

From: Monica Orendi
To: Patricia McGrady-Finneran
Date: 01/30/2008 8:29:10 AM
Subject: Fwd: RATS ID 2001-1 South Carolina

>>> "Melinda W. Bradshaw" <BRADSHMW@dhec.sc.gov> 1/29/2008 3:47 PM >>>
Monica-

I'll try to get the attachment through this time! I have a cover letter to Mr. Lewis and the actual document to review combined in this attachment for final review. Thank you for all your continued help!

Melinda

Mail Envelope Properties (47A07BA1.A8E : 21 : 10192)

Subject: Fwd: RATS ID 2001-1 South Carolina
Creation Date 01/30/2008 8:29:05 AM
From: Monica Orendi

Created By: MLO1@nrc.gov

Recipients

nrc.gov
TWGWPO01.HQGWDO01
PXM1 (Patricia McGrady-Finneran)

Post Office

TWGWPO01.HQGWDO01

Route

nrc.gov

Files	Size	Date & Time
MESSAGE	825	01/30/2008 8:29:05 AM
RATS ID 2001.doc	72192	01/30/2008 8:28:47 AM

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard

Junk Mail Handling Evaluation Results

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Junk Mail handling disabled by User
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January 28, 2008

Robert J. Lewis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Lewis:

Enclosed is a copy of the final revisions to the South Carolina Radiological Health's Radioactive Materials Regulations 61-63, Title A (final date of October 26, 2007). The final regulations are identified by strike through /underline text and correspond to the following equivalent amendments to NRC's regulations. This regulation was included in our earlier submittal letter dated November 14, 2007 but the RATS ID Number was inadvertently omitted.

<u>RATS ID</u>	<u>Title</u>	<u>State Section</u>
• 2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Radioactive Material – Parts 30, 31, 32	RHA Part II

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (803) 545-4400 or Melinda W. Bradshaw of my staff at (803) 545-4411 or bradshmw@dhec.sc.gov.

Sincerely,

Aaron A. Gantt, Bureau Chief
Bureau of Radiological Health
Department of Health and Environmental
Control

Enclosures:
As stated

mwb

PLEASE NOTE: ONLY THE RELEVANT FINAL REGULATION INFORMATION FOR RATS ID 2001-1 IS INCLUDED IN THIS TRANSMITTAL.

**BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
SUMMARY SHEET
October 11, 2007**

 X ACTION
 INFORMATION

I. **TITLE:** Public Hearing before the Board and Consideration for Final Approval
 Amendment of Regulation 61-63, Radioactive Material (Title A)
 State Register Document No. 3136
 Exempt from Legislative Review

II. **SUBJECT:** Request for finding of Need and Reasonableness Pursuant to S.C. Code
 Section 1-23-111.

III. **FACTS:**

1. The Nuclear Regulatory Commission continually updates regulations, and state regulations are amended regularly to incorporate federal updates. Section 274 of the Atomic Energy Act of 1954, as amended, and the Agreement between the U.S. Nuclear Regulatory Commission and the State of South Carolina, require that we adopt federal regulations for compatibility.

2. Pursuant to statutory authority provided in S.C. Code Section 13-7-10 et seq., the Department is requesting approval to amend Regulation 61-63, Radioactive Material (Title A). Proposed revisions are required to maintain compatibility with regulations promulgated by the U.S. Nuclear Regulatory Commission in Title 10, Code of Federal Regulations. The intended action revises requirements for general licensees, portable gauge licensees, manufacturers and distributors, and amends the regulations regarding the medical use of radioactive materials (Parts II, III and IV). Proposed regulations will comply with 10 CFR Parts 20, 30, 31, 32, 35, 40, and 70, Final Rules, published in the Federal Register on April 29, 2005, July 11, 2005, and March 27, 2006. A Table of Revisions and the Text of the Proposed Amendment are submitted as Attachments B and C.

3. A preliminary assessment report and fiscal impact statement are not required because these amendments will comply with federal law.

4. The statutory process for amendment of Regulation 61-63 was initiated by publication of a Notice of Drafting in the State Register on February 23, 2007. No comments were received concerning drafting of these updated regulations. A copy of the Notice is submitted as Attachment E.

5. The proposed amendment was reviewed internally by appropriate staff as required by DHEC administrative policy. Copies of the Proposed regulation were submitted for comment to the Technical Advisory Radiation Control Council (TARCC). No comments were received from these reviews.

6. Staff were granted initial approval by the Board on July 12, 2007, to public notice the proposed regulation and hold a staff-informational forum. A Notice of Proposed Regulation was published in the State Register on July 27, 2007, as Document No. 3136; an excerpt from that publication is submitted as Attachment D. The Notice provided notice of opportunity for the interested public to comment on the proposed regulation in writing, to attend a staff informational forum and to appear at a public hearing before the DHEC Board.

7. The staff informational forum was held on August 30, 2007. No comments were received at the staff informational forum nor during the public comment period.

8. Department staff are requesting a public hearing before the Board and a finding of need and reasonableness of the proposed regulations. If approved by the Board, the regulations will be submitted to the Legislative Council for publication as final in the State Register on October 26, 2007.

IV. ANALYSIS:

1. It is necessary to update existing regulations as changes occur at the federal level in order to maintain compatibility with the federal government and other Agreement States. This will 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.

2. These revisions incorporate applicable regulatory additions and changes issued by the U.S. Nuclear Regulatory Commission since the last revisions were adopted and issued in 2006.

3. A Statement of Need and Reasonableness is submitted as Attachment A.

V. **RECOMMENDATION:** Department staff recommends that based upon the public hearing and attached information, that the Board find for the need and reasonableness of the proposed regulation and approve it for publication as final in the State Register.

Submitted by:

Approved by:

Aaron A. Gantt, Chief
Bureau of Radiological Health

Pamela M. Dukes
Deputy Commissioner
Health Regulation

Attachments:

- A. Statement of Need and Reasonableness
- B. Table of Revisions
- C. Text of Revisions
- D. Excerpt from State Register Notice of Proposed Regulations

- E. State Register Notice of Drafting
- F. Applicable Law: copy of S.C. Code Section 13-7-40

ATTACHMENT A
STATEMENT OF NEED AND REASONABLENESS FOR
AMENDMENT OF R.61-63, RADIOACTIVE MATERIALS (TITLE A)
October 11, 2007

The statement of need and reasonableness was determined based on staff analysis pursuant to S.C. Code Section 1-23-115(c)(1)-(3) and (9)-(11):

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

Purpose: To amend Regulation 61-63 in accordance with changes to Federal Regulation 10 CFR Part 20, 30, 31, 32, 35, 40 and 70, Final Rules.

Legal Authority: This change to state law is authorized by S.C. Code Section 13-7-40 and required by Section 274 of the Atomic Energy Act, 40 U.S.C. Section 2021b.

Plan for Implementation: Existing staff of the Bureau of Radiological Health will implement these changes. The additional requirements are expected to require 30 man days of effort. Impact on other program areas will be slight.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION AND EXPECTED BENEFIT: This regulatory amendment is exempt from the requirements of a Preliminary Fiscal Impact Statement or a Preliminary Assessment Report because each change is necessary to maintain compatibility with Federal regulations. In amending the Federal regulations, the U.S. Nuclear Regulatory Commission found the following:

The proposed regulation revises requirements for general licensees, portable gauge licensees, manufacturers and distributors.

The proposed regulation amends the regulations governing the training for medical use of radioactive material.

DETERMINATION OF COSTS AND BENEFITS: No additional cost will be incurred by the State or its political subdivisions by the implementation of this amendment. Existing staff and resources will be utilized to implement this amendment to the regulation. It is anticipated that the amendment will not create any significant additional cost to the regulated community based on the fact that 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: It is necessary to update existing regulations as changes occur at the federal level in order to maintain compatibility with the federal government and other Agreement States. This will 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. The proposed amendments eliminate possible duplicative or redundant requirements.

ATTACHMENT B
TABLE OF REVISIONS FOR AMENDMENT OF R.61-63
October 11, 2007

PART II

<u>SECTION</u>	<u>REVISION</u>
R.61-63.2.4.2.3.4.1	Adds omitted testing requirements.
R.61-63.2.4.2.3.7	Adds omitted requirements for General License exports.
R.61-63.2.4.2.3.14	Adds export requirements.
R.61-63.2.4.2.3.15	Adds reporting requirement for general licensees.

ATTACHMENT C
TEXT OF REVISIONS
R.61-63, Radioactive Materials, Title A
October 11, 2007

LEGEND:

Underlined text = new text being added.

~~Strikeout text~~ = existing text being deleted.

PART II

LICENSING OF RADIOACTIVE MATERIALS

2.4.2.3.4 Shall maintain records showing compliance with the requirements of RHA 2.4.2.3.2 and 2.4.2.3.3. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of the persons performing, testing installation services, and removal from installation concerning the radioactive material, its shielding or containment;

The licensee shall retain these records as follows:

2.4.2.3.4.1 Each record of a test for leakage of radioactive material required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.2 Each record of a test of the on-off mechanism and indicator required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.3 Each record that is required by paragraph RHA 2.4.2.3.3 of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

2.4.2.3.7 Shall transfer or dispose of the device containing radioactive material only by export as provided by RHA 2.4.2.3.14 of this section, by transfer to another general licensee as authorized in RHA 2.4.2.3.8 or to a person authorized to receive the device by a specific license issued by this Department or by the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved under RHA 2.4.2.3.7.2. In complying with this section, the licensee:

2.4.2.3.7.1 Shall furnish a report to the Department within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address, and license number of the person receiving the device (license number not applicable if exported); and the date of the transfer.

2.4.2.3.14 Shall not export the device containing radioactive material except in accordance with 10CFR part 110, Code of Federal Regulations;

2.4.2.3.15 Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Chief of the Bureau of Radiological Health, SC Department of Health and Environmental Control, by an appropriate method listed in RHA 1.13 of this regulation, a written justification for the request.