



W. Marshall Taylor Jr., Acting Director

Promoting and protecting the health of the public and the environment

March 25, 2015

Pamela Henderson, Deputy Director
Division Material Safety, State, Tribal
and Rulemaking Programs Agreements
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission (NRC)
T8-E24
Washington, D.C. 20555-0001

Dear Ms. Henderson:

The South Carolina Department of Health and Environmental Control (SCDHEC) has reviewed the Nuclear Regulatory Commission's (NRC) comments in the letter of March 6, 2015, following the submission of the final revisions to South Carolina regulations Radioactive Materials Regulation 61-63, Title A.

With regards to the NRC's comments, SCDHEC proposes to adopt the revisions per the comments provided in order to meet the Compatibility Category requirements as designated by the NRC. The revisions to South Carolina regulations Radioactive Materials Regulation 61-63, Title A shall be adopted during our next opportunity to amend our regulations. The regulations are to be revised (per comments) as found in the enclosed document.

If you have any questions, please feel free to contact Susan Jenkins of my staff at 803-898-0377 or jenkinse@dhec.sc.gov.

Sincerely,

David Scaturo, PE, PG, Director
Division of Waste Management
Bureau of Land & Waste Management

cc: Mr. Aaron Gantt, Chief
Bureau of Radiological Health

Enclosure

1. 2.4.2.4 The general license in RHA 2.4.2.1 does not authorize the manufacture of devices containing radioactive material.

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.

2. 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 offshore waters, as defined in 10 CFR 150.3(f), 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.

3. 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 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). 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, 20852-2738. A copy of the document is also on file at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC 20408.

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.

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 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). 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, 20852-2738. 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.

4. 2.20.2.2.13 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 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.

2.20.2.2.13 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.

5. 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 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.

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.

6. 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 information, or safeguards information modified handling.

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.

7. #10

8. 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 an Agreement State, unless authorized by a specific license issued in accordance with RHA 2.6 or equivalent provisions of 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 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.

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 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.

9. 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 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.

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.

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 set forth in Regulation 61-63, 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 under Part 2, 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.

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, 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 under Part 2, 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.

10. 2.22.1 The transportation of radioactive material shall be in accordance with the requirements in 10 CFR Part 71 as revised January 1, 2006, which is incorporated by reference, with the exception of the following sections: 71.2, 71.6, 71.14(b), 71.19, 71.24, 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, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100. 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.

2.22.1 The transportation of radioactive material shall be in accordance with the requirements in 10 CFR Part 71 ~~as revised January 1, 2006~~, which is incorporated by reference, with the exception of the following sections: 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.24, 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, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101, 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.

COMPATIBILITY COMMENTS ON SOUTH CAROLINA REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	RHA 2.4.2.4	31.5(d)	2012-1	C	<p>Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere</p> <p>SC omits the word "import" in Section RHS 2.4.2.4.</p> <p>SC needs to add the words <i>or import</i> between "manufacture" and "of devices"</p> <p>SC needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 31.5(d).</p>
2	RHA 2.4	31.6	2012-1	C	<p>General license to install devices generally licensed in §31.5</p> <p>SC omits requirements for a general license to install devices generally licensed in RHA 2.4.</p> <p>SC needs to add an equivalent provision that meets the essential objectives of 10 CFR 31.6 in order to meet the Compatibility Category C designation assigned to 10 CFR 31.6.</p>
3	RHA 5.6.1	34.20(a)(1)	2012-3	B	<p>Performance requirements for industrial radiography equipment</p> <p>RHA 5.6.1 contains outdated information for acquiring a copy of American National Standard N432-1980. RHA 5.6.1 reads, "...A copy of the document is also on file at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC 20408."</p> <p>SC needs to revise the information for acquiring a copy of American National Standard N432-1980 stated above to align RHA 5.6.1 with 10 CFR</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>34.20(a)(1).</p> <p>SC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 34.20(a)(1).</p>
4	RHA 2.20.2.2	30.15	2012-4	B	<p>Certain items containing byproduct material</p> <p>SC omits the phrase "<i>pursuant to</i>" in Section RHA 2.20.2.2.</p> <p>SC needs to add "<i>pursuant to</i>" between the word "license" and "RHA 2.5" in RHA 2.20.2.2.13.</p> <p>SC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.15.</p>
5	RHA 2.7.14.8.2	32.56	2012-4	B	<p>Luminous safety devices for use in aircraft: Requirements for license to manufacturer, assemble, repair or initially transfer.</p> <p>Same: Material transfer reports.</p> <p>SC omits the phrase "<i>NRC or</i>" in Section RHA 2.7.14.8.2.</p> <p>SC needs to add "<i>NRC or</i>" between the word "the" and "responsible Agreement State agency" in RHA 2.7.14.8.2.</p> <p>SC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.56.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
6	RHA 12.7	37.27(a)	2013-1	B	<p>Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material</p> <p>SC omits the words “materials, access to safeguards” in Section 12.7.1.5.</p> <p>SC needs to insert “materials, access to safeguards” between the words “radioactive” and “information” in Section 12.7.1.5</p> <p>SC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 37.27(a).</p>
7	RHA 2.22	71.97	2013-1	B	<p>Advance notification of shipment of irradiated reactor fuel and nuclear waste</p> <p>RHA 2.22 incorporates the requirements of 10 CFR Part 71 by reference, with some exceptions, as revised January 1, 2006. The adopted revision of Part 71 is outdated and does not contain any amendments to Part 71 that occurred after January 1, 2006, or the changes to 71.97 associated with RATS ID 2013-1.</p> <p>SC needs to address the comment above in order to meet the Compatibility Category B designation assigned to 10 CFR 71.97.</p>
8	RHA 2.3.5	40.22(e)	2013-2	B	<p>Small quantities of source material</p> <p>SC omits the phrase “of the NRC” in section RHA 2.3.5.</p> <p>SC needs to change 2.3.5 to read “No person may initially transfer or distribute source material to persons generally licensed under RHA 2.3.1.1</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>and 2.3.1.2, or equivalent regulations of the NRC or 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.”</p> <p>SC need to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 40.22(e).</p>
9	RHA 2.20.2.3 2.20.2.5.6.1 2.20.2.5.6.2	30.20(a) 30.22(a)	2012-4	B	<p>Gas and aerosol detectors containing byproduct material</p> <p>Certain industrial devices</p> <p>SC regulations state that “any person is exempt from the requirements for a license in these regulations” (2.20.2.3); and “exempt from the requirements for a license set forth in Regulations 61-63” (2.20.2.5.6.1). As written, this creates a larger exemption than stated in 10 CFR 30.20 and 30.22 (e.g., it creates an exemption from the licensing requirements in Part 71).</p> <p>SC needs to identify the equivalent State Sections that correspond to those stated in 10 CFR 30.20(a) and 30.22(a), (i.e., Parts 19, 20, 30 through 36), in order to meet the Compatibility Category B designation assigned to 10 CFR 30.20 and 30.22.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
10	RHA 2.22	10 CFR 71	N/A	NRC	<p>Transportation of Radioactive Material</p> <p>SC adopted 10 CFR Part 71 by reference in RHA 2.22.1. This section states "The transportation of radioactive material shall be in accordance with the requirements in 10 CFR Part 71 as revised January 1, 2006 which is incorporated by reference, with exception of the following sections: 71.2, 71.6, 71.14(b), 71.19, 71.24, 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, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, and 71.100."</p> <p>Reference to 10 CFR 71.24, needs to be removed from RHA 2.22.1 as it does not exist. In addition, the following regulations within 10 CFR Part 71 need to be added to the listing of excepted sections: 71.11, 71.52, 71.53, 71.101, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125 as these sections are reserved to the NRC.</p> <p>SC needs to make the above changes to meet the Compatibility Category NRC designation assigned to the above sections of 10 CFR Part 71.</p>



PROMOTE PROTECT PROSPER

South Carolina Department of Health
and Environmental Control

2600 Bull Street, Columbia, SC 29201-1708

Visit DHEC's website at <http://www.scdhec.gov>

Pamela Henderson, Deputy Director
Div. Material Safety, State, Tribal and Rulemaking Prog. Agreements
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission (NRC)
T8-E24
Washington, D.C. 20555-0001



neopost[®]
03/26/2015
FIRST-CLASS MAIL
PRSR
US POSTAGE \$001.023

ZIP 29201
041L12208831