Control
Maternal and Child Health
Public Health Preparedness

There are no DHEC Emergency Regulations in effect at this time.

PENDING REGULATION DEVELOPMENT ACTIVITY FOR:

The following program areas have pending regulation development activities at this time.

ENVIRONMENTAL AFFAIRS

AIR QUALITY – Proposed Amendments

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

State Register Document TBD

Summary:

- (1) The Department proposes amending Regulation 61-62.1, Definitions and General Requirements, Section II, Permit Requirements, to expand and improve consistency in language regarding general and registration permits.
- (2) The Department proposes amending the introductory paragraph to Regulation 61-62.5, Standard No. 2, Ambient Air Quality Standards, to remove the sentence describing the test method for Gaseous Fluorides to improve the accuracy and clarity of the regulation's text.
- (3) The Department proposes amending Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NO_x), to update applicability and exemptions, as well as to propose corrections for internal consistency, punctuation, codification, and spelling.
- (4) The Department proposes amending Regulation 61-62.5, Standard No. 7, Prevention of Significant Deterioration, to update applicability and exemptions, as well as to propose corrections for internal consistency, punctuation, codification, and spelling.
- (5) The Department proposes amending Regulation 61-62.5, Standard No. 7.1, Nonattainment New Source Review (NSR), to improve the overall clarity and structure of the regulation, as well as to propose corrections for internal consistency, punctuation, codification, and spelling.
- (6) The Department proposes amending Regulation 61-62.70, Title V Operating Permit Program; Regulation 61-62.1, Definitions and General Requirements; Regulation 61-62.5, Standard No. 7, Prevention of Significant Deterioration; and Regulation 61-62.5, Standard No. 7.1, Nonattainment New Source Review (NSR), to update public participation procedures.

The Department may also propose other changes to Regulation 61-62, Air Pollution Control Regulations and Standards, that may include definitional updates, clarification of certain permitting provisions, and other changes or additions as deemed necessary, as well as corrections for internal consistency,

clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

History and Status:

Notice of Drafting published:

October 27, 2017

Drafting comment period closed:

November 27, 2017

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

State Register Document TBD

Summary:

The United States Environmental Protection Agency (“EPA”) promulgates amendments to the Code of Federal Regulations throughout each calendar year. Recent federal amendments to 40 CFR Parts 60, 61, and 63 include technical amendments regarding New Source Performance Standards, National Emission Standards for Hazardous Air Pollutants (NESHAP), and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories.

The Department proposes amending: 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; 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, 2017, through December 31, 2017. The Department also proposes changes to R. 61-62.68, Chemical Accident Prevention Provisions, to include corrections for internal consistency, clarification, chemical nomenclature, codification, and spelling to improve the overall text as necessary. Additionally, the Department proposes striking paragraph (a)(6) of Section 70.3, Applicability, in R.61-62.70, Title V Operating Permit Program, to maintain state compliance with federal regulations.

The Department also proposes the repeal of R.61-62.96, the Nitrogen Oxides (NO_x) and Sulfur Dioxide (SO₂) Budget Trading Program, in its entirety. The Department adopted R.61-62.97, the Cross-State Air Pollution Rule (CSAPR) Trading Program, on August 25, 2017. R.61-62.96 is based on the federal Clean Air Interstate Rule (“CAIR”), which EPA has since replaced with federal CSAPR requirements implemented by R.61-62.97. As a result, federal CAIR requirements implemented by R.61-62.96 are no longer in effect.

The Department may also propose federal law related changes to Regulation 61-62, Air Pollution Control Regulations and Standards, to include corrections for internal consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

In accordance with 1976 Code Section 1-23-120(H), legislative review is not required because the Department proposes promulgating the amendments to maintain compliance with federal law.

History and Status:

Notice of Drafting published:

March 23, 2018

Drafting comment period closed:

April 23, 2018

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OCEAN AND COASTAL RESOURCE MANAGEMENT – Proposed Amendment

R.30-14, Administrative Procedures (Coastal Division)

State Register Document 4810

Summary:

The Department of Health and Environmental Control (“Department”) proposes amending R.30-14, Administrative Procedures with respect to the review process for revising jurisdictional lines and erosion rates affecting beachfront properties. 1976 Code Section 48-39-280 requires the Department to establish and review the position of beachfront jurisdictional setback lines, baselines, and erosion rates once every seven (7) to ten (10) years. Existing Coastal Division Regulation 30-14.F provides that a landowner may request a review of the jurisdictional lines or erosion rate affecting his or her property within one (1) year of adoption. However, statutory changes under Act No. 387 of 2006 limit the review of a Department decision to fifteen (15) calendar days. This proposed regulatory amendment would clarify 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 Department’s Office of Ocean and Coastal Resource Management for staff determination. The amendment would provide landowners a timely review and would comply with Act No. 387 of 2006.

The Department published proposed revisions to the state’s beachfront jurisdictional setback lines, baselines and erosion rates on October 6, 2017. Based on comments received from landowners, community leaders, the conservation community and others during the initial 30-day public comment period, the Department extended the public comment period until April 6, 2018. Existing jurisdictional lines will remain in place until final revised lines are adopted.

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

Link to Notice of Final Regulation submitted for legislative review:

<http://www.scstatehouse.gov/regs/4810.docx>

***Note: This Notice of Final Regulation did not receive a joint resolution of approval or meet the requisite 120 days of legislative review. As such, the amendments have not taken legal effect.

History and Status:

Notice of Drafting published:	November 24, 2017
Drafting comment period closed:	December 27, 2017
Board approval to publish Notice of Proposed Regulation:	February 8, 2018
Notice of Proposed Regulation published:	February 23, 2018
Proposed Regulation comment period closed:	March 26, 2018
Public Hearing:	March 27, 2018
General Assembly review period of Notice of Final Regulation began:	March 28, 2018

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ENVIRONMENTAL HEALTH SERVICES – Proposed Amendments and Repeals

R.61-25, Retail Food Establishments

R.61-37, Retail Food Establishment Inspection Fees

State Register Document TBD

Summary:

Currently, R.61-25 is based on the 2013 Federal Food and Drug Administration (“FDA”) Food Code (“Food Code”), which the FDA has revised and replaced with the 2017 Food Code. The Department proposes amending R.61-25 to incorporate much of the revisions appearing in the 2017 Food Code. The Department further proposes amending the fee scale currently appearing in R.61-37, and, in the interest of efficiency, moving the amended fee scale to R.61-25 and repealing R.61-37. The amended fee scale would be a more concise scale based on process (risk) level or type of establishment, instead of the current eight-tiered gross sales method. The fee scale revision would also include a fee increase, as the Department has not updated the fees in approximately 18 years.

The Department may also include stylistic changes, such as corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

General Assembly review is required.

History and Status:

Notice of Drafting published:

April 27, 2018

Drafting comment period will close:

May 28, 2018

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R.61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products

R.61-36, Frozen Desserts

State Register Document TBD

Summary:

The Department proposes amending R.61-36 and the requirements of R.61-35. Currently, R.61-36 and R.61-35 are both based on 21 CFR Part 110, which has been replaced by 21 CFR Part 117. In the interest of efficiency, the Department proposes repealing R.61-35 and merging its amended requirements into R.61-36. The Department further proposes adding requirements for manufacturing cheese, butter, and other non-grade “A” milk products to R.61-36 and renaming the regulation R.61-36, Manufactured Grade Dairy

Products. The South Carolina Department of Agriculture previously regulated these products (also based on 21 CFR Part 110), but, going forward, oversight will reside with the DHEC pursuant to an agreement between the two agencies.

In addition to revising and adding standards, the proposed amendments will provide for an initial permit fee and annual renewal fee to support Department implementation.

The Department may also include stylistic changes, such as corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

General Assembly review is required.

History and Status:

Notice of Drafting published:	April 27, 2018
Drafting comment period will close:	May 28, 2018

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R.61-55, Septic Tank Site Evaluation Fees

R.61-56, Onsite Wastewater Systems

R.61-56.1, License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets

R.61-56.2, Licensing of Onsite Wastewater Master Contractors

State Register Document TBD

Summary:

The Department proposes amending Regulation 61-56, Onsite Wastewater Systems, to add new system standards, clarify and amend definitions, and clarify and update selected sections. The amendments will clarify and modernize the regulation to address needed updates in administering the Onsite Wastewater program.

The Department further proposes amending the fee schedule currently appearing in R.61-55 and, in the interest of efficiency, moving the amended fee scale to R.61-56. This will entail repealing R.61-55 and simultaneously adding its provisions, as amended, to R.61-56. The proposed amendments will include amended definitions, increase in fees, a new, expedited permitting process with associated fees, and assignment of application fees to specific performed services. These amendments would update fees to

an appropriate level for implementing site evaluations for proposed individual sewage treatment and disposal systems.

The Department also proposes amending provisions of R.61-56.1 and R.61-56.2 and merging R.61-56.1 and R.61-56.2 into R.61-56 to improve efficiency and clarity for Department staff, regulated entities, and the public. This will entail repealing R.61-56.1 and R.61-56.2 and simultaneously adding their provisions, as amended, to R.61-56. The proposed amendments will include changes to licensing and fee requirements for pumpers and haulers currently under R.61-56.1. The proposed amendments also will revise provisions currently contained in R.61-56.2 to implement a tiered licensing program to establish improved competency of onsite wastewater system contractors/installers. This approach includes new requirements for examination, continuing education, and an associated licensure fee.

The Department may also include stylistic changes for internal consistency, such as corrections for clarity in wording, references, grammar, outlining and codification, and such other changes as necessary to improve the overall quality of the regulation.

Legislative review is required.

History and Status:

Notice of Drafting published:

April 27, 2018

Drafting comment period will close:

May 28, 2018

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LAND AND WASTE MANAGEMENT – Proposed Amendments

R.61-79, Hazardous Waste Management Regulations (Imports and Exports of Hazardous Waste Rule)

State Register Document TBD

Summary:

The Department proposes amending Regulation 61-79 to adopt a final rule published in the Federal Register by the United States Environmental Protection Agency (“EPA”). The final rule is summarized below.

The Department proposes adopting the “Imports and Exports of Hazardous Waste” Rule, published on November 28, 2016, at 81 FR 85696-85729 and 82 FR 41015-41016. The rule amends existing requirements regarding the export and import of hazardous wastes from and into the United States. The Department proposes adopting the rule to maintain compliance with federal law and provide greater protection to human health and the environment by:

1. Making 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,
2. Enabling electronic submittal to the EPA of all export and import-related documents (e.g., export notices, export annual reports), and
3. Enabling 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.

The Department may also include stylistic changes, such as corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

General Assembly review is not required.

History and Status:

Notice of Drafting published:

April 27, 2018

Drafting comment period will close:

May 28, 2018

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R.61-79, Hazardous Waste Management Regulations (Hazardous Waste Generator Improvements Rule)

State Register Document TBD

Summary:

The Department proposes amending Regulation 61-79 to adopt a final rule published in the Federal Register by the United States Environmental Protection Agency (“EPA”). The Department’s adoption of the entirety of the rule is not required by federal law. The final rule is summarized below.

The Department proposes adopting the “Hazardous Waste Generator Improvements Rule,” published on November 28, 2016, at 81 FR 85732-85829. Adopting the rule would 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.

The Department may also include stylistic changes, such as corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

While the majority of the rule is equivalent to current state regulations and optional for state adoption, several provisions are more stringent and must be adopted by the Department to maintain federal program authorization. However, due to the interrelated nature of the equivalent provisions and the more stringent provisions, the Department proposes adopting the rule in a single drafting that will undergo General Assembly review.

History and Status:

Notice of Drafting published:

April 27, 2018

Drafting comment period will close:

May 28, 2018

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EMERGENCY MEDICAL SERVICES AND TRAUMA – New Regulation

R.61-118, South Carolina Stroke Care System

State Register Document 4760

Summary:

The Department of Health and Environmental Control (“Department”) proposes a new regulation to address the requirements of the Stroke System of Care Act of 2011, S.C. Code Sections 44-61-610 et seq. (Supp. 2016). The proposed regulation establishes a process of application and recognition of acute care hospitals wishing to be recognized as stroke centers within South Carolina. The proposed regulation establishes a statewide stroke registry for the collection and analysis of stroke care by acute care hospitals within the State. Additionally, the proposed regulation adopts a nationally recognized, standardized stroke-triage assessment tool, posted on the Department’s website and distributed to all Emergency Medical Services (“EMS”) agencies licensed by the Department. Legislative review is required.

Link to Notice of Final Regulation: <http://www.scstatehouse.gov/regs/4760.docx>

History and Status:

Notice of Drafting published:	April 28, 2017
Drafting comment period closed:	May 29, 2017
Board approval to publish Notice of Proposed Regulation:	September 7, 2017
Notice of Proposed Regulation published:	September 22, 2017
Proposed Regulation comment period closed:	October 23, 2017
Public Hearing:	December 7, 2017
General Assembly review period of Notice of Final Regulation began:	January 2018
Withdrawn and resubmitted to the General Assembly to incorporate changes requested by the Senate Medical Affairs committee:	February 16, 2018
Notice of Final Regulation published; Amendment takes legal effect:	May 25, 2018

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HEALTH FACILITIES LICENSING – Proposed Amendments and Proposed New Regulation

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

State Register Document 4740

Summary:

The Department of Health and Environmental Control is amending Regulation 61-16. These amendments are necessary to incorporate recent changes in state law as well as changes to current practices and standards. The amendment incorporates provisions allowing dietitians to prescribe diets and other dietary services; incorporate requirements of S.C. Code Sections 44-41-410 through -480 relating to the provision of abortion services; incorporate existing inspection and construction fees; and incorporate new safe haven requirements.

Link to Notice of Final Regulation: <http://www.scstatehouse.gov/regs/4740.docx>

History and Status:

Notice of Drafting published:	September 23, 2016
Drafting comment period closed:	October 24, 2016
Board approval to publish Notice of Proposed Regulation:	December 8, 2016
Notice of Proposed Regulation published:	December 23, 2016
Proposed regulation comment period closed:	January 23, 2017
Public Hearings:	June 8, 2017 April 13, 2017 (cancelled) February 9, 2017 (cancelled)
General Assembly review period of Notice of Final Regulation began:	January 2018
Notice of Final Regulation published; Amendment takes legal effect:	May 25, 2018

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R.61-78, Standards for Licensing Hospices

State Register Document 4800

Summary:

On May 19, 2017, Governor Henry McMaster signed into law Act No. 61 amending the Hospice Licensure Act. The Department proposes amending R.61-78 to incorporate the provisions of Act No. 61 into its oversight of hospices. The Department may also include stylistic changes, which may include corrections

for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation. Legislative review is required.

Link to Notice of Final Regulation submitted for legislative review:

<http://www.scstatehouse.gov/regs/4800.docx>

History and Status:

Notice of Drafting published:	June 23, 2017
Drafting comment period closed:	July 24, 2017
Board approval to publish Notice of Proposed Regulation:	November 9, 2017
Notice of Proposed Regulation published:	November 24, 2017
Proposed regulation comment period closed:	December 27, 2017
Public Hearing:	February 8, 2018
General Assembly review period of Notice of Final Regulation began:	February 2018

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R.61-125, Proposed New Regulation for Crisis Stabilization Unit Facilities

State Register Document 4809

Summary:

The Department of Health and Environmental Control (“Department”) proposes a new regulation to establish licensure and regulatory requirements for Crisis Stabilization Unit (“CSU”) Facilities. These facilities provide a short-term residential program offering psychiatric stabilization services and brief, intensive crisis services to individuals eighteen (18) years of age or older, twenty-four (24) hours a day, seven (7) days a week. Legislative review is required.

Link to Notice of Final Regulation submitted for legislative review:

<http://www.scstatehouse.gov/regs/4809.docx>

***Note: This Notice of Final Regulation did not receive a joint resolution of approval or meet the requisite 120 days of legislative review. As such, the amendments have not taken legal effect.

History and Status:

Notice of Drafting published:	May 26, 2017
Drafting comment period closed:	June 26, 2017
Board approval to publish Notice of Proposed Regulation:	January 4, 2018
Notice of Proposed Regulation published:	January 26, 2018

Proposed regulation comment period closed: February 26, 2018
Public Hearing: March 27, 2018
March 8, 2018 (cancelled)
General Assembly review period of Notice of Final Regulation began: March 28, 2018

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RADIOLOGICAL HEALTH – Amendment

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

State Register Document 4791

Summary:

The federal Atomic Energy Act of 1954 enables the United States Nuclear Regulatory Commission (“Commission”) to enter into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear materials. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. *Id.* To renew South Carolina’s ongoing agreement with the Commission, the Department of Health and Environmental Control (“DHEC”) amends Regulation 61-63 for compliance with the Commission’s federal regulatory updates. The amendments add clarification or corrections to Parts II, V, VII, and XII of the regulation. Additionally, for Part II, the amendments enable specific licensees to install and service generally licensed devices. For Part XII, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, the amendments enable individuals receiving security-related information to protect it from public disclosure. These amendments comply with federal regulations 10 CFR Parts 19, 20, 30, 31, 32, 34, 37, 40, 61 and 71.

In accordance with S.C. Code Section 1-23-120(H), the amendments did not require legislative review as DHEC promulgates the amendments to comply with federal law indicated above.

Link to Notice of Final Regulation: <http://www.scstatehouse.gov/reg/4791.docx>

History and Status:

Notice of Drafting published:	April 28, 2017
Drafting comment period closed:	May 29, 2017
Board approval to publish Notice of Proposed Regulation:	October 12, 2017
Notice of Proposed Regulation published:	October 27, 2017
Proposed Regulation comment period closed:	November 27, 2017
Public Hearings:	February 8, 2018 December 7, 2017 (cancelled)
Notice of Final Regulation published; Amendment took legal effect:	February 23, 2018

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PUBLIC HEALTH STATISTICS AND INFORMATION SERVICES – Proposed Amendment

R.61-120, South Carolina Immunization Registry

State Register Document TBD

Summary:

The Department proposes amending 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. HEDIS is a tool used by health plans to measure performance on important dimensions of care and service, including immunization data for clients. Proposed amendments to the regulation will also include: (1) details regarding the availability and use of a patient portal, which will be a feature of the new Registry allowing patients to access his or her immunization records; (2) clarifications pertaining to patient consent for the new patient portal; and (3) revisions to bring the regulation into conformity with updates and improvements to the Registry and advancements in public health practice.

The Department may also include stylistic changes, such as deletions of obsolete language, corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

General Assembly review is required.

History and Status:

Notice of Drafting published:	April 27, 2018
Drafting comment period will close:	May 28, 2018

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