



February 3, 2020

Kevin Williams, Deputy Director
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
And Safeguards
U.S. Nuclear Regulatory Commission
T8-E18
Washington, D.C. 20555-0001

Dear Mr. Williams:

Enclosed is a copy of the final revisions to the South Carolina Radiological Health Rules Regulation 61-63, Title A, February 23, 2018. The final regulations are identified by line-in/line-out text (or similar identification) and correspond to the following equivalent amendments to NRC's regulations.

<u>Rats ID</u>	<u>Title</u>	<u>State Section</u>
• 2012-1	Revised for text clarification	RHA 2.4.2.4
• 2012-1	Addition to allow specific licensees to install and service generally licensed devices	RHA 2.4

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200.

The February 2018 Edition of the South Carolina regulation can be found at the following link https://www.scstatehouse.gov/state_register.php. If you have any questions, please feel free to contact Lynne Garner at 803-898-0493 or garnerld@dhec.sc.gov

Sincerely,

A handwritten signature in blue ink, appearing to read 'Stacey French', is written over a light blue circular stamp.

Stacey L. French, P.E.
Director, Division of Waste Management
Bureau of Land and Waste Management

Enclosures:
As stated

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Document No. 4791
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 13-7-40

61-63. Radioactive Materials (Title A).

Synopsis:

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 do not require legislative review as DHEC promulgates the amendments to comply with federal law indicated above.

The Department had a Notice of Drafting for this amendment published in the *State Register* on April 28, 2017.

Section-by-Section Discussion of Amendments:

2.3.5

Revised to add text for clarification.

2.4.2.4

Revised to add text for clarification.

2.4.2.6 through subparagraphs 2.4.2.6.3

Added to allow specific licensees to install and service generally licensed devices.

2.7.14.8.2

Revised to add text for clarification.

2.20.2.2.13

Revised to add text for clarification.

2.20.2.3

Revised to add text for clarification.

2.20.2.5.6.1

Revised to add text for clarification.

2.22.1

Revised to delete reference and add new exceptions.

3.55.1.1

Revised to change text for accuracy of information.

5.6.1

Revised to add text for clarification and add new web address.

7.32.8

Added. This provision was previously omitted during a prior revision.

12.5.2.2

Revised to change reference.

12.7.1.5

Revised to add text for clarification.

12.7.3.1

Text is removed and added to reflect correct name and email address. Web address added.

12.8.1.10

Revised to add text for clarification.

12.12.4.1

Revised to remove text.

12.23.1.1

Revised to remove and replace web address.

12.23.6

Added to require the protection of security related information.

Instructions:

Amend R.61-63 pursuant to each individual instruction provided with the text below.

Text:

61-63. Radioactive Materials (Title A).

Revise 2.3.5 as shown.

2.3.5 No person may initially transfer or distribute source material to persons generally licensed under RHA 2.3.1.1 and 2.3.1.2, or equivalent regulations of the NRC or of an Agreement State, unless authorized by a specific license issued in accordance with RHA 2.6 or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by RHA 2.3.1 of this section before August 27, 2013, without specific authorization may continue for one (1) year beyond this date. Distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

Revise 2.4.2.4 as shown.

2.4.2.4 The general license in RHA 2.4.2.1 does not authorize the manufacture or import of devices containing radioactive material.

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Add 2.4.2.6 and subparagraphs 2.4.2.6.1 through 2.4.2.6.3 as shown.

2.4.2.6 Any person who holds a specific license issued by the NRC or an Agreement State authorizing the holder to manufacture, install, or service a device described in RHA 2.4.2 through 2.4.2.5 is hereby granted a general license to install and service such device and a general license to install and service such device in South Carolina, provided that:

2.4.2.6.1 [Reserved]

2.4.2.6.2 The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or Agreement State.

2.4.2.6.3 Such person assures that any labels required to be affixed to the device under regulations of the NRC or Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

Revise 2.7.14.8.2 as shown.

2.7.14.8.2 Each person licensed under RHA 2.7.14 shall report annually all transfers of devices to persons for use under a general license in an NRC or Agreement State's regulations that are equivalent to RHA 2.4.4 to the NRC or responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular NRC licensee or Agreement State during the reporting period, this information must be reported to the NRC or responsible Agreement State agency upon request of the Department.

Revise 2.20.2.13 as shown.

2.20.2.13 Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in RHA 2.20.2.2, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to RHA 2.5, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to RHA 2.20.2.2.

Revise 2.20.2.3 as shown.

2.20.2.3 Gas and aerosol detectors containing byproduct material. Except for persons who manufacture, possess, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license of Parts II, III, IV, V, VI, VIII, and XI in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32 which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a Licensing State with comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under RHA 2.20.2.3, should apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with RHA 2.29.

Revise 2.20.2.5.6.1 as shown.

2.20.2.5.6.1 Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license of Parts II, III, IV, V, VI, VIII, and XI set forth in Regulation 61-63, Radioactive Materials (Title A) to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to Section 32.30 of 10 CFR Part 32, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

Revise 2.22.1 as shown.

2.22.1 The transportation of radioactive material shall be in accordance with the requirements in 10 CFR Part 71, which is incorporated by reference, with the exception of the following sections: 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a)-(c), 71.91(b), 71.99, 71.100, 71.101(c)(2), 71.101(g), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125. The provisions of this section apply to the transportation of radioactive material, or delivery of radioactive material to a carrier for transportation, regardless of whether or not the carrier is also subject to the rules and regulations of the Nuclear Regulatory Commission contained in Title 10 CFR Part 71 and other agencies of the United States having jurisdiction.

Revise 3.55.1.1 as shown.

3.55.1.1 A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest [Shipping Paper]) and 541 (Uniform Low-Level Radioactive Waste Manifest [Container and Waste Description]) and, if necessary, on applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest [Manifest Index and Regional Compact Tabulation]). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest. NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained from the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-5877. This appendix includes information requirements of the Department of Transportation. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency (EPA) regulations, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this part. Licensees are not required by the Department to comply with the manifesting requirements of this part when they ship:

Revise 5.6.1 as shown.

5.6.1 Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136 issued January

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1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone (212) 642-4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission library, 11545 Rockville Pike, Rockville, Maryland, 20852. A copy of the document is also on file at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202)741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Department may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

Add 7.32.8 as shown.

7.32.8 In addition to the other requirements of this section, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

7.32.8.1 The manifest information that must be electronically stored is:

7.32.8.1.1 That required in Part III, Appendix D, RHA 3.55 with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

7.32.8.1.2 That information required in RHA 7.32.5.

7.32.8.2 As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium, or other medium as required by the Department.

Revise 12.5.2.2 as shown.

12.5.2.2 Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RHA 12.6.3.

Revise 12.7.1.5 as shown.

12.7.1.5 Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information modified handling.

Revise 12.7.3.1 as shown.

12.7.3.1 For the purpose of complying with Subpart B, Department licensees shall submit to the U.S. Nuclear Regulatory Commission, Director Division of Facilities and Security U.S NRC 11545 Rockville Pike Rockville, MD 20852 ATTN: Criminal History Program, Mail Stop TWB-05 B32M, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable,

other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

Revise 12.8.1.10 as shown.

12.8.1.10 Commercial vehicle drivers for road shipments of Category 1 and Category 2 quantities of radioactive material;

Revise 12.12.4.1 as shown.

12.12.4.1 Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

Revise as 12.23.1.1 shown.

12.23.1.1 The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at <https://scp.nrc.gov/special/designee.pdf>. A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the Department may be made by email to RAMQC_shipments@dhec.sc.gov or by fax to 803-898-0391. Notifications to the Department must be to the Director, Division of Land & Waste Management, Bureau of Waste Management, 2600 Bull Street, Columbia, SC 29201.

Add 12.23.6 as shown.

RHA 12.23.6 Protection of information. State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the kind specified in RHA 12.23.2 shall protect that information against unauthorized disclosure as specified in RHA 12.12.4 of this part.

Statement of Need and Reasonableness:

The following is based on an analysis of the factors listed in 1976 Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: Amendment to R.61-63, Radioactive Materials (Title A).

Purpose: The Department of Health and Environmental Control amends Regulation 61-63 for compliance with federal regulations 10 CFR Parts 19, 20, 30, 31, 32, 34, 37, 40, 61 and 71.

Legal Authority: 1976 Code Section 13-7-40.

Plan for Implementation: The DHEC Regulation Development Update (accessible at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>) provides a summary of and link to these amendments. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Department personnel will take appropriate steps to inform the regulated community of the amendments and any associated information.

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DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

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. To renew South Carolina's ongoing agreement with the Commission, the Department of Health and Environmental Control amends Regulation 61-63 for compliance with the Commission's federal regulatory updates. The amendments are beneficial in that they ensure state oversight of required standards.

DETERMINATION OF COSTS AND BENEFITS:

Neither the state nor its political subdivisions will incur additional cost through implementation of these amendments. Existing staff and resources will be utilized to implement these amendments to the regulation. The amendments will not create any significant additional cost to the regulated community since requirements or changes to the regulation will be substantially consistent with the current guidelines and review guidelines utilized by the Department.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

These amendments seek to ensure an effective regulatory program for radioactive material users under state jurisdiction and protection of the public and workers from unnecessary exposure to ionizing radiation.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

None. Federal requirements will apply to all affected users. These amendments eliminate possible duplicative or redundant requirements.

Document No. 4678
SOUTH CAROLINA HUMAN AFFAIRS COMMISSION
CHAPTER 65
Statutory Authority: 1976 Code Sections 31-21-30 and 31-21-100

65-223. Investigation Procedures.

Synopsis:

Regulation 65-223 explains and refines the procedures for Agency investigations based on complaints of unlawful conduct under the Fair Housing Law.

Notice of Drafting for the proposed amended regulation was published in the *State Register* on September 23, 2016.

Instructions:

Replace Regulation 65-223 as printed below.