

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1967 S.C. Code Ann. Section 13-7-10 *et seq.*, as amended

R.61-63 Radioactive Materials (Title A)

Preamble:

The Nuclear Regulatory Commission (USNRC) promulgates amendments to 10 CFR 30, 40, 70 and 71 throughout each calendar year. Recent amendments include requirements for the National Source Tracking System (RATS-ID 2006-2 & 2006-3), published in the *Federal Register* on November 8, 2006 at 71 FR 65585, the Expanded Definition of Byproduct Material (RATS-ID 2007-3), published on October 1, 2007 at 72 FR 55864, and Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent (RATS-ID 2008-1), published on December 4, 2007 at 72 FR 68043.

The State is required to adopt certain federal amendments within three years of the effective date of changes in NRC regulations to maintain authorization by the USNRC for the State Radioactive Waste Management Program.

The Department intends to amend R.61-63, Radioactive Materials (Title A) to maintain conformity with federal requirements and ensure compliance with federal standards as required by Section 274 of the Atomic Energy Act of 1954. In addition, minor corrections and clarifications may be made to achieve conformity with prior federal regulations. These amendments will not be more stringent than the federal equivalent, and legislative review will not be required, nor is a preliminary assessment report or fiscal impact statement required.

A Notice of Drafting for the proposed amendments was published in the *State Register* on May 22, 2009. Notice was also published on the Department's Regulatory Information Internet site in its monthly Regulation Development Update, as well as on the DHEC Land and Waste Management Internet site. No comments were received.

Discussion of Proposed Revisions

1.2.6 - Revise definition for "byproduct material".

1.2.10 - Insert definition for "discrete source" and renumber balance of RHA 1.2.

1.2.20 - Insert definition for "particle accelerator" and renumber balance of RHA 1.2.

1.15.3.1 - Correct 105 to 10⁵ in both occurrences

1.15.3.2 - Correct 1012 to 10¹² in both occurrences

1.15.3.4 - Correct 105 to 10⁵ in both occurrences

2.1.1 Revise the list of prohibitions not allowed except as authorized.

2.4.2.2.1 through 2.4.2.2.3 - Add three new paragraphs on specific licenses issued regarding certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere.

2.4.2.3.11.1 - Revise paragraph to add detailed listing of radium-226 after Cobalt-60.

2.4.8 – 2.4.8.4 - Add new section on a general license for certain items and self-luminous products containing Radium-226.

2.5.7.1 – 2.5.7.2 - Revise requirements for an application for a specific license to use radioactive material in the form of a sealed source.

2.5.7.3 and subparts .1 & .2 Add new paragraphs on sources containing naturally occurring or accelerator produced radioactive material.

2.5.8 and subparts .1 through .4 - Add paragraphs concerning application to produce Positron Emission Tomography (PET) radioactive drugs.

2.7.4.2.6 - Add details on Cobalt-57 after the word “microcuries”

2.7.4.3.1 - Modify paragraph to add details to identifying radioactive contents.

2.7.5.1.2.1 - Modify paragraph to clarify scope of drug establishments on application evidence.

2.7.5.1.2.3-2.7.5.1.2.4 - Modify these two paragraphs on application evidence to accommodate adding paragraph 2.7.1.2.5.

2.7.5.1.2.5 - Add paragraph on application evidence for Positron Emission Tomography..

2.7.5.2.2.2 - Modify to correct cross reference:

2.7.5.2.4 - 2.7.5.2.4.1-2 - Modify 2.7.5.2.4 as shown and add subparagraphs 2.7.5.2.4.1 and .2 on requirements for the designation of a nuclear pharmacist.

2.7.5.2.5 -and subparagraphs 2.7.5.2.5.1-.6 - Revise paragraphs on requirements for designation of a nuclear pharmacist and how to provide certification.

2.7.8 Add new Section designating Requirements for specific license.

2.10.8 - Add paragraph on terms and conditions of licenses.

2.10.9.1 – 2.10.9.4 - Add paragraphs on terms and conditions of licenses.

2.11.11.4 - Revise cross reference to reflect changes in regulation.

2.20.2.2.1.8 - Revise paragraph on Radium-226 timepieces.

2.20.2.3 - Revise paragraph on gas and aerosol detectors containing byproduct material to add criteria for determining who is regulated.

2.20.2.5.2 - Revise paragraph on exempt quantities of byproduct material possessed before September 25, 1971.

2.24 Table of Exempt Quantities - Change column headings by replacing the words “Radioactive Material” with “Byproduct Material” and add the heading “Micro Curies” in Column two and four. Add

in alphanumeric order: Germanium-68 (Ge-68) (Microcuries: 10); change microcuries for Cesium-129 (Cs-129) from 10 to 100; and add in alphanumeric order: Yttrium-88 (Y-88) (Microcuries: 10).

2.31, Schedule E, QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE. - Add Radium-226 to table in alphanumeric order.

3.2.63 - Add definition for “Nationally tracked source” and renumber balance of 3.2.

3.2.91 - Modify definition for “Total Effective Dose Equivalent” (TEDE), replacing the words “deep dose” with the words “effective dose”.

3.5.3 - Modify paragraph on assigned deep-dose equivalent.

3.31 - Retitle Section, “DISPOSAL OF SPECIFIC WASTES AND CERTAIN BYPRODUCT MATERIAL”

3.31.3 – 3.31.4 -Revise paragraph 3.31.3 on the disposal of specific wastes and byproduct material and add new paragraph 3.31.4. The deleted material from old paragraph 3.31.3 becomes a new paragraph, 3.31.5.

3.32.5 - Add paragraph on shipping manifest for byproduct material for disposal.

3.34.7 - Modify paragraph on requirements of record management prior to license termination to correct changed reference in regulation.

3.48 REPORTS TO INDIVIDUALS OF EXCEEDING DOSE LIMITS - Revise introductory paragraph following 3.48 heading on reports required to be given to individuals and the Department of any exposure exceeding occupational dose limits.

3.53 Appendix B, List of Elements - Add Nitrogen and Oxygen, alphabetically.

3.53 [Appendix B] Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposures; Effluent Concentrations; Concentrations for Release to Sewerage - Add Nitrogen and Oxygen by Atomic Number.

Part III, Appendix G RHA 3.58 - Add appendix for NATIONALLY TRACKED SOURCES – SERIALIZATION AND REPORTS OF TRANSACTIONS.

4.2.10 - Insert definition for “consortium” and renumber balance of Section RHA 4.2.

4.2.26 - Insert definition for “Positron Emission Tomography (PET) radionuclide production facility” and renumber balance of Section RHA 4.2.

4.6.1 - Modify paragraph on medical use license by removing the word “radioactive” before “material” and replace it with the word “byproduct”.

4.27 - Modify the title by removing the word “radioactive” before “material” and replace it with the word “byproduct”.

4.27.2.2.1 - .3 Revise section to add 4.27.2.2.3 to list of requirements.

4.27.3.3 and subparts 4.27.3.3.1&.2 - Revise paragraph for determination of doses.

4.35 - Revise title replacing the word “Radioactive” with the word “Byproduct”

4.35.1 - Revise introductory paragraph and 4.35.1 and add subparagraphs 4.35.1.1 – 4.35.1.2 to list requirements under 4.35.1 on unsealed radioactive material for uptake

4.35.2 - Revise paragraph unsealed radioactive material for uptake.

4.37 - Revise title to Section, removing the term “Radioactive” and adding “Byproduct”

4.37.1 Revise introductory paragraph and section 4.37.1 and add subparts 4.37.1.1-2 defining unsealed radioactive material for imaging.

4.37.2 - Revise paragraph on unsealed radioactive material for imaging.

4.38.1 - Revise paragraph on permissible Molybdenum 99 concentration and add subparagraphs 4.38.1.1 – 4.38.1.2 to add details of requirement.

Part 4 Subpart E, RHA 4.40 - Revise title to Section, Section 4.40 and introductory paragraph by removing “Radioactive” and adding “Byproduct” before the word “Material”.

4.40.1 and subparagraphs 4.40.1.1 & .2 and 4.40.2 - Revise paragraph on written directives and add subparagraphs to list requirements under 4.40.1.

4.40.2 Revise paragraph to list specifics in who is authorized in the production of PET radionuclides.

6.5.2 - and subparagraphs 6.5.2.1 – 6.5.2.2 Revise paragraph and add paragraphs on dose information to workers

6.5.4 - Revise paragraph on reporting to the Department.

7.2.22 - Revise definition for “Waste”.

Notice of Staff Informational Forum and Public Comment Period:

Staff of the Department of Health and Environmental Control invites interested members of the public and regulated community to attend a staff conducted informational forum to be held on Tuesday, January 26, 2010, at 10:00 a.m. in Room 1041 at the Stern Building at 8911 Farrow Road Suite 106. The purpose of the forum is to answer questions and to receive public comments from interested persons on the proposed amendment of R.61-63.

Interested persons are also provided an opportunity to submit written comments on the proposed regulation at the forum or during a public comment period by writing to Richard Haynes, Director, Division of Waste Management, 2600 Bull Street, Columbia, SC 29201. To be considered, written comments must be received no later than 5:00 p.m. on January 26, 2010, the close of the public comment period. Comments received by the deadline date shall be considered by staff in formulating the final proposed regulation for public hearing before the Board as noticed below.

Information or copies of the proposed text for public notice and comment may be obtained at the Department's *Regulation Development Update* under the Land and Waste Category at <http://www.scdhec.gov/regulatory.htm>, or at the Land and Waste website at: <http://www.scdhec.gov/lwm/html/public.html> or by calling Carolyn McLaughlin at (803) 896-4254.

Relevant public comments received at the Forum and during the public comment period above-noticed shall be submitted to the Board of Health and Environmental Control in a Summary of Public Comments and Department Responses for consideration at the public hearing as noticed below.

Notice of Public Hearing and Opportunity for Public Comment Pursuant to S.C. Code Sections 1-23-110 and 1-23-111:

Interested members of the public and regulated community are invited to make oral or written comments on the proposed amendment of R.61-63 at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly scheduled meeting on March 11, 2010. The public hearing will be held in the Board Room of the Commissioner's Suite, Third Floor, Aycock Building of the Department of Health and Environmental Control at 2600 Bull Street, Columbia, S.C. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The Board's agenda will be published by the Department in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes and, as a courtesy, are asked to provide written comments of their presentations for the record.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness complies with SC Code Ann. Section 1-23-115(C)(1)-(3) and (9)-(11)

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

Purpose: The Department intends to amend R.61-63, Radioactive Materials (Title A) to maintain conformity with federal requirements and ensure compliance with federal standards as required by Section 274 of the Atomic Energy Act of 1954. In addition, minor corrections and clarifications may be made to achieve conformity with prior federal regulations. These amendments will not be more stringent than the federal equivalent, and legislative review will not be required, nor is a preliminary assessment report or fiscal impact statement required.

Legal Authority: S.C. Ann. Code Sections 13-7-10 *et. seq.* and required by Section 274 of the Atomic Energy Act of 1954.

Plan for Implementation: Upon final approval by the Board of Health and Environmental Control and publication in the *State Register* as a final regulation, amended regulations will be provided to the regulated community at cost through the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS: Adoption of the proposed amendments of R.61-63 will enable compliance with recent federal amendments. See purpose above.

The Department intends to amend R.61-63, Radioactive Materials (Title A) to maintain conformity with federal requirements and ensure compliance with federal standards as required by Section 274 of the Atomic Energy Act of 1954. In addition, minor corrections and clarifications may be made to achieve conformity with prior federal regulations.

The regulation will be amended to implement a National Source Tracking System for certain sealed sources. The amendments will require licensees to report certain transactions involving these sealed sources to the National Source Tracking System. These transactions include manufacture, transfer, receipt, disassembly, or disposal of nationally tracked sources. The amendments will also require each licensee to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually reconcile the information in the system with the licensee's actual inventory. The manufacturers will be required to assign a unique serial number to each nationally tracked source.

The regulation is being amended to establish an expanded definition of Byproduct Material to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct).

The regulation is amended with respect to the Occupational Dose Records, Labeling Containers and the Total Effective Dose Equivalent. The changes limit the routine reporting of annual doses to those workers whose annual dose exceeds a specific dose threshold or who request a report. The changes modify the labeling requirements for certain containers holding licensed material within posted areas in nuclear power facilities. The rule removes the requirement that licensees attempt to obtain cumulative exposure records for workers unless these individuals are being authorized to receive a planned special exposure. The revisions reduce the administrative and information collection burdens on NRC and Agreement State licensees without affecting the level of protection for the health and safety of workers and the public or the environment.

DETERMINATION OF COSTS AND BENEFITS: This regulatory amendment is exempt from the requirements of a Preliminary Fiscal Impact Statement or a Preliminary Assessment Report because the proposed changes are necessary to maintain compliance with federal regulations. There are no known additional costs to the state and its political subdivisions.

UNCERTAINTIES OF ESTIMATES: There are no known uncertainties.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: This amendment will provide updates to the National Source Tracking System (NSTS), the expanded definition of byproduct material, and the requirements for occupational dose records, labeling containers, and total effective dose equivalent. The adoption of these regulations 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: The State's authority to implement federal requirements, which are believed to be beneficial to the public health and environment, would be compromised if these amendments were not adopted in South Carolina.

Text:

~~Indicates Matter Stricken~~

Indicates New Matter

The following sections have been added, deleted, or revised. All other sections of R.61-63 will remain. Deleted text is indicated by strikethrough; new text is indicated by underlining.

1.2.6 - Revise definition for “byproduct material”.

1.2.6 “Byproduct material” means:

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or ~~utilizing~~ using special nuclear material; ~~and~~

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “byproduct material” within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Nuclear Regulatory Commission, (NRC) in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

1.2.10 - Insert definition for “Discrete source” and renumber balance of RHA 1.2.

1.2.10 “Discrete source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

1.2.20 - Insert definition for “Particle accelerator” and renumber balance of RHA 1.2.

1.2.20 “Particle accelerator” means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, “accelerator” is an equivalent term.

In 1.15.3.1 correct 10⁵ to 10⁵ in both occurrences

1.15.3.1 Authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding ~~10⁵~~10⁵ times the applicable quantities set forth in Appendix C, RHA 3.54 or when a combination of isotopes is involved if R divided by ~~10⁵~~ 10⁵ is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix C, RHA 3.54.

In 1.15.3.2 correct 10¹² to 10¹² in both occurrences

1.15.3.2 Authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding ~~10¹²~~ 10¹² times the applicable quantities set forth in Appendix

C, RHA 3.54 (or when a combination of isotopes is involved if R, as defined in RHA 1.15.3.1, divided by ~~10¹²~~ 10¹² is greater than 1).

In 1.15.3.4 correct 105 to 10⁵ in both occurrences

1.15.3.4 Authorizing the possession of unsealed special nuclear material in quantities exceeding ~~10⁵~~ 10⁵ times the applicable quantities set forth in Appendix C, RHA 3.54 or when a combination of isotopes is involved if R divided by ~~10⁵~~ 10⁵ is greater than 1 (unity rule), where R is the sum of the ratios of the quantity of each isotope to the applicable value in Appendix C, RHA 3.54.

Part II Licensing of Radioactive Material

2.1.1 revise the list of prohibitions not allowed except as authorized to read as follows:

2.1.1 No person shall ~~receive, use, possess, transfer, or dispose of radioactive material manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material~~ except as authorized in a specific or general license issued pursuant to these regulations, or as otherwise provided in these regulations.

Add subparagraphs 2.4.2.2.1 - 2.4.2.2.3 as shown:

2.4.2.2.1 A specific license issued under Part 2 of this Regulation; or

2.4.2.2.2 An equivalent specific license issued by an Agreement State; or

2.4.2.2.3 An equivalent specific license issued by a State with provisions comparable to Part 2 of this Regulation.

At 2.4.2.3.11.1 add detailed listing of radium-226 after Cobalt-60 as shown:

2.4.2.3.11.1 When the device contains at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, or 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph RHA 2.4.2.3.11.3 (iv), represents a separate general licensee and requires a separate registration and fee.

Add new section 2.4.8 through 2.4.8.4 on a general license for certain items and self-luminous products containing Radium-226.as follows:

2.4.8 Self-Luminous Products Containing Ra-226

2.4.8.1 A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs 2.4.8.2, 2.4.8.3, and 2.4.8.4 of this section, Radium-226 contained in the following products manufactured prior to November 30, 2007.

2.4.8.1.1 Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2.4.8.1.2 Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

2.4.8.1.3 Luminous items installed in air, marine, or land vehicles.

2.4.8.1.4 All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

2.4.8.1.5 Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of Radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spintariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

2.4.8.2 Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in 2.4.8.1 of this section are exempt from the provisions of Parts 3 and 6 of this Regulation, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

2.4.8.3 Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 2.4.8.1 of this section:

2.4.8.3.1 Shall notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Division of Waste Management, South Carolina Department of Health & Environmental Control, 2600 Bull Street, Columbia SC, 29201 within 30 days.

2.4.8.3.2 Shall not abandon products containing Radium-226. The product, and any radioactive material from the product, may only be disposed of according to Part 3 of this Regulation or by transfer to a person authorized by a specific license to receive the Radium- 226 in the product or as otherwise approved by the Department.

2.4.8.3.3 Shall not export products containing Radium-226 except in accordance with this Regulation.

2.4.8.3.4 Shall dispose of products containing Radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive Radium-226 by a specific license issued under this Regulation, or equivalent regulations of an Agreement State, or as otherwise approved by the Department.

2.4.8.3.5 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 Director of the Division of Waste Management, South Carolina Department of Health & Environmental Control, 2600 Bull Street, Columbia SC, 29201, a written justification for the request.

2.4.8.4 The general license in paragraph 2.4.8.1 of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing Radium-226, except that timepieces may be disassembled and repaired.

2.5.7.1-2 Revise requirements for an application for a specific license to use radioactive material in the form of a sealed source as indicated:

2.5.7.1 Identify the source or device by manufacturer and model number as ~~requested~~ registered with the Department pursuant to RHA 2.29, the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State; or registered with the NRC under the provisions of 10 CFR 32.210, with an Agreement State, or for a source or a device containing Radium-226 or accelerator-produced radioactive material with a State under provisions comparable to the NRC; or

2.5.7.2 Contain the information identified ~~in RHA 2.29.2-~~ by the NRC in 10 CFR 32.210(c);
or

Add new paragraphs 2.5.7.3 and subparts .1 & .2 as follows:

2.5.7.3 For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under the provisions of 10 CFR 32.310 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified by the NRC, the applicant must provide:

2.5.7.3.1 All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

2.5.7.3.2 Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

Add new paragraphs 2.5.8 and subparts .1 - .4 as follows:

2.5.8 An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part 4 of this Regulation shall include:

2.5.8.1 A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part 2 of this Regulation for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2.5.8.2 Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Part 2 of this Regulation.

2.5.8.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Part 2 of this Regulation.

2.5.8.4 Information identified in Part 2 of this Regulation on the PET drugs to be noncommercially transferred to members of its consortium.

At 2.7.4.2.6 add detail on Cobalt-57 after microcuries as follows:

2.7.4.2.6 Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq) each.

At 2.7.4.3.1 Modify paragraph to add details to identifying radioactive contents as follows:

2.7.4.3.1 Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (0.37 MBq) of Iodine-125, Iodine-131, Selenium-75, or Carbon-14; 50 microcuries (1.85 MBq) of Hydrogen-3 (tritium); or 20 microcuries (0.74 MBq) of Iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of Iodine-129 and 0.005 microcurie (0.185 kBq) of Americium-241 each; or Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq); and

Modify 2.7.5.1.2.1 through .4 as shown and add a new paragraph 2.7.5.1.2.5:

2.7.5.1.2.1 ~~Registered or licensed~~ with the U.S. Food and Drug Administration (FDA) ~~as a drug manufacturer; as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);~~

2.7.5.1.2.3 Licensed as a pharmacy by a State Board of Pharmacy; ~~or~~

2.7.5.1.2.4 Operating as a nuclear pharmacy within a Federal medical institution; ~~or~~

2.7.5.1.2.5 A Positron Emission Tomography (PET) drug production facility registered with a State agency.

Modify 2.7.5.2.2.2 to correct cross reference:

2.7.5.2.2.2 This individual meets the requirements specified in ~~RHA 4.22.2 and 4.24~~ Part 4 of this Regulation, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

Modify 2.7.5.2.4 as shown and add subparagraphs 2.7.5.2.4.1 and .2 on designation of a pharmacist and providing certification.

2.7.5.2.4 May designate a pharmacist (as defined in RHA 4.2) as an authorized nuclear pharmacist if ~~the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Department under this part.~~

2.7.5.2.4.1 The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

2.7.5.2.4.2 The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

Modify 2.7.5.2.5 as shown and add subparagraphs 2.7.2.5.1 through 2.7.2.5.6

~~2.7.5.2.5 Shall provide to the Department: a copy of each individual's certification by the Board of Pharmaceutical Specialties, the NRC or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs 2.7.5.2.2.1 and 2.7.5.2.2.3 of this section, the individual to work as an authorized nuclear pharmacist.~~

2.7.5.2.5.1 A copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State as specified in Part 4 of this Regulation with the written attestation signed by a preceptor as required by Part 4 of this Regulation; or

2.7.5.2.5.2 The Commission or Agreement State license; or

2.7.5.2.5.3 Commission master materials licensee permit; or

2.7.5.2.5.4 The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

2.7.5.2.5.5 Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

2.7.5.2.5.6 A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs RHA 2.7.5.2.2.1 and 2.7.5.2.2.3, the individual to work as an authorized nuclear pharmacist.

2.7.8 Add whole new Section designating Requirements for specific license.

2.7.8 Calibration or reference sources containing Americium-241 or Radium-226: Requirements for license to manufacture or initially transfer.

2.7.8.1 An application for a specific license to manufacture or initially transfer calibration or reference sources containing Americium-241 or Radium-226, for distribution to persons generally licensed under RHA 2.4, will be approved if:

2.7.8.1.1 The applicant satisfies the general requirements of RHA 2.6;

2.7.8.1.2 The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

2.7.8.1.2.1 Chemical and physical form and maximum quantity of Americium 241 or Radium-226 in the source;

2.7.8.1.2.2 Details of construction and design;

2.7.8.1.2.3 Details of the method of incorporation and binding of the Americium-241 or Radium-226 in the source;

2.7.8.1.2.4 Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of Americium-241 or Radium-226, to demonstrate that the Americium-241 or Radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

2.7.8.1.2.5 Details of quality control procedures to be followed in manufacture of the source;

2.7.8.1.2.6 Description of labeling to be affixed to the source or the storage container for the source;

2.7.8.1.2.7 Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the source.

2.7.8.1.3 Each source will contain no more than 5 microcuries of Americium-241 or Radium-226.

2.7.8.1.4 The Department determines, with respect to any type of source containing more than 0.005 microcuries of Americium-241 or Radium-226, that:

2.7.8.1.4.1 The method of incorporation and binding of the Americium-241 or Radium-226 in the source is such that the Americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

2.7.8.1.4.2 The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 2.7.8.4 of this Section.

2.7.8.2 Each person licensed under this Section shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or initial transferor

2.7.8.3 Each person licensed under this Section shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of Americium-241 or Radium-226 before transferring the source to a general licensee under RHA 2.4. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be

deemed to be leaking or losing Americium-241 or Radium-226 and shall not be transferred to a general licensee under RHA 2.4 or equivalent regulation.

2.7.8.4 An applicant for a license under this Section shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226, as follows:

2.7.8.4.1 Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

2.7.8.4.2 Dry wipe test. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

2.7.8.4.3 Wet wipe test. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

2.7.8.4.4 Water soak test. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

2.7.8.4.5 Dry wipe test. On completion of the preceding test in this section, the dry wipe test described in 2.7.8.4.2 shall be repeated.

2.7.8.4.6 Observations. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

Insert a new paragraph at 2.10.8 as shown:

2.10.8 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

Add new section 2.10.9.1 through 2.10.9.4 re: terms and conditions of licenses as shown:

2.10.9.1 Authorization under Part 2 of this Regulation to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2.10.9.2 Each licensee authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

2.10.9.2.1 Satisfy the labeling requirements in Part 2 of this Regulation for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

2.10.9.2.2 Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Part 2 of this Regulation.

2.10.9.3 A licensee that is a pharmacy authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

2.10.9.3.1 an authorized nuclear pharmacist that meets the requirements in Part 2 of this Regulation; or

2.10.9.3.2 an individual under the supervision of an authorized nuclear pharmacist as specified in Part 2 of this Regulation.

2.10.9.4 A pharmacy, authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Part 2 of this Regulation.

2.11.11.4 - Revise paragraph to correct reference.

2.11.11.4 Records required by RHA ~~3.34.4~~ 3.34.5 and 3.34.6 have been received.

2.20.2.2.1.8 Revise paragraph on Radium-226 timepieces as shown.

2.20.2.2.1.8 1 microcurie (37 kBq) of Radium-226 per timepiece in intact timepieces ~~acquired~~ manufactured prior to ~~the effective date of this regulation.~~ November 30, 2007.

Modify 2.20.2.3 as follows:

2.20.2.3 Gas and aerosol detectors containing byproduct material. Except for persons who manufacture, possess, ~~or 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 life or property from fires and airborne hazards provided that detectors containing byproduct material shall have been manufactured, imported, or 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 or a Licensing State which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured 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.

2.20.2.5.2 Revise paragraph on exempt quantities of byproduct material possessed before September 25, 1971.

2.20.2.5.2 Any person, who possesses ~~radioactive material~~ byproduct material received or acquired before September 25, 1971, under the general license formerly provided in Paragraph 2.4.1 is exempt from the requirements for a license set forth in this Part to the extent that ~~such~~ this person possesses, uses, transfers, or owns byproduct material. ~~such radioactive material~~. ~~Such exemption does not apply for Radium-226.~~

RHA 2.24 Table of Exempt Quantities - Change column headings as shown and add in alphanumeric order: Germanium-68 (Ge-68) (Microcuries: 10); change microcuries for Cesium-129 (Cs-129) from 10 to 100; and add Yttrium-88 (Y-88) (Microcuries: 10).

**PART II
SCHEDULE B**

Exempt Quantities

RHA 2.24

Radioactive Material Byproduct Material	Microcuries	Radioactive Material Byproduct Material	Microcuries
		Germanium-68 (Ge-68)	10
Cesium-129 (Cs-129)	10 100		
		Yttrium-88 (Y-88)	10

RHA 2.31, Schedule E, QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE.

Add Radium-226 alphabetically to table as shown:

Radium-226 0.001 100

Part III Standards for Protection Against Radiation

3.2.63 - Add definition for “Nationally tracked source” and renumber balance of 3.2.

3.2.63 “Nationally tracked source” means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in Appendix G to Part 3 of these Regulations. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Modify 3.2.91 as shown:

3.2.91 "Total Effective Dose Equivalent" (TEDE) means the sum of the ~~deep-dose~~ effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Modify 3.5.3 as shown:

3.5.3 When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Department. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

Revise Section title adding: AND CERTAIN BYPRODUCT MATERIAL”

RHA 3.31 DISPOSAL OF SPECIFIC WASTES AND CERTAIN BYPRODUCT MATERIAL

3.31.3 Revise paragraph on disposal of byproduct.

3.31.3 The licensee shall maintain records in accordance with RHA 3.41. Licensed material as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in RHA 1.2.6 may be disposed of in accordance with Part 3 of this Regulation, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility authorized to dispose of such material, must meet the requirements of RHA 3.32.

3.31.4 – 3.31.5 Add paragraphs on disposal of byproduct.

3.31.4 A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in RHA 1.2.6, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

3.31.5 The licensee shall maintain records in accordance with RHA 3.41.

3.32.5 - Add paragraph on shipping manifest for byproduct material for disposal.

3.32.5 Any licensee shipping byproduct material as defined in paragraphs 3 and 4 of the definition of byproduct material set forth in RHA 1.2.6 intended for ultimate disposal at a land disposal facility licensed under Part 7 of this Regulation must document the information required on the NRC’s Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D to this part.

3.34.7 - Modify paragraph on requirements of record management prior to license termination to correct changed cross reference in regulation.

3.34.7 Prior to license termination, each licensee shall forward the records required by RHA ~~1-15.11~~ 1.15.13 to the Department.

Revise paragraph following 3.48 heading on reports required to be given to individuals and the Department of any exposure exceeding occupational dose limits.

RHA 3.48 REPORTS TO INDIVIDUALS OF EXCEEDING DOSE LIMITS

When a licensee is required, pursuant to the provisions of RHA 3.46, 3.47, and 3.49, to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Department. ~~a copy of the report that is being submitted to the Department to the individual.~~ This report must be transmitted at a time no later than the transmittal to the Department.

3.53 Appendix B, List of Elements - Add Nitrogen and Oxygen, alphabetically.

Name	Symbol	Atomic No.
Nitrogen	N	7
Oxygen	O	8

RHA 3.53 [Appendix B] Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposures; Effluent Concentrations; Concentrations for Release to Sewerage

Add Nitrogen and Oxygen by Atomic Number.

			Table 1 Occupational Values			Table 2 Effluent Concentrations		Table 3 Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average
			Oral Ingestion	Inhalation				
Atomic No	Radionuclide	Class	ALI (uCi)	ALI (uCi)	DAC (uCi/ml)	Air (uCi/ml)	Water (uCi/ml)	Conc. (uCi/ml)
7	<u>Nitrogen-13²</u>	<u>Submersion¹</u>			<u>4E-6</u>	<u>2E-8</u>		
8	<u>Oxygen-15²</u>	<u>Submersion¹</u>			<u>4E-6</u>	<u>2E-8</u>		

Part III, Appendix G RHA 3.58 - Add appendix for NATIONALLY TRACKED SOURCES – SERIALIZATION AND REPORTS OF TRANSACTIONS.

APPENDIX G

RHA 3.58 NATIONALLY TRACKED SOURCES - SERIALIZATION AND REPORTS OF TRANSACTIONS

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report to the National Source

Tracking System as specified in paragraphs 3.58.1 through 3.58.5 of this section for each type of transaction.

3.58.1 Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.1.1 The name, address, and license number of the reporting licensee;

3.58.1.2 The name of the individual preparing the report;

3.58.1.3 The manufacturer, model, and serial number of the source;

3.58.1.4 The radioactive material in the source;

3.58.1.5 The initial source strength in becquerels (curies) at the time of manufacture; and

3.58.1.6 The manufacture date of the source.

3.58.2 Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.2.1 The name, address, and license number of the reporting licensee;

3.58.2.2 The name of the individual preparing the report;

3.58.2.3 The name and license number of the recipient facility and the shipping address;

3.58.2.4 The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

3.58.2.5 The radioactive material in the source;

3.58.2.6 The initial or current source strength in becquerels (curies);

3.58.2.7 The date for which the source strength is reported;

3.58.2.8 The shipping date;

3.58.2.9 The estimated arrival date; and

3.58.2.10 For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

3.58.3 Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.3.1 The name, address, and license number of the reporting licensee;

3.58.3.2 The name of the individual preparing the report;

3.58.3.3 The name, address, and license number of the person that provided the source;

3.58.3.4 The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

3.58.3.5 The radioactive material in the source;

3.58.3.6 The initial or current source strength in becquerels (curies);

3.58.3.7 The date for which the source strength is reported;

3.58.3.8 The date of receipt; and

3.58.3.9 For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

3.58.4 Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.4.1 The name, address, and license number of the reporting licensee;

3.58.4.2 The name of the individual preparing the report;

3.58.4.3 The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

3.58.4.4 The radioactive material in the source;

3.58.4.5 The initial or current source strength in becquerels (curies);

3.58.4.6 The date for which the source strength is reported;

3.58.4.7 The disassemble date of the source.

3.58.5 Each Licensee who disposes of nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

3.58.5.1 The name, address, and license number of the reporting licensee;

3.58.5.2 The name of the individual preparing the report;

3.58.5.3 The waste manifest number;

3.58.5.4 The container identification with the nationally tracked source;

3.58.5.5 The date of disposal; and

3.58.5.6 The method of disposal.

3.58.6 The reports discussed in paragraphs 3.58.1 through 3.58.5 of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

3.58.6.1 The on-line National Source Tracking System;

3.58.6.2 Electronically using a computer-readable format;

3.58.6.3 By facsimile;

3.58.6.4 By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

3.58.6.5 By telephone with follow-up by facsimile or mail.

3.58.7 Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs 3.58.1 through 3.58.5 of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

3.58.8 Each licensee that possesses Category 1 nationally tracked sources shall have reported its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall have reported its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph 3.58.6.1 through 3.58.6.4 of this section. The initial inventory report must include the following information:

3.58.8.1 The name, address, and license number of the reporting licensee;

3.58.8.2 The name of the individual preparing the report;

3.58.8.3 The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

3.58.8.4 The radioactive material in the sealed source;

3.58.8.5 The initial or current source strength in becquerels (curies); and

3.58.8.6 The date for which the source strength is reported.

Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

<u>Radioactive Material</u>	<u>Category 1 (TBq)</u>	<u>Category 1 (Ci)</u>	<u>Category 2 (TBq)</u>	<u>Category 2 (Ci)</u>
<u>Actinium-227</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Americium-241</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Americium-241/Be</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Californium-252</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Cobalt-60</u>	<u>30</u>	<u>810</u>	<u>0.3</u>	<u>8.1</u>
<u>Curium-244</u>	<u>50</u>	<u>1400</u>	<u>0.5</u>	<u>14</u>
<u>Cesium-137</u>	<u>100</u>	<u>2700</u>	<u>1</u>	<u>27</u>
<u>Gadolinium-153</u>	<u>1000</u>	<u>27000</u>	<u>10</u>	<u>270</u>
<u>Iridium-192</u>	<u>80</u>	<u>2200</u>	<u>0.8</u>	<u>22</u>
<u>Plutonium-238</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Plutonium-239/Be</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Polonium-210</u>	<u>60</u>	<u>1600</u>	<u>0.6</u>	<u>16</u>
<u>Promethium-147</u>	<u>40000</u>	<u>1100000</u>	<u>400</u>	<u>11000</u>
<u>Radium-226</u>	<u>40</u>	<u>1100</u>	<u>0.4</u>	<u>11</u>
<u>Selenium-75</u>	<u>200</u>	<u>5400</u>	<u>2</u>	<u>54</u>
<u>Strontium-90</u>	<u>1000</u>	<u>27000</u>	<u>10</u>	<u>270</u>
<u>Thorium-228</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Thorium-229</u>	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>
<u>Thulium-170</u>	<u>20000</u>	<u>540000</u>	<u>200</u>	<u>5400</u>
<u>Ytterbium-169</u>	<u>300</u>	<u>8100</u>	<u>3</u>	<u>81</u>

4.2.10 Add the definition for “Consortium”; renumber remaining definitions in RHA 4.2 Definitions

4.2.10 “Consortium” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

4.2.26 -Add the definition for “Positron Emission Tomography (PET) radionuclide production facility”; renumber remaining definitions in RHA 4.2 Definitions

4.2.26 “Positron Emission Tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

4.6.1 Modify paragraph on medical use license by removing the word “radioactive” before “material” and replace it with the word “byproduct”.

4.6.1 A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer ~~radioactive-byproduct~~ material for medical use only in accordance with a specific license issued by the NRC or an Agreement State, or as allowed in RHA 4.6.2.1 or 4.6.2.2 of this section.

4.27 Modify the title by removing the word “radioactive” before “material” and replace it with the word “byproduct”.

RHA 4.27 DETERMINATION OF DOSAGES OF UNSEALED RADIOACTIVE BYPRODUCT MATERIAL FOR MEDICAL USE

4.27.2.2.1 - .3 - revise section to add 4.27.2.2.3 to list of requirements.

4.27.2.2.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements; ~~or~~

4.27.2.2.2 An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; ~~or~~

4.27.2.2.3 A PET radioactive drug producer licensed under section 30.32(j) of this chapter) Part 2 of this Regulation or equivalent Agreement State requirements.

4.27.3.3 and subparts 4.27.3.3.1&.2 - Revise paragraph for determination of doses and add new subparts 4.27.3.3.1&.2.

4.27.3.3 Combination of volumetric measurements and mathematical calculations, based on the measurement made by: ~~a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements.~~

4.27.3.3.1 A manufacturer or preparer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.27.3.3.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements.

RHA 4.35 - Revise title to Section as shown:

RHA 4.35 USE OF UNSEALED RADIOACTIVE BYPRODUCT MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED

4.35.1 - Revise introductory paragraph and 4.35.1 and add subparagraphs 4.35.1.1 – 4.35.1.2 to list requirements under 4.35.1 on unsealed radioactive material for uptake

Except for quantities that require a written directive under RHA 4.17.2, a licensee may use any unsealed ~~radioactive~~ byproduct material prepared for medical use for uptake, dilution, or excretion studies that is--

4.35.1 Obtained from: ~~a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements;~~

4.35.1.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent Agreement State requirements; or

4.35.1.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.35.2 - Revise paragraph as shown:

4.35.2 ~~Prepared by~~ Excluding production of PET radionuclides, prepared by: an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43 and 4.39.3.2.7, or an individual under the supervision of either as specified in RHA 4.15; or

4.37 - Revise title to Section, removing the term “Radioactive” and adding “Byproduct” as shown:

RHA 4.37 USE OF UNSEALED ~~RADIOACTIVE~~ BYPRODUCT MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED

4.37.1 Revise introductory paragraph and section 4.37.1 and add subparts defining unsealed radioactive material for imaging.

Except for quantities that require a written directive under RHA 4.17.2, a licensee may use any unsealed radioactive byproduct material prepared for medical use for imaging and localization studies that is--

4.37.1 Obtained from: ~~a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements;~~

4.37.1.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent Agreement State requirements; or

4.37.1.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.37.2 - Revise paragraph on unsealed radioactive material for imaging.

4.37.2 ~~Prepared by~~ Excluding production of PET radionuclides, prepared by: an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43 and 4.39.3.2.7, or an individual under the supervision of either as specified in RHA 4.15;

4.38.1 - Revise paragraph on permissible Molybdenum 99 concentration and add subparagraphs 4.38.1.1 – 4.38.1.2 to add details of requirement.

4.38.1 A licensee may not administer to humans a radiopharmaceutical that contains: ~~more than 0.15 kilobecquerel of molybdenum 99 per megabecquerel of technetium 99m (0.15 microcurie of molybdenum 99 per millicurie of technetium 99m).~~

4.38.1.1 More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

4.38.1.2 More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

Part 4 Subpart E, RHA 4.40 - Revise title to Section, Section 4.40 and introductory paragraph by removing “radioactive” and adding “byproduct” before the word “material”.

PART 4 - SUBPART E--UNSEALED RADIOACTIVE BYPRODUCT MATERIAL--WRITTEN DIRECTIVE REQUIRED

RHA 4.40 USE OF UNSEALED RADIOACTIVE BYPRODUCT MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED

A licensee may use any unsealed radioactive byproduct material prepared for medical use and for which a written directive is required that is--

4.40.1 and subparagraphs 4.40.1.1 & .2 and 4.40.2 - Revise paragraph on written directives and add subparagraphs to list requirements under 4.40.1. Revise 4.40.2

4.40.1 Obtained from: ~~a manufacturer or preparer licensed under RHA 2.7.5 or equivalent NRC requirements; or~~

4.40.1.1 A manufacturer or preparer licensed under RHA 2.7.5 or equivalent Agreement State requirements; or

4.40.1.2 A PET radioactive drug producer licensed under Part 2 of this Regulation or equivalent Agreement State requirements; or

4.40.2 Excluding production of PET radionuclides, prepared by: ~~Prepared by~~ an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43; or an individual under the supervision of either as specified in RHA 4.15; or

6.5.2 and subparagraphs 6.5.2.1 – 6.5.2.2 Revise paragraph and add paragraphs on dose information to workers

6.5.2 Each licensee shall ~~advise each worker annually of the worker's dose~~ make dose information available to workers as shown in records maintained by the licensee pursuant to paragraphs 3.36.2 and 3.39. The licensee shall provide an annual report to each individual monitored pursuant to RHA 3.17 of the dose received in that monitoring year if:

6.5.2.1 The individual's occupational dose exceeds 100 mrem TEDE or 100 mrem to any individual organ or tissue; or

6.5.2.2 The individual requests his or her annual dose report.

6.5.4 - Revise paragraph on reporting to the Department.

6.5.4 When a licensee is required pursuant to RHA 3.45, 3.46, 3.47, and 3.49 to report to the Department any exposure of an individual to radiation or radioactive material, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included therein in the report to the Department. This report shall be transmitted ~~at a time not no~~ later than the transmittal to the Department.

7.2.22 - Revise definition for "Waste".

7.2.22 "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this

definition, low-level radioactive waste ~~has means the same meaning as in the Low Level Radioactive Waste Policy Amendments Act of 1985, P.L. 99-240,~~ radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 11 e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) 1.2.6, paragraphs 2, 3, and 4 of this Regulation.