

BOARD:
Allen Amsler
Chairman
Mark S. Lutz
Vice Chairman
Ann B. Kirol, DDS
Secretary



Catherine E. Heigel, Director

Promoting and protecting the health of the public and the environment

BOARD:
R. Kenyon Wells
Charles M. Joye II, P.E.
L. Clarence Batts, Jr.
John O. Hutto, Sr., MD
William Lee Hewitt, III

South Carolina Board of Health and Environmental Control

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Minutes of the December 10, 2015, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, December 10, 2015, 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 Lutz, Vice-Chairman
1st District

Ann B. Kirol, DDS, Secretary
5th District

Charles M. Joye, II, P.E.
3rd District

L. Clarence Batts, Jr.
4th District

John O. Hutto, Sr., MD
6th District

William Lee Hewitt, III
7th District

Also in attendance were Kevin Guion, Chief of Staff; W. Marshall Taylor, Jr., General Counsel; Lisa Lucas Longshore, Clerk of Board; Department staff and members of the public. (Attachment 0-2)

Chairman Amsler stated "notice of this meeting has been provided to all persons, organizations and news media, which have requested notification, as required by Section 33-4-80(e) of the South Carolina Code of Laws."

Item 1: Minutes of November 4, 2015, meeting (Attachment 1-1)

Mr. Lutz moved, seconded by Mr. Batts, to approve the minutes as presented for the November 4, 2015, meeting. The Board voted and Motion carried.

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

Ms. Robin Stephens, Assistant to the Deputy Director, Environmental Affairs, stated one (1) Administrative Order and thirty-three (33) Consent Orders had been issued with total penalties of \$55,885.

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 and one (1) Consent Order had been issued with total penalties of \$8,500.

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

Item 4: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-71, Well Standards, State Register Document No. 4571, Legislative Review is required
(Attachment 4-1)

Mr. David Baize, Assistant Bureau Chief, Bureau of Water, presented this item to the Board.

Regulation 61-71, Well Standards, was promulgated so the Department could enforce rules and regulations that contain the minimum standards for the construction, maintenance, and operation of the following wells: individual residential, irrigation, monitoring (including non-standard installations), and boreholes to ensure that underground sources of drinking water are not contaminated and public health is protected.

The Department proposed amending Regulation 61-71, Well Standards, to be consistent with the separation distance between private wells (individual residential and irrigation wells) and onsite wastewater systems (septic tank/tile fields) found in Regulation 61-56, Onsite Wastewater Systems, and clarify that Regulation 61-71 applies to injection wells as specified in Regulation 61-87, Underground Injection Control Regulations. Stylistic changes were made for clarity and consistency in language style to improve the overall quality of the Regulation.

A public hearing was conducted and no one requested the opportunity to speak. (Attachment 4-2)

After discussion, *Dr. Kirol moved, seconded by Mr. Batts, to find for the need and reasonableness of the Proposed Amendment of 61-71, Well Standards, and approve it for submission to the Legislature for review. The Board voted and Motion carried.*

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

Item 5: Public Hearing and Request for Final Review – Proposed Amendment of Regulation 61-56, Onsite Wastewater Systems, State Register Document No. 4591, Legislative Review is required (Attachment 5-1)

Mr. Rick Caldwell, Assistant Bureau Chief, Bureau of Environmental Health Services, presented this item to the Board.

Regulation 61-56, Onsite Wastewater Systems, governs the methods of disposition of sewage and prescribes design, construction and installation standards for onsite wastewater systems (septic tank systems).

The Department proposed the amendments to update and bring Regulation 61-56 in line with current statutes and changes in the technologies of design, construction and installation of onsite wastewater systems since the last revision. The amendments include updates in nomenclature and technology, as well as addition of definitions and clarifications of definitions, site requirements and system requirements. Additionally, to upgrade the overall quality and usefulness of the Regulation stylistic changes are being made for improved clarity and consistency.

A public hearing was conducted with a member of the public speaking. (Attachment 5-2) Mr. Chris Fincham, representing the South Carolina Soil Classifiers Board, presented modifications that were mutually agreed upon by the S.C. Soil Classifiers Advisory Council and SCDHEC for inclusion in the Proposed Regulation 61-56, Onsite Wastewater Systems Amendments. (Attachment 5-3)

After discussion, Mr. Joye moved, seconded by Mr. Batts, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-56, Onsite Wastewater Systems and approve it for submission to the Legislature for review with the following revisions that were raised, considered, or discussed by public comment: On page 12, revise the definition of “Expansive Soils”; On page 14, revise the definition of “Perched Zone of Saturation”; On page 14, revise the definition of “Redox Depletions”; On page 15, revise the definition of “Site Evaluation” as indicated on Attachment 5-3. The Board voted and Motion carried.

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 5-4)

Item 6: Public Hearing and Request for Final Approval – Proposed Repeal of Regulation 61-57, Development of Subdivision Water Supply and Sewage Treatment/Disposal Systems, State Register Document No. 4594, Legislative Review is required (Attachment 6-1)

Mr. Rick Caldwell, Assistant Bureau Chief, Bureau of Environmental Health Services, presented this item to the Board.

The Department proposes the repeal of Regulation 61-57, as it has become obsolete. S.C. Code Section 44-55-822, which now governs the approval process for onsite wastewater systems in

subdivisions and Regulation 61-56, Onsite Wastewater Systems, address any major requirements for subdivision onsite wastewater sewage treatment/disposal systems. Therefore, under current statutes and regulation, there exists sufficient authority to address, control and regulate any major environmental and/or public health issues related to the systems.

A public hearing was conducted and no one requested the opportunity to speak. (Attachment 6-2)

After discussion, *Mr. Lutz moved, seconded by Dr. Kirol, to find for the need and reasonableness of the Proposed Repeal of Regulation 61-57, Development of Subdivision Water Supply and Sewage Treatment/Disposal Systems, and approve it for submission to the Legislature for review. The Board voted and Motion carried.*

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 6-3)

Item 7: 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. 4590, Legislative Review is required
(Attachment 7-1)

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

The Department proposed to amend Regulation 61-62, Air Pollution Control Regulations and Standards as follows:

- to amend R.61-62.1, Definitions and General Requirements, Section I, Definitions and the SIP to add a definition for “Emission.” This revision is a result of comments received from the regulated community in 2013 related to the Department’s “2013 General Assembly Package” revisions approved on June 27, 2014. Because of public notice requirements, the Department was unable to submit this revision for approval at that time, but agreed that the change would be considered for approval as part of the current set of revisions (2015 General Assembly Package);
- to amend R.61-62.1, Definitions and General Requirements, Section II, Permit Requirements, to remove the requirement of a revised air dispersion modeling analysis for permit renewals. Amendments also include additional definitions for clarification and/or corrections for internal consistency, reference, punctuation, codification, and spelling to improve the overall text of Regulation 61-62.1 as necessary;
- to amend Regulation 61-62.5, Standard No. 4, Emissions from Process Industries, to clarify this regulation is not triggered for sources where the Department has removed Particulate Matter (“PM”) limits (from other sections of this regulation);
- to amend Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NOX), to clarify applicability and exemptions as well as to propose corrections for internal consistency, punctuation, codification, and spelling;

- to amend Regulation 61-62.70, Title V Operating Permit Program, to remove appeals language as this is generally defined by statutory law (Code Ann. Section 44-1-60 (Supp. 2012)) and is redundant, and to clarify qualification language for administrative amendments.
- to amend Regulation 61-62 to include corrections for 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 requested the opportunity to speak. (Attachment 7-2)

After discussion, *Dr. Hutto moved, seconded by Mr. Hewitt, 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 submission to the Legislature for review. The Board voted and Motion carried.*

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 7-3)

Item 8: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-64, X-Rays (Title B), State Register Document No. 4595, Legislative Review is required
(Attachment 8-1)

Mr. Charles Dittmer, Director, Division of Electronic Products, presented this item to the Board.

R.61-64, X-Rays (Title B) provides for radiation control and applies to all persons who receive, possess, use, transfer, own, service, or acquire any x-ray producing device. The cost of running the program to implement the provisions of this regulation is partially funded by the collection of fees from the regulated community as mandated by the Atomic Energy and Radiation Control Act.

Proposed changes seek to strengthen equipment performance standards. Language changes are proposed to clarify many sections of the regulation by making them more specific, better organized, and the intent of the regulation clearer. The proposed regulation increases registration fees to allow for the hiring of six additional inspectors. The fee increase will provide funding for the hiring of additional inspectors to increase the frequency of inspections.

A public hearing was conducted with a member of the public speaking. (Attachment 8-2)

After discussion, *Mr. Batts moved, seconded by Dr. Kirol, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-64, X-Rays (Title B), and approve it for submission to the Legislature for review. The Board voted and Motion carried.*

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 8-3)

Item 9: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-103, Standards for Licensing Residential Treatment Facilities for Children and Adolescents, State Register Document No. 4596, Legislative Review is required (Attachment 9-1)

Ms. Gwen Thompson, Director, Bureau of Health Facilities Regulation, presented this item to the Board.

The Department proposed amending R.61-103 to incorporate updates and clarification relating to licensing requirements, accident and incident reporting, admission and intake requirements, resident rights, program activities, in-service training, infection control and sanitation, record maintenance and retention, personnel requirements, medication management, fire and life safety requirements, and construction and design requirements. In addition, current provider-wide exceptions and memoranda applicable to residential treatment facilities for children and adolescents have been incorporated.

A public hearing was conducted with members of the public speaking. (Attachment 9-2)

After discussion, *Mr. Batts moved, seconded by Dr. Kirol, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-103, Standards for Licensing Residential Treatment Facilities for Children and Adolescents, and approve it for submission to the Legislature for review. The Board voted and Motion carried.*

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 9-3)

Item 10: Proposed Amendment of Regulation 61-24, Licensed Midwives, Legislative Review is required (Attachment 10-1)

Ms. Gwen Thompson, Director, Bureau of Health Facilities Regulation, and Michelle Hatcher, Perinatal Nurse Administrator, presented this item to the Board.

The Department proposed amending Regulation 61-24, Licensed Midwives which was last amended in 2013. The proposed amendments incorporate revisions and clarification relating to licensing requirements, interpretations, educational requirements, license revocation criteria, prenatal care, intrapartum care, postpartum care, care of the newborn, physician referral, record keeping, and reporting. Language has been added to incorporate current provider wide exceptions and memoranda applicable to licensed midwives. 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 Dr. Kirol, to grant approval to publish the Notice of Proposed Regulation 61-24, Licensed Midwives, 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.*

Representatives of the Midwifery Profession and representatives of the NACPM were in attendance and provided comments to the Board which Chairman Amsler provided to staff. (Attachment 10-2)

Item 11: Placement of Eluxadoline into Schedule IV for Controlled Substances (Attachment 11-1)

Ms. Rachel Richmon, Bureau of Drug Control, presented this item to the Board.

Eluxadoline is a new molecular entity with central nervous system opioid properties that was approved by the Food and Drug Administration (FDA) for use, with a prescription, in the treatment of irritable bowel syndrome with diarrhea. Based upon the recommendation of the Assistant Secretary for Health of the U.S. Department of Health and Human Services and review of all available data, the DEA found eluxadoline has an overall abuse potential comparable to schedule IV substances (such as pentazocine and butorphanol), a currently acceptable medical use in treatment in the United States, and may lead to limited psychological dependence similar to schedule IV drugs, but less than schedule III. Therefore, the DEA has determined eluxadoline, including its salts, isomers, and salts of isomers, warrants control in schedule IV of the CSA.

After discussion, *Dr. Hutto moved, seconded by Mr. Batts, to adopt the scheduling of eluxadoline and amend Section 44-53-250 by adding and designating 5-[[[(2S)-2-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]2-methoxybenzoic acid (eluxadoline), including its salts, isomers, and salts of isomers into Schedule IV of the South Carolina Controlled Substances Act. The Board voted and Motion carried.* Board Designation document (Attachment 11-2)

Item 12: Approval of Strategic Plan: Vision Statement, Mission Statement, Core Values and Strategies (Attachment 12-1)

Mr. Kevin Guion, Chief Operating Officer, presented the proposed Vision Statement, Mission Statement, Core Values and Strategies.

After discussion, *Dr. Kirol moved, seconded by Mr. Lutz, to approve the Strategic Plan Vision Statement, Mission Statement, Core Values and Strategies as presented. The Board voted and Motion carried.*

Item 13: Agency Affairs

Mr. Guion updated the Board on the following issues:

- Dams – working through Emergency Orders and Repair Orders;
- Budget Request – Presentation to House Ways and Means Committee;
- Recognition by Electric Cooperatives – Clean Power Initiative and Department’s work with stakeholders;
- Home Health license transfer on schedule.

Item 14: Legal Report

Ms. Cheryl Bullard, Deputy General Counsel, updated the Board on a “scrivener’s error” on an item before the Board in December 2014 where the Board approved a mass scheduling of Controlled Substances Schedule I as presented by Wendy Bell with SLED. Ms. Bullard provided the Board with a “List as provided to Board in December 2014, approved and posted on DHEC website”. (Attachment 14-1) and “Corrected Classifications” (Attachment 14-2)

Chairman Amsler asked for an Executive Session for the purpose of discussing a personnel matter.


Mr. Lutz moved, seconded by Dr. Kirol, to go into Executive Session for the purpose of discussing a personnel matter. The Board voted and Motion carried.

Chairman Amsler stated the Board was back in public session and while in Executive Session, no decisions were made.

Meeting adjourned.

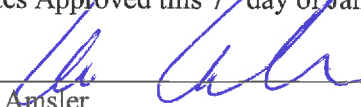
All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,



Ann B. Kirol, DDS, Secretary

Minutes Approved this 7th day of January 2016.



Allen Anisler
Chairman

Attachments:

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 November 4, 2015 minutes
- 2-1 Environmental Affairs Report
- 3-1 Health Regulation Report
- 4-1 Public Hearing – Proposed Amendment of Regulation 61-71, Well Standards
- 4-2 Public Hearing Sign-in Sheet
- 4-3 Verbatim transcript of public hearing
- 5-1 Public Hearing – Proposed Amendment of Regulation 61-56, Onsite Wastewater Systems
- 5-2 Public Hearing Sign-in Sheet
- 5-3 Changes to Proposed Amendment Package
- 5-4 Verbatim transcript of public hearing
- 6-1 Public Hearing – Proposed Repeal of Regulation 61-57, Development of Subdivision Water Supply and Sewage Treatment/Disposal Systems
- 6-2 Public Hearing Sign-in Sheet
- 6-3 Verbatim transcript of public hearing
- 7-1 Public Hearing – Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards
- 7-2 Public Hearing Sign-in Sheet
- 7-3 Verbatim transcript of public hearing
- 8-1 Public Hearing – Proposed Amendment of Regulation 61-64, X-Rays (Title B)
- 8-2 Public Hearing Sign-in Sheet
- 8-3 Verbatim transcript of public hearing
- 9-1 Public Hearing – Proposed Amendment of Regulation 61-103, Standards for Licensing Residential Treatment Facilities for Children and Adolescents
- 9-2 Public Hearing Sign-in Sheet
- 9-3 Verbatim transcript of public hearing
- 10-1 Proposed Amendment of Regulation 61-24, Licensed Midwives
- 10-2 Comments presented to Board
- 11-1 Placement of Eluxadoline into Schedule IV for Controlled Substances
- 11-2 Board Designation of Eluxadoline into Schedule IV for Controlled Substances
- 12-1 Approval of Strategic Plan: Vision Statement, Mission Statement, Core Values and Strategies
- 14-1 Correction to Controlled Substance scheduling from December 2014