

Document No.
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1976 Code Section 13-7-40, as amended

R.61-63. Radioactive Materials (Title A)

Preamble:

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, requires states to adopt federal regulations and updates for compatibility. The Department proposes to add or amend various sections in Parts II through V of R.61-63 for compatibility. Major topics include sections on deliberate misconduct, exemption for Carbon-14 urea for "in vivo" diagnostic use, reciprocal recognition of Agreement State licenses, criteria for the release of individuals administered radioactive material, and requirements for industrial radiography operations. Proposed regulations will comply with Title 10 CFR Parts 20 (May 29, 1997), 30 (February 27, 1997, January 2, 1998 and February 12, 1998), 34 (June 27, 1997), and 35 (May 29, 1997).

A Notice of Drafting for this amendment was published in the State Register on October 22, 1999. The revision is being promulgated to comply with federal law; neither a fiscal impact statement nor preliminary assessment report is required. See discussion of proposed revisions below and a statement of need and reasonableness provided herein.

Discussion of Proposed Revisions

- (1) Added section to describe a Deliberate Misconduct rule.

<u>SECTION</u>	<u>REVISION</u>
61-63.2.1.2	Describes what actions may be interpreted as deliberate misconduct and addresses possible enforcement action.

- (2) A new section that exempts capsules containing Carbon-14 urea for "in vivo" diagnostic use for humans.

<u>SECTION</u>	<u>REVISION</u>
61-63.2.20.2.7	Adds new section to permit any person to receive, possess, use, transfer, own or acquire for "in vivo" diagnostic use, capsules containing one microcurie of C-14 urea without a license.

- (3) Gives reference to the recognition of Agreement State Licenses in areas under exclusive Federal jurisdiction within an Agreement State.

<u>SECTION</u>	<u>REVISION</u>
61-63.2.21.1	Clarifies the locations in which reciprocal recognition of licenses is granted.

- 61-63.2.21.1.2 Revises this section to omit a waiver regarding filing of written notifications.
- 61-63.2.21.1.5 Revises section to designate areas for reciprocal recognition regarding possession of radioactive material.
- 61-63.2.21.1.6 Adds section to address reciprocal licensure in offshore waters.
- (4) Revises dose limits to exclude doses due to exposure of patients to radiation for medical purposes and due to exposure from individuals administered radioactive material and released in accordance with RHA 4.8.12.

SECTION REVISION

- 61-63.3.1 Revises dose limits to exclude doses due to exposure of patients to radiation for medical purposes and due to exposure from individuals administered radioactive material and released in accordance with RHA 4.8.12. medical purposes and due to exposure from individuals administered radioactive material and released in accordance with RHA 4.8.12.
- 61-63.3.2.48 Revises definition to exclude doses received from exposure to individuals administered radioactive material and released in accordance with RHA 4.8.12.
- 61-63.3.2.52 Revises definition to exclude doses received from exposure to individuals administered radioactive material and released in accordance with RHA 4.8.12.
- 61-63.3.13.1.1 and .3.13.1.2 Revises section to exclude doses from exposure to individuals administered radioactive material and released in accordance with RHA 4.8.12.

- (5) Changes posting requirements in hospitals due to revised patient release criteria.

SECTION REVISION

- 61-63.3.23.2 Section revised to use the term "licensee control" rather than "confinement" because the latter term no longer applies to RHA 4.8.12.
- 61-63.3.23.2.1 and 3.23.2.2 Sections deleted because these paragraphs no longer apply to the posting of patients' rooms.

- (6) New section added to change patient release criteria following medical administration of radioactive material.

SECTION REVISION

- 61-63.4.8.12 through 4.8.12.5 Revises section to change patient release criteria to a dose limit of 0.5 rem total effective dose equivalent to an individual from exposure to a released patient.
- 61-63.4.11.3.1.6 and 4.13.3.1.5 Sections deleted and placed in reserved status because these paragraphs are redundant now that RHA 4.8.12 has requirements for instructions for released patients.

- 61-63.4.13.3.1 Revised section to reference revised release criteria.
- 61-63.4.13.3.1.1 Section revised to delete inapplicable text due to revised release criteria for patients.
- (7) Revisions outlining current requirements for Industrial Radiography Operations.
- 61-63.5.1 Revised to clarify purpose for Part V regulations.
- 61-63.5.3 Revision of definitions.
- 61-63.5.4.2 Deletion of existing training program requirements and replacement with new
through 5.4.11 procedures for verification of training program.
- 61-63.5.5 Revision of limits on external radiation levels from storage containers and source changers.
- 61-63.5.6 Revision of miscellaneous locking requirements for radiography equipment.
- 61-63.5.7 Revision of labeling, storage and transportation requirements.
- 61-63.5.8 Revision of radiation survey instrument requirements.
- 61-63.5.9 Modification to include requirements for leak testing depleted uranium.
- 61-63.5.10 Section revised to specify content of inventory records.
- 61-63.5.11 Revision of requirements for maintaining utilization logs.
- 61-63.5.12 Training requirements revised and expanded for radiographer and radiographer's assistant.
- 61-63.5.13 Operating and emergency procedures revised to include additional instructions.
- 61-63.5.14 Personnel monitoring requirements revised to include wearing of electronic personal dosimeters and to specify exchange frequencies.
- 61-63.5.15 Section revised regarding surveillance of a radiographic operation at permanent radiographic installations.
- 61-63.5.17 Revision to survey requirement following each radiographic exposure.
- 61-63.5.19 Revision to require written procedures and records for inspection and maintenance of radiographic equipment.
- 61-63.5.20 Revision to regulation governing entrance to a permanent radiographic installation.
- 61-63.5.21 Section replaced with regulation outlining requirements for radiography performed at locations other than permanent radiographic installations.
- 61-63.5.22 Section replaced with training requirements for a Radiation Safety Officer.

- 61-63.5.23 Section added to specify form of records.
- 61-63.5.24 Section added to specify location of documents and records.
- 61-63.5.25 Section renumbered - No changes to content.
- 61-63.5.26 Section added to specify requirements of certification programs for radiographers.

Notice of Staff Informational Forum:

Staff of the Department of Health and Environmental Control invite interested members of the public to attend a staff-conducted informational forum to be held on April 24, 2000 at 10:00 a.m. in Room 103, 1st floor of the Heritage Building at the Department of Health and Environmental Control at 1777 St. Julian Place, Columbia, S.C. 29201.

Interested persons are also provided an opportunity to submit written comments to T. Pearce O'Kelley, Chief, Bureau of Radiological Health at South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201. Written comments must be received no later than 4:00 p.m. April 24, 2000. Comments received by the deadline date will be considered in formulating the final proposed amendment for public hearing before the Board of Health and Environmental Control as noticed below. Comments received shall be submitted to the Board in a Summary of Public Comments and Department Responses for consideration at the public hearing.

Copies of the proposed regulation for public notice and comment may be obtained by contacting Melinda Bradshaw at South Carolina Department of Health and Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 737-7400.

Notice of Board Public Hearing and Opportunity for Public Comment Pursuant to S.C. Code Sections 123-111:

Interested members of the public and regulated community are invited to make oral or written comments on the proposed regulation at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly-scheduled meeting on May 11, 2000 to be held in Room 3420 (Board Room) of the Commissioner's Suite, third floor, Aycock Building of the Department of Health and Environmental Control, 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 order of presentation for public hearings will be noted in the Board's agenda to be published by the Department ten days in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less, and as a courtesy are asked to provide written copies of their presentation for the record.

Interested persons are also provided an opportunity to submit written comments on the proposed amendments by writing to T. Pearce O'Kelley, Chief, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 737-7400. Comments must be received no later than 4:00 p.m. on April 24, 2000. Comments received shall be considered by the staff in formulating the final proposed regulation for public hearing on May 11, 2000, as noticed above. Comments received by the deadline shall be submitted to the Board in a Summary of Public Comments and Department Responses for consideration at the public hearing.

Statement of Need and Reasonableness:

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, 34, and 35.

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 provides recognition of Agreement State Licenses in areas under exclusive federal jurisdiction within an Agreement State.

The proposed regulation revises the criteria for the release of individuals administered radioactive material.

The proposed regulation incorporates numerous additions to the industrial radiography licensing and operational requirements. Included in this section are requirements for radiographer certification.

The proposed regulation exempts the radioactive drug Carbon-14 urea for "in-vivo" diagnostic use.

The proposed regulation identifies a Deliberate Misconduct Rule and outlines applicable enforcement actions.

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 the 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.

Text of Proposed Regulation 61-63 for Public Comment:

Replace R.61-63.2.1 and add 61-63.2.1.2 through 61-63.2.1.2.3.2 to read:

RHA 2.1 PURPOSE AND SCOPE

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

NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, by-product, or special nuclear material, intended for use by the general public may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

2.1.2 Deliberate misconduct

2.1.2.1 Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

2.1.2.1.1 Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

2.1.2.1.2 Deliberately submit to the Department, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

2.1.2.2 A person who violates RHA 2.1.2.1.1 or 2.1.2.1.2 of this section may be subject to enforcement action in accordance with the procedures in RHA 1.12.

2.1.2.3 For the purposes of RHA 2.1.2.1.1, deliberate misconduct by a person means an intentional act or omission that the person knows:

2.1.2.3.1 Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or

2.1.2.3.2 Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

R.61-63 2.20.2.7 is added to read:

2.20.2.7 Radioactive drug: Capsules containing Carbon-14 urea for "in vivo" diagnostic use for humans.

2.20.2.7.1 Except as provided in 2.20.2.7.2 and 2.20.2.7.3, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires capsules containing 1uCi(37kBq) Carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

2.20.2.7.2 Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part IV of these regulations.

2.20.2.7.3 Any person who desires to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to RHA 2.7.5.

2.20.2.7.4 Nothing in this section relieves persons from complying with applicable FDA, Federal, and other State requirements governing receipt, administration, and use of drugs.

R.61-63.2.21.1 is revised to read:

2.21.1 Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State, and issued by the Department having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State; in Non-Agreement States; Areas of exclusive Federal jurisdiction within Agreement States; and offshore waters for a period not in excess of 180 days in any calendar year provided that:

R.61-63.2.21.1.2 is revised to read:

2.21.1.2The out-of-state licensee notifies the Department in writing at least three (3) days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Department, obtain permission to proceed sooner; and

R.61-63.2.21.1.5 is revised to read:

2.21.1.5The out-of-state licensee shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person (i) specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material, or (ii) exempt from the requirements for a license for such material under paragraph 2.20.2.1.

R.61-63.2.21.1.6 is added:

2.21.1.6The general license granted in RHA 2.21.1 concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time.

R.61-63.3.1 is revised to read:

RHA 3.1 PURPOSE AND SCOPE

The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Department and apply to all licensees and registrants.

It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

The regulations in this part apply to persons licensed by the Department to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with RHA 4.8.12, or to exposure from voluntary participation in medical research programs.

R.61-63.3.2.48 is revised to read:

3.2.48 "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RHA 4.8.12, or from voluntary participation in medical research programs, or as a member of the public.

R.61-63.3.2.52 is revised to read:

3.2.52 "Public dose" means the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of the licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual had received, from exposure to individuals administered radioactive material and released in accordance with RHA 4.8.12, or from voluntary participation in medical research programs.

R.61-63.3.13: 61-63.3.13.1.1 through 61-63.3.13.1.2 is revised to read:

3.13.1.1 The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RHA 4.8.12, voluntary participation in medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with RHA 3.29, and

3.13.1.2 The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with RHA 4.8.12, does not exceed 0.002 rem (0.02 mSv) in any one hour.

R.61-63.3.23.2 is revised; R.61.3.23.2.1 and R.61-63.3.23.2.2 are deleted, to read:

3.23.2 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to RHA 3.22 provided that the patient could be released from licensee control pursuant to RHA 4.8.12.

R.61-63.4.8.12 through 4.8.12.5 is revised to read:

4.8.12 Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

4.8.12.1 The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 millisieverts). The total effective dose equivalent to a minor, pregnant female, or a potentially pregnant female may not exceed 100 millirem (1 millisievert).¹

4.8.12.2 The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 100 millirem (1 millisievert). If a breast-feeding infant or child could receive a radiation dose assuming there were no interruption of breast-feeding, the instructions shall also include:

4.8.12.2.1 Guidance on the interruption or discontinuation of breast-feeding and

4.8.12.2.2 Information on the consequences of failure to follow the guidance.

4.8.12.3 The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:

4.8.12.3.1 Using the retained activity rather than the activity administered,

4.8.12.3.2 Using an occupancy factor less than 0.25 at 1 meter,

4.8.12.3.3 Using the biological or effective half-life, or

4.8.12.3.4 Considering the shielding by tissue.

R.61-63.4.8.12 footnote is added to read:

¹Regulatory Guide, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 500 millirem (5 millisieverts).

4.8.12.4 The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if a radiation dose to an infant or child resulted from continued breast-feeding.

4.8.12.5 The licensee shall provide the released individual with written instructions on actions recommended to prevent the release of contaminated waste to the municipal waste stream.

R.61-63.4.11.3.1.6 text is deleted in its entirety and section placed in a reserved status:

4.11.3.1.6 (Reserved)

R.61-63.4.13.3.1 through 4.13.3.1.1 is revised to read:

4.13.3.1 For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to RHA 4.8.12, a licensee shall:

4.13.3.1.1 Not place the patient or the human research subject in the same room with an individual who is not receiving radiation therapy.

R.61-63.4.13.3.1.5 text is deleted in its entirety and section placed in a reserved status:

4.13.3.1.5 (Reserved)

R.61-63.5.1 is revised to read:

RHA 5.1 PURPOSE

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing radioactive material and radiation safety requirements for persons using these sealed sources in industrial radiography. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the requirements and provisions of Parts I, II, III, and VI of these regulations apply to applications and licenses subject to this part.

R.61-63.5.3 is revised to read:

RHA 5.3 DEFINITIONS as used in this Part:

5.3.1 *ALARA* (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits specified in Part III, Title A as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

5.3.2 *Annual refresher safety training* means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

5.3.3 *Associated equipments* means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

5.3.4 *Becquerel (Bq)* means one disintegration per second.

5.3.5 *Certifying Entity* means an independent certifying organization meeting the requirements in RHA 5.26, Appendix A, of this part or an Agreement State meeting the requirements in appendix A, Parts II and III of this part.

5.3.6 *Collimator* means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

5.3.7 *Control (drive) cable* means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

5.3.8 *Control drive mechanism* means a device that enables the source assembly to be moved to and from the exposure device.

5.3.9 *Control tube* means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

5.3.10 *Exposure head* means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

5.3.11 *Field station* means a facility where licensed material may be stored or used and from which equipment is dispatched.

5.3.12 *Gray* means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram. It is also equal to 100 rads.

5.3.13 *Guide tube (Projection sheath)* means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

5.3.14 *Hands-on experience* means experience in all of those areas considered to be directly involved in the radiography process.

5.3.15 *Independent certifying organization* means an independent organization that meets all of the criteria of RHA 5.26, Appendix A, to this part.

5.3.16 *Industrial radiography (radiography)* means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

5.3.17 *Lay-barge radiography* means industrial radiography performed on any water vessel used for laying pipe.

5.3.18 *Offshore platform radiography* means industrial radiography conducted from a platform over a body of water.

5.3.19 *Permanent radiographic installation* means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

5.3.20 *Practical Examination* means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

5.3.21 *Radiation Safety Officer for industrial radiography* means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of RHA 5.22.

5.3.22 *Radiographer* means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

5.3.23 *Radiographer certification* means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing and experience criteria.

5.3.24 *Radiographer's assistant* means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

5.3.25 *Radiographic exposure device* (also called a camera, or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

5.3.26 *Radiographic operations* means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

5.3.27 *S-tube* means a tube through which the radioactive source travels when inside a radiographic exposure device.

5.3.28 *Sealed source* means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

5.3.29 *Shielded position* means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

5.3.30 *Sievert* means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

5.3.31 *Source assembly* means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

5.3.32 *Source changer* means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

5.3.33 *Storage area* means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

5.3.34 *Storage container* means a container in which sealed sources are secured and stored.

5.3.35 *Temporary jobsite* means a location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

5.3.36 *Underwater radiography* means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

R.61-63.5.4 through R.61-63.5.4.11 is revised to read:

RHA 5.4 ISSUANCE OF SPECIFIC LICENSES FOR USE OF SEALED SOURCES IN RADIOGRAPHY

An application for a specific license for use of sealed sources in industrial radiography will be approved if:

5.4.1 The applicant satisfies the general requirements specified in RHA 2.6 of these regulations.

5.4.2 The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of RHA 5.12.

5.4.3 The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

5.4.4 The applicant submits written operating and emergency procedures as described in RHA 5.13.

5.4.5 The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed 6 months as described in RHA 5.12.5.

5.4.6 The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

5.4.7 The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (RHA 5.22) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

5.4.8 If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the following:

5.4.8.1 Instruments to be used;

5.4.8.2 Methods of performing the analysis; and

5.4.8.3 Pertinent experience of the person who will analyze the wipe samples.

5.4.9 If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in RHA 5.8.

5.4.10 The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

5.4.11 The applicant identifies the locations where all records required by this part and other parts of this regulation will be maintained.

R.61-63.5.5 is revised to read:

RHA 5.5 Limits on external radiation levels from storage containers and source changers.

The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisieverts) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

R.61-63.5.6 is revised to read:

RHA 5.6 PERFORMANCE AND LOCKING REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

Equipment used in industrial radiographic operations must meet the following minimum criteria:

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., 1430 Broadway, New York, New York 10018; Telephone (212) 642-4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission library, 11545 Rockville Pike, Rockville, Maryland, 20852. A copy of the document is also on file at the Office of the Federal Register, 800 North Capitol Street N.W., 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.

5.6.2 In addition to the requirements specified in RHA 5.6.1, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

5.6.2.1 Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:

- (i) Chemical symbol and mass number of the radionuclide in the device;
- (ii) Activity and the date on which this activity was last measured;
- (iii) Model number and serial number of the sealed source;
- (iv) Manufacturer of the sealed source; and
- (v) Licensee's name, address, and telephone number

5.6.2.2 Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

5.6.2.3 Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

5.6.3 In addition to the requirements specified in RHA 5.6.1 and RHA 5.6.2, the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers.

5.6.3.1 The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

5.6.3.2 The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

5.6.3.3 The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

5.6.3.4 Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "**Danger-Radioactive.**" The label must not interfere with the safe operations of the exposure device or associated equipment.

5.6.3.5 The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

5.6.3.6 Guide tubes must be used when moving the source out of the device.

5.6.3.7 An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiographic operations.

5.6.3.8 The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

5.6.3.9 Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

5.6.4 All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of the above sections.

5.6.5 Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in RHA 5.15. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

5.6.6 Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

5.6.7 Notwithstanding RHA 5.6.1 of this section, equipment used in industrial radiographic operations need not comply with section 8.9.2 (c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

R.61-63.5.7 is revised to read:

RHA 5.7 LABELING, STORAGE, AND TRANSPORTATION.

5.7.1 The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording

CAUTION*

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

* _____ or "DANGER"

5.7.2 The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR part 71.

5.7.3 Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

5.7.4 The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss tampering, or unauthorized removal of the licensed material from the vehicle.

R.61-63.5.8 is revised to read:

RHA 5.8 RADIATION SURVEY INSTRUMENTS

5.8.1 The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make the radiation surveys required by this part and by Part III. Instrumentation required by this section must be capable of measuring a range from 2 millirems (0.02 millisieverts) per hour through 1 rem (0.01 sievert) per hour.

5.8.2 The licensee shall have each radiation survey instrument required under RHA 5.8.1 calibrated:

5.8.2.1 At intervals not to exceed 6 months and after instrument servicing, except for battery changes;

5.8.2.2 For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 2 and 1000 millirems (0.02 and 10 millisieverts) per hour; and

5.8.2.3 So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

5.8.3 Each licensee shall maintain records of the calibrations of its radiation survey instruments and retain each record for 3 years after it is made.

R.61-63.5.9 is revised to read:

RHA 5.9 LEAK TESTING, REPAIR, TAGGING, OPENING, MODIFICATION AND REPLACEMENT OF SEALED SOURCES

5.9.1 The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Department in accordance with RHA 5.4 the U.S. Nuclear Regulatory Commission, or any Agreement State.

5.9.2 Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the

Nuclear Regulatory Commission or by an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample and must be performed by a person specifically authorized by the Commission or an Agreement State to perform the analysis.

5.9.3 Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

5.9.4 Any test conducted pursuant to RHA 5.9.1 and 5.9.2 which reveals the presence of 0.005 microcuries or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with regulations of the Department. Within five days after obtaining results of the leak test, the licensee shall file a report with the Department describing the equipment involved, the test results and the corrective action taken.

5.9.5 Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of .005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department or an Agreement State to perform the analysis. Should such testing reveal the presence of .005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months. A record of the DU leak-test must be made in accordance with RHA 5.9.3.

5.9.6 Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

R.61-63.5.10 is revised to read:

RHA 5.10 QUARTERLY INVENTORY AND RECEIPT/TRANSFER RECORDS

5.10.1 Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and for devices containing depleted uranium received and possessed under this license.

5.10.2 The licensee shall maintain records of the quarterly inventory and retain each record for 3 years after it is made.

5.10.3 The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

5.10.4 Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using DU for shielding and retain each record for 3 years after it is made.

5.10.5 These records must include the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass (for DU), and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

R.61-63.5.11 is revised to read:

RHA 5.11 UTILIZATION LOGS.

5.11.1 Each licensee shall maintain utilization logs showing for each sealed source the following information:

5.11.1.1A description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located;

5.11.1.2The identity and signature of the radiographer to whom assigned; and

5.11.1.3The plant or site where used and dates of use, including the dates removed and returned to storage.

5.11.2 The licensee shall retain the logs required by RHA 5.11.1 for 3 years after the log is made.

R.61-63.5.12 is revised to read:

RHA 5.12 TRAINING

5.12.1 The licensee may not permit any individual to act as a radiographer until the individual:

5.12.1.1Has received training in the subjects in RHA 5.12.7, in addition to a minimum of 2 months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A, RHA 5.26. (An independent organization that would like to be recognized as a certifying entity shall submit its request to the Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201) or

5.12.1.2The licensee may, for two years following the effective date of regulations, allow an individual who has not met the requirements of RHA 5.12.1.1 to act as a radiographer after the individual has received training in the subjects outlined in RHA 5.12.7 and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Department.

5.12.2 In addition, the licensee may not permit any individual to act as a radiographer until the individual:

5.12.2.1Has received copies of and instruction in the requirements described in Department regulations contained in this part; in RHA 6.7, and 2.1.2; in the applicable sections of parts III and VI; in applicable DOT regulations as referenced in 10 CFR part 71, in the specific license(s) under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures;

5.12.2.2Has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.

5.12.2.3Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

5.12.2.4Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described in RHA 5.12.2.1 and 5.12.2.3 by successful completion of a practical examination covering this material.

5.12.3 The licensee may not permit any individual to act as a radiographer's assistant until the individual:

5.12.3.1Has received copies of and instruction in the requirements described in Department regulations contained in this part, in RHA 6.7 and 2.1.2, in the applicable sections of parts III and VI, in applicable DOT regulations as referenced in 10 CFR part 71, in the specific license(s) under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures;

5.12.3.2Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

5.12.3.3Has demonstrated understanding of the instructions provided under RHA 5.12.3.1 of this section by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in 5.12.3.2 of this section by successfully completion of a practical examination on the use of such hardware.

5.12.4 The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

5.12.5 Except as provided in RHA 5.12.5.4, the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's regulations, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

5.12.5.1Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

5.12.5.2Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of RHA 5.12.2.3 and the radiographer's assistant must re-demonstrate knowledge of the training requirements of RHA 5.12.3.2 by a practical examination before these individuals can next participate in a radiographic operation.

5.12.5.3The Department may consider alternatives in those situations where the individual serves as both radiographer and RSO.

5.12.5.4 In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

5.12.6 The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with RHA 5.12.10.

5.12.7 The licensee shall include the following subjects required in RHA 5.12.1 of this section:

5.12.7.1 Fundamentals of radiation safety including:

5.12.7.1.1 Characteristics of gamma radiation;

5.12.7.1.2 Units of radiation dose and quantity of radioactivity;

5.12.7.1.3 Hazards of exposure to radiation;

5.12.7.1.4 Levels of radiation from licensed material; and

5.12.7.1.5 Methods of controlling radiation dose (time, distance, and shielding);

5.12.7.2 Radiation detection instruments including:

5.12.7.2.1 Use, operation, calibration, and limitations of radiation survey instruments;

5.12.7.2.2 Survey techniques; and

5.12.7.2.3 Use of personnel monitoring equipment;

5.12.7.3 Equipment to be used including:

5.12.7.3.1 Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtailed).

5.12.7.3.2 Storage, control, and disposal of licensed material; and

5.12.7.3.3 Inspection and maintenance of equipment.

5.12.7.4 The requirements of pertinent Federal and State regulations; and

5.12.7.5 Case histories of accidents in radiography.

5.12.8 Licensees will have until one year following the effective date of these regulations to comply with the additional training requirements specified in RHA 5.12.2.1 and RHA 5.12.3.1.

5.12.9 Licensees will have until two years following the effective date of these regulations to comply with the certification requirements specified in RHA 5.12.1.1. Records of radiographer certification

maintained in accordance with RHA 5.12.10.1 provide appropriate affirmation of certification requirements specified in RHA 5.12.1.1.

5.12.10 Each licensee shall maintain the following records (of training and certification) for 3 years after the record is made:

5.12.10.1 Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

5.12.10.2 Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the RSO.

R.61-63.5.13 is revised to read:

RHA 5.13 OPERATING AND EMERGENCY PROCEDURES

The licensee's operating and emergency procedures shall include instructions in at least the following:

5.13.1 The handling and use of sources of radiation to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in these regulations;

5.13.2 Methods and occasions for conducting radiation surveys;

5.13.3 Methods for controlling access to radiographic areas;

5.13.4 Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

5.13.5 Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm rate meter alarms unexpectedly.

5.13.6 Transporting sources of radiation to field locations, including packing of sources of radiation in the vehicles, posting of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

5.13.7 Minimizing exposure of individuals in the event of an accident;

5.13.8 The procedure for notifying proper persons in the event of an accident;

5.13.9 Maintenance of records; and

5.13.10 The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;

5.13.11 The procedure(s) for identifying and reporting defects and noncompliance, as required by Part VI of these regulations.

5.13.12 Source recovery procedure if licensee will perform source recovery;

5.13.13 Each licensee shall maintain a copy of current operating and emergency procedures until the Department terminates the license. Superseded material must be retained for 3 years after the change is made. Location of these documents shall be in accordance with RHA 5.24.

R.61-63.5.14 is revised to read:

RHA 5.14 PERSONNEL MONITORING CONTROL

5.14.1 The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading pocket dosimeter, an alarm rate meter and either a film badge or a thermoluminescent dosimeter (TLD) except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each film badge and TLD must be assigned to and worn by only one individual.

5.14.2 Pocket dosimeters or electronic personal dosimeters must be read and exposures recorded at the beginning and end of each shift. The licensee shall retain each record of these exposures for two years after the record is made.

5.14.3 Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records must be maintained for two years after the operability test is performed.

5.14.4 If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's film badge or TLD must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in records to be maintained by the licensee until the Department terminates the license.

If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD. The results of the calculated exposure and the time period for which the film badge or TLD was lost or damaged must be included in the records to be maintained until the Department terminates the license.

5.14.5 Film badges must be replaced at periods not to exceed one month and TLD's must be replaced at periods not to exceed three months. After replacement, each film badge or TLD must be processed as soon as possible. Reports received from the film badge or TLD processor must be retained for inspection

until the Department terminates each license that authorizes the activity that is subject to the record keeping requirement or until the Department authorizes their disposal.

5.14.6 Each alarm rate meter must:

5.14.6.1 Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

5.14.6.2 Be set to give an alarm signal at a preset dose rate of 500 mR/hr.;

5.14.6.3 Require special means to change the preset alarm function; and

5.14.6.4 Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable rate meters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of these calibrations must be maintained for two years.

R.61-63.5.15 is revised to read:

RHA 5.15 SURVEILLANCE

During each radiographic operation the radiographer, or the other individual present, as required by RHA 5.21, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part III, except at permanent radiographic installations where all entryways are locked and the requirements of RHA 5.20 are met.

R.61-63.5.16: No changes

R.61-63.5.17 is revised to read:

RHA 5.17 RADIATION SURVEYS AND SURVEY RECORDS

The licensee shall ensure that:

5.17.1 A sufficient number of adequately calibrated and operable radiation survey instruments are available at the location of its radiographic operations whenever radiographic operations are being performed, and at the storage area, as defined in RHA 5.3.33 whenever a radiographic exposure device, a storage container, or source is being placed in storage.

5.17.2 A survey with a calibrated and operable radiation survey instrument is made after each exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device must be surveyed. If the radiographic exposure device has a source guide tube, the survey must include the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

5.17.3 A survey with a calibrated and operable radiation survey instrument is made at any time a source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in RHA 5.3.33 to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device must be surveyed.

5.17.4 A record of the storage survey required in RHA 5.17.3 is made and is retained for three years for inspection by the Department when that storage survey is the last one performed in the work day.

R.61-63.5.18: No changes

R.61-63.5.19 is revised to read:

RHA 5.19 INSPECTION AND MAINTENANCE OF RADIOGRAPHIC EXPOSURE DEVICES, TRANSPORT AND STORAGE CONTAINERS, ASSOCIATED EQUIPMENT, SOURCE CHANGERS AND SURVEY INSTRUMENTS.

5.19.1 The licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

5.19.2 Each licensee shall have written procedures for:

5.19.2.1 Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

5.19.2.2 Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

5.19.3 Records of equipment problems and of any maintenance performed under paragraphs 5.19.1 and 5.19.2 of this section must be made in accordance with the following:

5.19.3.1 Each licensee shall maintain records of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

5.19.3.2 The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

R.61-63.5.20 is revised to read:

RHA 5.20 PERMANENT RADIOGRAPHIC INSTALLATION

5.20.1 Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

5.20.1.1 An entrance control of the type described in RHA 3.18.1.1 that reduces the radiation level upon entry into the area, or

5.20.1.2 Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

5.20.2 The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in RHA 5.20.1.1) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee implements the continuous surveillance requirements of RHA 5.15 and uses an alarming rate meter.

5.20.3 Each licensee shall maintain records of alarm system and entrance control device tests required under RHA 5.20.2 and retain each record for 3 years after it is made.

R.61-63.5.21 is revised to read:

RHA 5.21 CONDUCTING INDUSTRIAL RADIOGRAPHIC OPERATIONS.

5.21.1 Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of RHA 5.12.3. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

5.21.2 All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the Department.

5.21.3 A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Department, by an Agreement State, or by the Nuclear Regulatory Commission.

5.21.4 Licensees will have until one year from the effective date of these regulations to meet the requirements for having two qualified individuals present at locations other than a permanent radiographic installation as specified in RHA 5.21.1.

R.61-63.5.22 is revised to read:

RHA 5.22 RADIATION SAFETY OFFICER FOR INDUSTRIAL RADIOGRAPHY.

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

5.22.1 The minimum qualifications, training, and experience for RSOs for industrial radiography are as follows:

5.22.1.1 Completion of the training and testing requirements of RHA 5.12.1;

5.22.1.2 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

5.22.1.3 Formal training in the establishment and maintenance of a radiation protection program.

5.22.2 The Department will consider alternatives when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

5.22.3 The specific duties and authorities of the RSO include, but are not limited to:

5.22.3.1 Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part III of these regulations, and reviewing them regularly to ensure that the procedures in use conform to current Part III procedures, conform to other Departmental regulations and to the license conditions.

5.22.3.2 Overseeing and approving all phases of the training program for radiographic personnel, ensuring and appropriate and effective radiation protection practices are taught.

5.22.3.3 Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

5.22.3.4 Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by RHA 3.46 of this regulation; and

5.22.3.5 Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

5.22.4 Licensees will have until two years following the effective date of these regulations to meet the requirements of RHA 5.22.1 or 5.22.2.

New R.61-63.5.23 and R.61-63.5.24 are added to read:

RHA 5.23 FORM OF RECORDS.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RHA 5.24 LOCATION OF DOCUMENTS AND RECORDS.

5.24.1 Each licensee shall maintain copies of records required by this part and other applicable parts of this regulation at the location specified in RHA 5.4.11.

5.24.2 Each licensee shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

5.24.2.1 The license authorizing the use of licensed material;

5.24.2.2 A copy of parts II, III and V of Radioactive Materials Regulation 61-63, Title A.

5.24.2.3 Utilization records for each radiographic exposure device dispatched from that location as required by RHA 5.11;

5.24.2.4 Records of equipment problems identified in daily checks of equipment as required by RHA 5.19.3.1;

5.24.2.5 Records of alarm system and entrance control checks required by RHA 5.20.3 if applicable;

5.24.2.6 Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by RHA 5.14;

5.24.2.7 Operating and emergency procedures required by 5.13.13;

5.24.2.8 Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by RHA 5.8.3;

5.24.2.9 Evidence of the latest calibrations of alarm rate meters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by RHA 5.14;

5.24.2.10 Latest survey records required by RHA 5.17.4;

5.24.2.11 The shipping papers for the transportation of radioactive materials required by RHA 2.22; and

5.24.2.12 When operating under reciprocity pursuant to RHA 2.21, a copy of the NRC or Agreement State license authorizing the use of licensed materials.

Existing R.61-63.5.22 is revised to R.61-63.5.25 to read:

RHA 5.25 REPORTING REQUIREMENTS

5.25.1 In addition to the reporting requirements specified in RHA 2.32, each licensee shall provide a written report to the S.C. Department of Health & Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, S.C. 29201 within 30 days of the occurrence of any of the following incidents involving radiographic equipment.

5.25.1.1 Unintentional disconnection of the source assembly from the control cable.

5.25.1.2 Inability to retract the source assembly to its fully shielded position and secure it in this position.

5.25.1.3 Failure of any component (critical to safe operation of the device) to properly perform its intended function.

5.25.2 The licensee shall include the following information in each report submitted under RHA 5.25.1 of this section:

5.25.2.1A description of the equipment problem.

5.25.2.2Cause of each incident, if known.

5.25.2.3Manufacturer and model number of equipment involved in the incident.

5.25.2.4Corrective actions taken or planned to prevent recurrence.

5.25.2.7Qualifications of personnel involved in the incident.

5.25.3 Reports of overexposure submitted under RHA 3.46 which involve failure of safety components of radiography equipment must also include the information specified in RHA 5.25.2 of this section.

New R.61-63.5.26 Appendix A is added to read:

RHA 5.26 APPENDIX A. RADIOGRAPHER CERTIFICATION

5.26.1 Requirements for an Independent Certifying Organization. An independent certifying organization shall:

5.26.1.1Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;

5.26.1.2Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;

5.26.1.3Have a certification program open to nonmembers, as well as members;

5.26.1.4Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;

5.26.1.5Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;

5.26.1.6Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

5.26.1.7Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

5.26.1.8Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

5.26.1.9Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

5.26.1.10 Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

5.26.1.11 Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

5.26.1.12 Exchange information about certified individuals with the Department and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

5.26.1.13 Provide a description to the Department of its procedures for choosing examination sites and for providing an appropriate examination environment.

5.26.2 Requirements for Certification Programs. All certification programs must:

5.26.2.1 Require applicants for certification to:

5.26.2.1.1 Receive training in the topics set forth in RHA 5.12.7 or equivalent Agreement State regulations, and

5.26.2.1.2 Satisfactorily complete a written examination covering these topics;

5.26.2.2 Require applicants for certification to provide documentation that demonstrates that the applicant has:

5.26.2.2.1 Received training in the topics set forth in RHA 5.12.7 or equivalent Agreement State regulations;

5.26.2.2.2 Satisfactorily completed a minimum period of on-the-job training; and

5.26.2.2.3 Has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;

5.26.2.3 Include procedures to ensure that all examination questions are protected from disclosure;

4.25.1.3.1 Include procedures for denying an application, revoking, suspending, and reinstating a certificate;

5.26.2.5 Provide a certification period of not less than 3 years nor more than 5 years;

5.26.2.6 Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.

5.26.2.7 Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

5.26.3 Requirements for Written Examinations. All examinations must be:

5.26.3.1 Designed to test an individual's knowledge and understanding of the topics listed in RHA 5.12.7 or equivalent Agreement State requirements or NRC requirements;

5.26.3.2 Written in a multiple-choice format;

5.26.3.3 Have test items drawn from a question bank containing psychometrically valid questions based on the material in RHA 5.12.7.