

Mark R. Elam, Chairman Jim P. Creel, Jr., Vice-Chairman Charles M. Joye, II, P.E., Secretary J.B. (Sonny) Kinney Seema Shrivastava-Patel Richard V. Lee, Jr. Alex A. Singleton Robert R. Morgan, Jr., MD, MBA

Minutes of the September 10, 2020, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, September 10, 2020, at 10:00 a.m. in the Boardroom (#3420) at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Mark Elam, Chairman Jim P. Creel, Jr., Vice-Chairman J.B. (Sonny) Kinney, 1st District Robert Morgan, MD, 4th District Richard V. Lee, Jr., 5th District

In attendance via telephone Seema Shrivastava-Patel, 2nd District Charles M. Joye, II, P.E., 3rd District Alex A. Singleton, 6th District

Also, in attendance were W. Marshall Taylor, Acting Director, Rupinderjit S. Grewal, Legal Counsel; M. Denise Crawford, Clerk; and Department staff. The meeting was also available via Livestream.

Chairman Elam 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 13, 2020 meeting (Attachment 1-1)

Mr. Kinney moved, seconded by Mr. Lee, to approve the minutes as presented. The Board voted and Motion carried.

<u>Item 2: Administrative Orders and Consent Orders issued by Healthcare Quality</u> (Attachment 2-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, nine (9) Consent Orders with assessed civil penalties totaling \$10,350.00 have been issued.

After discussion, the Board accepted this item as information.

<u>Item 3: Administrative Orders and Consent Orders issued by Environmental Affairs</u> (Attachment 3-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, twenty-four (24) Consent Orders with assessed civil penalties totaling \$121,530.00 and ten (10) Administrative Orders with assessed civil penalties totaling \$3,300.00 have been issued.

After discussion, the Board accepted this item as information.

<u>Item 4: Revision of the Hearing Procedures for Certified Nursing Aides</u> (Attachment 4-1)

Ms. LaTonya Williams, Director, Director of the Office of Training and Compliance, Healthcare Quality, presented this item to the Board.

Pursuant to an agreement with the United States Department of Health and Human Services ("USDHHS") to carry out the provisions of Title XVIII of the Social Security Act and annual contracts with South Carolina Department of Health and Human Services ("SCDHHS") for the provision of survey and certification services for Title XIX² of the Social Security Act, the South Carolina Department of Health and Environmental Control ("Department") is the state survey agency for providers/suppliers participating in the federal Medicare and Medicaid programs ("the programs"). The Department performs a number of functions concerning the programs including, but not limited to, identifying potential participants, conducting investigations and fact-finding surveys, certifying and recertifying providers to participate, and explaining requirements for participation.

Each state is required by federal law to maintain a registry of all nurse aides certified in the state. 42 U.S.C.A. §§ 1395i-3(e)(2) and -1396r(e)(2). The nurse aide registry must provide for the inclusion of specific findings by the state survey agency of abuse, neglect, or misappropriation of resident property involving an individual listed on the registry. *Id.* SCDHHS maintains South Carolina's nurse aide registry. Nursing facilities participating in the programs are prohibited from employing individuals who have had a finding of abuse, neglect, or misappropriation of resident property in the state nurse aide registry. 42 C.F.R. § 483.12(a)(3)(ii).

As the state survey agency, the Department is responsible for investigating allegations of neglect, abuse, and misappropriation of resident property by nurse aides in nursing facilities participating in the programs. See 42 U.S.C.A. §§ 1395i-3(g)(1)(C) and -1396r(g)(1)(C); 42 C.F.R. § 488.335(a). If the Department makes a preliminary determination that the abuse, neglect, or misappropriation occurred, it must notify the nurse aide of the nature of the allegations and of the nurse aide's right to request a hearing to rebut the allegations. 42 C.F.R. § 488.335(c). If the nurse aide requests a hearing, the Department complete the hearing and the hearing record within 120 days from the day it receives the request for the hearing. 42 C.F.R. § 488.335(d)(1). The Department must hold the hearing at a reasonable place and time convenient for the nurse aide. 42 C.F.R. § 488.335(d)(2). If the hearing results in a finding of neglect, abuse, or misappropriation of resident property, the Department must report the finding to the nurse aide registry. 42 C.F.R. § 488.335(f).

The Board of Health and Environmental Control ("Board") adopted the Hearing Procedure for Nurse Aides ("Hearing Procedures") on November 18, 1992. The Hearing Procedures were last

amended by the Board on March 12, 2015. The Department proposed to update and revise the current Hearing Procedure for nurse aides contesting allegations of abuse, neglect, or misappropriation of property to provide for a more streamlined review and investigation and to reflect the reorganization to Healthcare Quality.

The proposed update and revision of Hearing Procedure removes Office of General Counsel review as a required component of the review and investigation. The proposed update also reflects the changes with the reorganization of the Department's Division of Health Regulation to the Division of Healthcare Quality, the proposed Hearing Procedures removes references to the Bureau of Certification and, instead, generally references the Department.

The Department recommended that the Board grant approval to implement the updated and revised Hearing Procedure for Certified Nurse Aides effective September 10, 2020.

After discussion, Mr. Kinney moved, seconded by Mr. Lee, to grant approval to implement the updated and revised Hearing Procedures for Certified Nurse Aides. The Board voted and Motion carried.

<u>Item 5: Placement of Isotonitazene in Schedule I for Controlled Substances</u> (Attachment 5-1)

Ms. Heather Diebold, Director, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. 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 the Department. Section 44-53- I 60(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Code 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 Chairn1en 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 Acting Administrator of the federal Drug Enforcement Administration ("DEA") issued a temporary order to place N,N-diethyl-2-(2-(4 isopropoxybenzyl)- 5-nitro-IHbenzimidazol-1- yl)ethan-l- amine (isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the federal Controlled Substances Act ("federal CSA"). The federal CSA allows the DEA to temporarily schedule a substance for two years in order to avoid an imminent hazard to the public safety as defined in the federal CSA. The Attorney General may extend the temporary scheduling for up to one year during the pendency of proceedings to permanently schedule the substance. The federal order to temporarily schedule isotonitazene in the federal CSA became effective August 20, 2020, in Federal Register, Volume 85, Number 162, pages 51342-51346; https://www. https://ww.v .gov info.gov/content/pkg/FR-2020-08-20/pdlt2 020-1795 I .pdf.

The Acting Administrator of the DEA determined that the temporary scheduling of isotonitazene in schedule I of the federal CSA was necessary to avoid an imminent hazard to the public safety. 21 U.S.C. § 811(h). As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, isotonitazene. 21 U.S.C. § 81I(c) requires the Administrator to consider the substances' history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health in making a determination. In addition, 21 U.S.C. 81 I(h)(3) requires consideration of certain factors including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

1) History and Current Pattern of Abuse

The availability of synthetic opioids in the illicit drug market continues to pose an imminent hazard to the public safety. In recent years, adverse health effects associated with the abuse of synthetic opioids and the continued evolution and increased popularity of these substances have been a serious concern. As the United States continues to experience an unprecedented epidemic of opioid misuse and abuse, the presence of new synthetic opioids with no approved medical use exacerbates the epidemic. Trafficking and abuse of new synthetic opioids are deadly new trends. Beginning April 2019, isotonitazene emerged on the illicit synthetic drug market in the United States, as evidenced by its identification in drug seizures and in biological samples collected and submitted to National Medical Services (NMS) Laboratory. Isotonitazene has been encountered by United States law enforcement primarily in powder form, as well as being identified as a single substance or in combination with other substances. Evidence suggests that individuals are using isotonitazene as a replacement to heroin or other opioids, either knowingly or unknowingly.

2) Scope, Duration, and Significance of Abuse

Isotonitazene, similar to etonitazene, another schedule I drug, has been described as a potent synthetic opioid and evidence suggests it is being abused for its opioidergic effects. The abuse of isotonitazene, similar to other synthetic opioids, has resulted in adverse health effects. Isotonitazene has been positively identified in eighteen death investigations between August 2019 and January 2020. Law enforcement data indicates that isotonitazene has appeared in the United States' illicit drug market. The population likely to abuse isotonitazene appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in isotonitazene fatal overdose cases. Because abusers of isotonitazene are likely to obtain it through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well characterized. This population abusing opioids is likely to be at risk of abusing isotonitazene. Individuals who initiate use of isotonitazene are likely to be at risk of developing substance use disorders, overdoses, and death similar to that of other opioid analgesics.

3) Potential Risks to the Public

The increase in opioid overdose deaths in the United States has been exacerbated by the availability of potent synthetic opioids in the illicit drug market. Data obtained from preclinical studies demonstrates isotonitazene exhibits a pharmacological profile similar to that of etonitazene and other mu-opioid receptor agonists. As with any mu-opioid receptor agonist, the potential health and safety risks for users are high. The public health risks attendant to the abuse of heroin and other mu-opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. The introduction of potent synthetic opioids such as isotonitazene into the illicit market exacerbates problematic opioid use for those seeking these powerful opioids.

The Acting Administrator of the DEA concludes that N,N-diethyl-2-(2-(4 isopropoxybenzyl)- 5-nitro-IH- benzimidazol-1-yl)ethan-I- amine (isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts meets the criteria for temporary placement in schedule I of the federal CSA. Because isotoniazene has a high potential for abuse, there is no currently accepted medical use for isotoniazene in treatment in the United States, and a lack of accepted safety for use in treatment under medical supervision temporary scheduling was necessary to avoid an imminent hazard to the public safety.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the placement of isotonitazene in Schedule I for controlled substances in South Carolina and the amendment of Section 44- 53-190(B) of the South Carolina Controlled Substances Act to include:

() N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-lHbenzimidazol-l-yl)ethan-1-amine, its isomers, esters, ethers, salts and salts of isomers, esters and ethers

The Department recommended the Board place isotonitazene in Schedule I of the South Carolina Controlled Substances Act.

After discussion, Mr. Lee moved, seconded by Dr. Morgan, to designate the additional substances named in the DEA Notice published in the Federal Register on August 20, 2020, and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.

<u>Item 6: Deletion of FDA-Approved Cannabidiol Drugs Containing No More Than 0.1%</u> <u>Tetrahydrocannabinols in Schedule V for Controlled Substances</u> (Attachment 6-1)

Ms. Heather Diebold, Director, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule V substances are listed in Section 44-53-270 of the South Carolina Code of Laws. 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 for the Department to expeditiously designate a 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 Chainnen 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.

On June 25, 2018, the Food and Drug Administration ("FDA") approved Cannabidiol 100 mg/ml solution, tradename Epidiolex ("Epidiolex") as a prescription drug for the

treatment of seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome. On September 28, 2018, the Acting Administrator of the Drug Enforcement Administration placed FDA-approved drugs that contain cannabidiol derived from cannabis and containing no more than 0.1 percent

tetrahydrocannabinols, including Epidiolex and any future FDA-approved generic versions of such formulation made from cannabis, in Schedule V of the federal Controlled Substances Act ("federal CSA"). On August 21, 2020, the Drug Enforcement Administration ("DEA") issued an interim final rule to remove FDA-approved drugs that contain cannabidiol derived from cannabis and containing no more than 0.1 percent tetrahydrocannabinols from Schedule V of the federal CA, effective August 21, 2020, in Federal Register, Volume 85, Number 163, pages 51639-51645; https://wv.'W. govinfo.gov/content/pkg/FR-2020-08-21ipdf/2020-17356.pdf.

The Drug Enforcement Administration ("DEA"), pursuant to 21 CFR 1308.15, previously controlled drug products in Schedule V of the federal CSA separately in finished dosage formulations approved by FDA and that, under Controlled Substance Code Number 7367. contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. The FDA-approved substances described under Drug Code 7367 are no longer controlled, by virtue of the Agriculture Improvement Act of 2018 ("AIA"), and as a result, DEA is removing the listing for "Approved cannabidiol drugs" under schedule V of the federal CSA.

The Department recommended the deletion of FDA-approved drugs that contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols from Schedule V for controlled substances in South Carolina the same manner as the federal Drug Enforcement Administration.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommended the deletion of FDA approved drugs that contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols from Schedule V for controlled substances in South Carolina in Section 44-53-270 of the South Carolina Code of Laws.

The Department recommended the Board delete FDA-approved drugs that contain cannabidiol ("CBD") derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols in Schedule V of the South Carolina Controlled Substances Act.

After discussion, Mr. Creel moved, seconded by Mr. Lee, to delete FDA-approved drugs that contain Cannabidiol derived from cannabis and substances containing no more than 0.1% residual Tetrahydrocannabinols in Schedule V of the S. C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.

Regulation Amending R.61-96, Athletic Item 7: Notice of Proposed **Trainers** (Attachment 7-1)

Mr. Russell Morrison, Office of Policy and Communications, Healthcare Quality, presented this item to the Board.

The Bureau of Healthcare Professionals ("Bureau") proposed the Notice of Proposed Regulation amending Regulation 61-96, *Athletic Trainers*, for publication in the September 25, 2020, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-75-10 et seq., which requires the Department of Health and Environmental Control ("Department") to develop standards and prescribe regulations for the improvement of athletic training services in the state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Bureau proposed amending R.61-96 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to terminology widely used and understood within the provider community, and revise requirements for obtaining certification, inspections and investigations, continuing education, patient care, documentation, and the incorporation of statutory changes allowing for monetary penalties. The proposed amendments also update the structure of the regulation throughout for consistency with other Department regulations.

The Department had a Notice of Drafting published in the February 28, 2020, State Register. A copy of the Notice of Drafting appears herein as Attachment B. The Department received eighty-one public comments by the March 30, 2020, close of the public comment period. Attachment C presents a summary of the public comments received and Department responses.

The Bureau held a stakeholder meeting on March 16, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

Appropriate Department staff conducted an internal review of the proposed amendments on July 28, 2020.

Department staff received comments on the proposed amendments from the Athletic Trainers' Advisory Committee on July 31, 2020.

The Bureau of Healthcare Professionals requested the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 25, 2020, *State Register*.

After discussion, Mr. Kinney moved, seconded by Mr. Lee, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-96, Athletic Trainers, 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. Chairman Elam abstained.

<u>Item 8: Notice of Proposed Regulation Amending R.61-43, Standards for the Permitting of Agricultural Animal Facilities</u> (Attachment 8-1)

Mr. Chuck Williams, Manager, Groundwater Protection and Agricultural Permitting Section, Bureau of Water, Environmental Affairs, presented this item to the Board.

The Bureau of Water ("Bureau") proposed the Notice of Proposed Regulation amending R.61-43, Standards for the Permitting of Agricultural Animal Facilities, for publication in the

September 25, 2020, South Carolina State Register ("State Register"). Legal authority resides in S.C. Code Sections 44-1-60, 44-1-65, 46-45-80, and 48-1-10 et seq., which authorizes the South Carolina Department of Health and Environmental Control ("Department") to promulgate applicable regulations, procedures, or standards as may be necessary to protect human health and the environment. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these amendments.

The Bureau proposed amending R.61-43 to incorporate Act 139 of 2018, which amended S.C. Code Sections 44-1-60 and 46-45-80 and added Section 44-1-65. S.C. Code Section 44-44-1-65 establishes specific requirements for review and appeal of decisions by the Department regarding the permitting, licensing, certification, or other approval of poultry and other animal facilities, except for swine facilities. Section 44-1-60 sets procedures for reviewing permits for poultry and other animal facilities, except swine facilities, relating to appeals from Department decisions giving rise to contested cases. Section 46-45-80 includes provisions regarding setback distances for poultry and other animal facilities, except swine facilities, so as to prohibit requiring additional setback distances if established distances are achieved, allow waiver of the established setback distances in certain circumstances, and other purposes. Since the above- referenced statutory provisions added and removed requirements currently contained in R.61-43, the Department proposes further amendments to reflect these changes.

The Bureau also proposed amendments to correct typographical errors, citation errors, and other errors and omissions that have come to the Department's attention. These include correcting form references and regulation references, updating definitions, adding and/or omitting language and punctuation, clarification, reorganizing sections for consistency, and other such changes.

The Bureau held five stakeholder meetings between March 28, 2019 and August 25, 2020 to solicit stakeholder input, including open-invitation meetings, in person and virtually, and individual interest groups. The Bureau utilized the Department's website and agency calendar to advertise these meetings and emailed invitations to identified stakeholders. Bureau received feedback from the stakeholders and personnel considered their comments and suggestions regarding the proposed changes to the regulation.

The Department had a Notice of Drafting published in the June 26, 2020, State Register. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the July 27, 2020, close of the public comment period.

Department staff conducted an internal review of the proposed amendments on August 3, 2020.

The Bureau of Water requested the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 25, 2020, State Register.

After discussion, Mr. Lee moved, seconded by Dr. Morgan, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-43, Standards for the Permitting of Agricultural Animal Facilities, in the State Register, to provide opportunity for public comment, to received and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried 7-1. Mr. Creel voted no.

Item 9: Notice of Proposed Regulation Amending R.30-1, Statement of Policy, and R.30-12, Specific Project Standards for Tidelands and Coastal Waters (Attachment 9-1)

Ms. Elizabeth von Kolnitz, Chief, Office of Ocean and Coastal Resource Management, Environmental Affairs, presented this item to the Board.

The Office of Ocean and Coastal Resource Management proposed the Notice of Proposed Regulation amending R.30-1, Statement of Policy, and R.30-12, Specific Project Standards for Tidelands and Coastal Waters, for publication in the September 25, 2020, South Carolina State Register ("State Register"). Legal authority resides in S.C. Code Sections 48-39-10 et seq., which instructs the Department to implement policies to promote the economic and social welfare of the citizens of the state while protecting the sensitive and fragile areas in the coastal counties and promoting sound development of coastal resources. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed new regulations.

The Department proposed new sections R.30-1.D(31) and R.30-12.Q to provide a definition and add project standards for living shorelines. Coastal property owners and other stakeholders in South Carolina have expressed an increased interest in the use of living shorelines as an alternative to hardened erosion control structures within the estuarine environment. Coastal Division regulations currently do not provide guidance specific for living shoreline installations. The lack of a regulatory definition or specific project standards for living shorelines has resulted in longer permitting review times and uncertainties about project performance. The proposed new sections will allow for a more efficient authorization process by defining which projects qualify as a living shoreline and establishing specific standards for living shoreline installations. The proposed new sections will also help ensure a project's design will accomplish its intended goals.

The Department had a Notice of Drafting published in the April 24, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments during the public comment period.

In 2015, the Department commenced a Living Shoreline initiative in partnership with the South Carolina Department of Natural Resources and South Carolina's two National Estuarine Research Reserves to evaluate the performance of different living shoreline methods over time and under a range of environmental conditions. As a result of this collaboration, a technical report was produced in 2019 to provide science-based information to guide living shoreline project standards in South Carolina.

The Department convened a Living Shorelines Working Group that includes members of federal, state, and local governments, as well as nongovernment organizations (NGOs). The Working Group met four times between February 2017 and May 2019 to provide input on various aspects of living shorelines including regulatory guidance, research, and education and outreach. The Working Group will continue to meet in the future to assist in educational and training opportunities associated with living shorelines.

In February 2020, the Department held an inter-agency coordination meeting with key agencies involved in the living shorelines process from permitting through the installation phase. Specific agencies included the U.S. Army Corps of Engineers, U.S. Coast Guard, U.S. Fish and Wildlife Service, NOAA National Marine Fisheries Service, SC Department of Natural

Resources, DHEC Shellfish Program, and DHEC Bureau of Water. Representatives from local governments and NGOs also participated in the discussion.

Department staff conducted an internal review of the proposed amendments on August 21, 2020.

The Office of Ocean and Coastal Resource Management requested the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 25, 2020, State Register.

After discussion, Mr. Creel moved, seconded by Mr. Lee, to grant approval to publish the Notice of Proposed Regulation amending Regulation 30-1, Statement of Policy, and Regulation 30-12, Specific Project Standards for Tidelands and Coastal Waters, 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.

<u>Item 10: Public Hearing for Notice of Final Regulation Amending R.61-63, Radioactive Materials (Title A), Document No. 4958</u> (Attachment 10-1)

Ms. Stacey French, Director, Division of Waste Management, Environmental Affairs, presented this item to the Board.

The Bureau of Land and Waste Management ("Bureau") proposed the Notice of Final Regulation amending R.61-63, Radioactive Materials (Title A) for publication in the September 10, 2020, South Carolina State Register ("State Register"). Legal authority resides in S.C. Code Section 13-7-70, which designates the Department of Health and Environmental Control ("Department") as the agency responsible for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as they are for compliance with federal law. The amendments will take legal effect as of the September 25, 2020, publication in the State Register.

Pursuant to R.61-63, Radioactive Materials (Title A), the Department requested approval to ensure state standards comply with the Nuclear Regulatory Commission's ("Commission") regulatory updates. The federal Atomic Energy Act of 1954 enables the Commission to enter into agreements with governors allowing for state regulation of byproduct, source, and special nuclear material. 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 ("Department") amends R.61-63 for compliance with the Commission's federal regulatory updates. The proposed amendments add clarification and corrections to Part II of the regulation. Additionally, the proposed amendments authorize the Department to review general licensees' quality assurance programs for the use of Commission-approved Type B Packaging for transportation of radioactive material as required in NRC regulation Title 10, Code of Federal Regulations ("CFR") Part 71.

The Department had a Notice of Drafting published in the October 25, 2019, State Register.

The Bureau held a stakeholder meeting on November 14, 2019, to discuss the schedule

and implementation process for the proposed amendments.

The Bureau submitted draft text of the proposed amendments to the Technical Advisory Radiation Control Council ("TARCC") on January 7, 2020, for review. The Bureau received no comments from TARCC resulting from the review.

Appropriate Department staff conducted an internal review of the proposed amendments on January 14, 2020.

The Department had a Notice of Proposed Regulation published in the February 28, 2020, *State Register*. The Department received no public comments by the March 30, 2020, close of the public comment period.

The Bureau also submitted copies of the proposed amendments to the Commission for compatibility review on June 7, 2017. The Commission responded with comments dated July 25, 2017. The Bureau integrated these comments into the proposed amendments where applicable.

The Bureau also submitted copies of the proposed amendments to the Commission for compatibility review on June 7, 2017. The Commission responded with comments dated July 25, 2017. The Bureau integrated these comments into the proposed amendments where applicable.

The Bureau requested the Board to find need and reasonableness of the attached proposed amendment of R.61-63, *Radioactive Materials (Title A)*, for legal effect as of September 25, 2020, publication in the *State Register*.

A public hearing was conducted with no one present wishing to speak. (Attachment 10-2)

After discussion, Mr. Lee moved, seconded by Mr. Kinney, that based on the public hearing and documents submitted by Department staff, to find for the need and reasonableness of the proposed amendment of Regulation 61-63, Radioactive Materials (Title A), Document No. 4958, and grant approval to publish the Notice of Final Regulation for legal effects as of the September 25, 2020, publication in the State Register. The Board voted and Motion carried.

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 10-3)

Item 11: Agency Affairs

Dr. Brannon Traxler, Physician Consultant, Division of Acute Disease Epidemiology, Bureau of Public Health Preparedness, provided an update on the COVID 19 (Coronavirus).

After discussion, the Board accepted this as information.

W. Marshall Taylor, Jr., Acting Director, provided an update to the Board on the agency response to COVID 19, recognized Department staff for their continued efforts to maintain normal operations, and the Department's coordination with its partners during the pandemic.

After discussion, the Board accepted this as information.

W. Marshall Taylor, Jr., Acting Director, provided an update to the Board on the Department's presentation to the Senate Finance Committee. (Attachment 11-1)

After discussion, the Board accepted this as information.

Executive Session

Mr. Creel made a motion that the Board go into Executive Session pursuant to SC Code Section 30-4-70(A)(1) and (A)(2) to obtain legal advice related to a personnel matter. Mr. Lee seconded the motion and the motion carried unanimously.

Chairman Elam stated the Board was back in public session and while in Executive Session no actions were taken.

Chairman Elam informed the Board that he had appointed a sub-committee to review applicants for the position as agency Director. Vice Chairman Jim P. Creel, Jr., Seema Shrivastava-Patel, Charles M. Joye, II, P.E., along with Chairman Elam would serve on the sub-committee.

Item 12: Final Review Conference - Docket No. 20-RFR-44, Grey Ghost Properties, LLC, Issuance of an amendment to permit 2008-0066-1IT-P for the authorization of wet slips, side-tie dockage, a drystack, drystack storage launch pier, drystack storage queuing docks, a wave attenuator, a harbor masters building and the reconfiguration of the existing shrimp docks. (Attachment 12-1)

Ms. Elizabeth von Kolnitz, Chief, Office of Ocean and Coastal Resource Management, Environmental Affairs, presented this item to the Board. Ms. von Kolnitz advised the Board that Department staff and the applicant, Grey Ghost Properties, LLC, had reached an agreement to modify the permit and the Request for Final Review had been withdrawn.

After discussion, the Board accepted this as information.

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

Respectfully submitted,

Minutes approved this 8th day of October 2020.

ATTEST:

Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 September 10, 2020 Minutes
- 2-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 4-1 Revision of the Hearing Procedures for Certified Nursing Aides
- 5-1 Placement of Isotonitazene in Schedule I for Controlled Substances
- 6-1 Deletion of FDA-Approved Cannabidiol Drugs Containing No More Than 0.1% Tetrahydrocannabinols in Schedule V for Controlled Substances
- 7-1 Notice of Proposed Regulation Amending R.61-96, Athletic Trainers
- 8-1 Notice of Proposed Regulation Amending R.61-43, Standards for the Permitting of Agricultural Animal Facilities
- 9-1 Notice of Proposed Regulation Amending R.30-1, Statement of Policy, and R.30-12, Specific Project Standards for Tidelands and Coastal Waters
- 10-1 Public Hearing for Notice of Final Regulation Amending R.61-63, *Radioactive Materials* (Title A), Document No. 4958
- 10-2 Public Hearing Sign in Sheet
- 10-3 Public Hearing Transcript
- 11-1 Senate Finance Committee handout
- 12-1 Final Review Conference Docket No. 20-RFR-44, Grey Ghost Properties, LLC, Issuance of an amendment to permit 2008-0066-1IT-P for the authorization of wet slips, side-tie dockage, a drystack, drystack storage launch pier, drystack storage queuing docks, a wave attenuator, a harbor masters building and the reconfiguration of the existing shrimp docks.