



Allen Amsler, *Chairman*
Mark S. Lutz, *Vice Chairman*
Ann B. Kirol, DDS, *Secretary*
R. Kenyon Wells

Board:
Charles M. Joye II, PE
L. Clarence Batts, Jr.
David W. Gillespie, MD
William Lee Hewitt, III

South Carolina Board of Health and Environmental Control

September 8, 2016

The South Carolina Board of Health and Environmental Control met on Thursday, September 8, 2016, at 10:00 a.m. in the Board Room of the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Allen Amsler, Chairman, Member-at-Large
Mark S. Lutz, Vice-Chairman, 1st District
Ann B. Kirol, DDS, Secretary, 5th District
R. Kenyon Wells, 2nd District
Charles M. Joye, II, P.E., 3rd District
L. Clarence Batts, 4th District
David W. Gillespie, MD, 6th District
William Lee Hewitt, III, 7th District

Also in attendance were Catherine E. Heigel, Director; W. Marshall Taylor, Jr., General Counsel; Lisa L. Longshore, Clerk; Department staff and members of the public. (Attachment 0-2)

Chairman Amsler called the meeting to order and stated notice of this meeting had been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

Item 1: Minutes of August 11, 2016, meeting (Attachment 1-1)

Mr. Hewitt moved, seconded by Mr. Wells to approve the minutes as presented for the August 11, 2016, Board meeting. The Board voted and Motion carried.

Item 2: Administrative and Consent Orders issued by Environmental Affairs
(Attachment 2-1)

Ms. Robin Stephens, Compliance Assistance and Enforcement, Environmental Affairs, stated two (2) Administrative Orders and one hundred nine (109) Consent Orders had been issued with total penalties of \$122,150.

After discussion, ***the Board accepted this item as information.***

Item 3: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 3-1)

Ms. Bentley White, Health Regulation Program Manager, stated one (1) Administrative Order, three (3) Consent Orders and one (1) Emergency Order had been issued with total penalties of \$4,000.

The Board accepted this item as information.

Item 4: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and the South Carolina Air Quality Implementation Plan (“SIP”), State Register Document No. 4650, Legislative Review is not required (Attachment 4-1)

Mr. Robbie Brown, Director, Division of Air Assessment and Regulations, presented this item to the Board.

Pursuant to the South Carolina Pollution Control Act, along with the federal Clean Air Act, the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations.

The United States Environmental Protection Agency (“EPA”) promulgates amendments to the Code of Federal Regulations (“CFR”) throughout each calendar year. Recent federal amendments to 40 CFR Parts 51, 52, 60, 61, 63 and 70 include clarification, guidance and technical revisions to SIP requirements promulgated pursuant to 42 U.S.C. Sections 7410 & 7413, New Source Performance Standards (“NSPS”) mandated by 42 U.S.C. Section 7411, and federal National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for Source Categories mandated by 42 U.S.C Section 7412.

The Department proposed to amend Regulation 61-62 as follows:

- 61-62.1, Section III, Emissions Inventory and Emissions Statements; Regulation 61-62.60, South Carolina Designated Facility Plan and New Source Performance Standards; Regulation 61-62.63, National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories; Regulation 61-62.5, Standard No. 2, Ambient Air Quality Standards; and the SIP, to adopt the federal amendments to these standards put forth from January 1, 2015, through December 31, 2015;
- Regulation 61-62.1, Section II, Permit Requirements; Regulation 61-62.5, Standard No.1, Emissions From Fuel Burning Operations; and Regulation 61-62.5, Standard No. 4, Emissions from Process Industries, to address periods of excess emissions during startup, shutdown, or malfunction ("SSM") events as required by the EPA in response to a national petition for rulemaking and to address a finding of substantial inadequacy (referred to as a "SIP call") (80 FR 33840, June 12, 2015);
- Regulation 61-62 that include corrections for internal consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

A public hearing was conducted, and no one in attendance wished to speak. (Attachment 4-2)

After discussion, ***Dr. Kirol moved, seconded by Mr. Lutz, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and the South Carolina Air Quality Implementation Plan ("SIP"), and approve it for publication in the State Register as final. The Board voted and Motion carried.***

A verbatim transcript of this proceeding is included as part of the record. (Attachment 4-3)

Item 5: Withdrawn from the agenda by staff

Item 6: Proposed Amendment of Regulation 61-47, Shellfish, Legislative Review is required (Attachment 6-1)

Mr. Mike Pearson, Manager, Shellfish Sanitation Section, presented this item to the Board.

The Department proposed to amend R.61-47, Shellfish, to provide further clarification and specific technical requirements regarding the harvesting and handling of molluscan shellfish during the warmer months of the year (i.e., months that require additional temperature controls). The amendments will allow for the harvest of molluscan shellfish during months that require additional temperature controls in a manner that is consistent with the national shellfish sanitation program and protects the health of the consumers of molluscan shellfish. The amendment will include a requirement for certified shippers to only accept shellfish from harvesters that have received annual training for the safe and sanitary harvesting and handling of shellfish. The amendment will update the reference date for the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish from 2013 to 2015 (the latest version of the document). The amendment will include stylistic changes to correct for spelling, clarity, readability, grammar, and codification for overall improvement of the text of the regulation.

After discussion, ***Mr. Lutz moved, seconded by Mr. Batts, to grant approval to publish the Notice of Proposed Regulation 61-47, Shellfish, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item #7: Proposed Amendment of Regulation 61-105, Infectious Waste Management Regulations, Legislative Review is required (Attachment 7-1)

Mr. David Scaturo, Director, Division of Hazardous Waste Management, presented this item to the Board.

These proposed regulations require facilities having a permit by rule to notify the Department of the type of treatment they will utilize and clarify requirements for any waste facilities that are pre-treating. The proposed regulations include body art facilities (tattoo and body piercing) in the types of facilities that generate infectious waste in order to make the Infectious Waste Management Regulation consistent with Health Licensing requirements. Recordkeeping requirements include a timeframe for records to be provided to the Department after an inspection. Timeframes are addressed for variances and alternative treatment technology approvals, including expiration and opportunities for renewal. The requirements also allow better communication with facilities and tracking of facilities. Annual reporting requirements for treatment facilities are revised and clarified to require amounts of waste treated to correspond to the state of origin. Demonstration of need requirement is more consistent with those of other similar programs. The

definition(s) and requirements for storage of waste will be clarified. Requirements for financial assurance documentation requirements are revised to better protect the Department and South Carolina residents. The standards for waste treatment technologies are updated. Finally, the proposed regulations include non-substantive stylistic revisions and a table of contents will be added.

These amendments seek to provide greater protections for the public, remove any perceived uncertainty with respect to existing provisions, and ensure consistency with U.S. Department of Transportation regulations.

After discussion, ***Mr. Batts moved, seconded by Mr. Joye, to grant approval to publish the Notice of Proposed Regulation 61-105, Infectious Waste Management Regulations, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 8: Proposed Amendment of Regulation 61-12, Standards for Licensing Abortion Clinics, Legislative Review is required (Attachment 8-1)

Eva Johnson, Director, Medical Management Office, Division of Health Licensing, presented this item.

The Department proposed amending R.61-12 pursuant to the S.C. Code Section 1-23-120(J) requirement that the Department perform a review of its regulations every five (5) years and update them if necessary. These amendments are necessary to revise requirements for obtaining licensure, compliance for licensure, accident and incident reporting requirements, abortion reporting, inspections and violations, complaint reporting, patient rights, infection control, in-service training, record maintenance and retention, personnel requirements, fire and life safety requirements, and construction design requirements. Department staff has added language incorporating current provider-wide exceptions and memoranda applicable to abortion clinics. In addition, corrections have been made for clarity, readability, grammar, references, codification, and overall improvement to the text of the regulation.

After discussion, ***Mr. Batts moved, seconded by Mr. Hewitt, to grant approval to publish the Notice of Proposed Regulation 61-12, Standards for Licensing Abortion Clinics, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 9: Proposed Amendment of Regulation 61-68, Water Classifications and Standards, Legislative Review is required (Attachment 9-1)

Mr. Jeffrey DeBessonnet, Director, Division of Water Facilities Permitting, presented this item to the Board.

The Department proposed to amend R.61-68 to strengthen and improve the existing regulation and make appropriate revisions of the State's water quality standards in accordance with the Federal Clean Water Act ("CWA"). The Department reviews, and amends at its discretion, this regulation once every three years in order to incorporate desirable most recently published Federal criterion recommendations and guidance. Hence, this review process is often referred to as the "triennial review." The Department proposes to adopt a revised standard for ambient water quality criteria for the protection of human health for ninety-four chemical pollutants, and a revised standard for aquatic life water quality criteria for cadmium to reflect the most current final published criteria in accordance with Sections 304(a) and 307(a) of the CWA.

After discussion, ***Mr. Wells moved, seconded by Mr. Lutz, to grant approval to publish the Notice of Proposed Regulation 61-68, Water Classifications and Standards, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 10: Proposed Amendment of Regulation 61-94, WIC Vendors, Legislative Review is required (Attachment 10-1)

Ms. Lorraine Glover, Manager, Vendor Management, Women, Infants and Children Division, presented this item to the Board.

The Department proposed to amend and update Regulation 61-94. The amendment pertains to provisions included in the Child Nutrition and WIC Reauthorization Act of 2004 (P.L. 108-265). The provisions required the establishment of a vendor peer group system, distinct peer competitive price criteria, allowable reimbursement levels for each peer group and other vendor related provisions to ensure program integrity. In addition, a final rule, published by the United States Department of Agriculture, Food and Nutrition Services in the Federal Register on March 4, 2014, revised the WIC food packages. The proposed revisions align the WIC food packages with the Dietary Guidelines for Americans

and infant feeding practice guidelines of the American Academy of Pediatrics. This rule also encompassed vendor related amendments. All of the vendor provisions and amendments are implemented to ensure adequate and appropriate monitoring of the Program's food delivery system to prevent fraud, waste and abuse from occurring and to safeguard program benefits.

The Department's proposed amendment includes stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, definitions, references, codification and overall improvement of the text of the regulation.

After discussion, ***Dr. Gillespie moved, seconded by Mr. Batts, to grant approval to publish the Notice of Proposed Regulation 61-94, WIC Vendors, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 11: Placement of Thiafentanil into Schedule II of the SC Controlled Substances Act (Attachment 11-2)

Ms. Anne Marie Ravenna, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the S.C. Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Schedule II substances are listed in Section 44-53-210. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by DHEC. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated. Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a

substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on August 26, 2016, its interim final rule placing the substance thiafentanil (4-(methoxycarbonyl)-4-(Nphenmethoxyacetamido)-1-[2-(thienyl)ethyl]piperidine), including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existences of such isomers, esters, ethers and salts is possible, into schedule II of the Federal Controlled Substances Act (CSA), effective immediately. This action is based on a finding by the DEA that the placement of thiafentanil into schedule II of the Federal CSA is necessary because it has a potential for abuse similar to other schedule II substances.

Thiafentanil is a potent opioid and an analogue of fentanyl, a Schedule II substance. On March 23, 2016, the DEA received notice that the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration had approved the use of Thianil (a salt form of thiafentanil) for use in the immobilization of nondomestic, non-food-producing minor species hoofstock and recommended placement of thiafentanil into schedule II of the federal CSA.

When determining whether a substance should be placed into Schedule II of the S.C. Controlled Substances Act, Section 44-53-200 of the S.C. Code of Laws requires the Department place a substance in Schedule II if it meets the following criteria:

- (a) It has a high potential for abuse;
- (b) It has a currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and
- (c) Abuse may lead to severe psychic or physical dependence.

According to its interim final rule, the DEA conducted its own review and determined thiafentanil met the criteria for placement in schedule II of the federal

CSA because a review of available data showed it had a high potential for abuse, a currently accepted medical use with severe restrictions, and that abuse of thiafentanil may lead to severe psychological or physical dependence.

After discussion, ***Mr. Hewitt moved, seconded by Mr. Joye, to designate the additional substances as named in the DEA notice published in the Federal Register on August 26, 2016, and amend Section 44-53-210 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.*** Board Designation document (Attachment 11-2)

Item 12: S.C. Board of Health and Environmental Control 2017 meeting dates
(Attachment 12-1)

Mr. Batts moved, seconded by Dr. Kirol, to approve the dates for 2017. The Board voted and Motion carried. (These dates will be published on the agency web page.)

Item 13: Agency Affairs

Director Heigel reported on the following:

- Dam Program activities during the Hurricane Hermine event ;
- Budget for FY18 and 3% budget reduction analysis;
- Solar Energy Site in Spartanburg County.

After discussion, ***the Board accepted this as information.***

Item 14: Final Review Conference - Docket No. 16-RFR-60, End of Wave Dissipation System Study Period and Removal Notification for Isle of Palms, Harbor Island and Beachwood East (Attachment 14-1)

Dr. Gillespie recused himself from reviewing in this matter. (Attachment 14-2)

Ms. Jacquelyn Dickman, Legal Counsel to the Board, introduced this matter to the Board.

Bradley D. Churdar for SCDHEC

Matthew D. Hamrick for SI Seawalls and Fencing, et al.

Newman Jackson Smith for Seascape Villas Horizontal Property Regime

Butch Bowers for Ocean Club Horizontal Property Regime

Daniel S. Slotchiver for Carole Slotchiver

Mary D. Shahid for Michael and Rosemary Safdi, Michael and Mary Ricci, Hasmuka P. Rama, Philip Derrick Hampton and Travis E. Hampton, William and Nancy Longfield, Patricia R. Gardner, Paul J. Conway, Kathryn V. Balazs, Ruth Ann Skinner, and JB Beachwood, LLC

After presentations (Attachment 14-3) by the parties and discussion, ***Mr. Hewitt moved, seconded by Mr. Wells, to go into Executive Session for the obtaining legal advice in relation to this matter. The Board voted and Motion carried.***

Mr. Amsler announced the Board was back in public session and while in Executive Session no actions were taken.

After further discussion, ***Mr. Lutz moved, seconded by Mr. Batts, to overturn the staff decision requiring the removal of the Wave Dissipation System at this time. The Board voted and Motion carried.***

Having no further business, Chairman Amsler adjourned the meeting.

All referenced attachments are made a permanent part of these minutes.

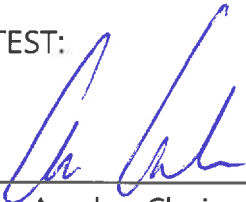
Respectfully submitted,



Ann B. Kiro, DDS, Secretary

Minutes approved this 13th day of October 2016.

ATTEST:



Allen Amsler, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 August 11, 2016 minutes
- 2-1 Administrative and Consent Orders issued by Environmental Affairs
- 3-1 Administrative Orders, Consent Orders and Sanctions issued by Health Regulation
- 4-1 Public Hearing – Proposed Amendment of R.61-62, Air Pollution Regulations and Standards
- 4-2 Public Hearing Sign-in Sheet
- 4-3 Verbatim Transcript of Public Hearing
- 6-1 Proposed Amendment of R.61-47, Shellfish
- 7-1 Proposed Amendment of R.61-105, Infectious Waste Management Regs
- 8-1 Proposed Amendment of R.61-12, Standards for Licensing Abortion Clinics
- 9-1 Proposed Amendment of R.61-68, Water Classifications and Standards
- 10-1 Proposed Amendment of R.61-94, WIC Vendors
- 11-1 Placement of Thiafentanil into Schedule II of the SC Controlled Substances Act
- 12-1 S.C. Board of Health and Environmental Control 2017 Meeting dates
- 14-1 Final Review Conference – Docket No. 16-RFR-60, End of Wave Dissipation System Study Period and Removal Notification for Isle of Palms, Harbor Island and Beachwood East
- 14-2 Statement of Recusal by Dr. Gillespie
- 14-3 Presentation by parties