SECTION 1.
REGISTRATION OF SOURCES OF RADIATION

PART B.
DEFINITIONS

RH-10. **Definitions**.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, ~~or~~ any other state or political subdivision or agency thereof; and

2. ~~any~~ Any legal successor, representative, agent, or agency of the foregoing, ~~other than the~~ but not including United States ~~Nuclear Regulatory Commission and other federal government~~ Government agencies.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

PART C.
REGISTRATION OF RADIATION MACHINES

RH-21. **Initial Registration**.

f. An application for registration will be approved if the Department determines that an application meets the requirements of the Act and these Rules. The registration authorizes the proposed activity in such form and containing such conditions and limitations as the Department deems appropriate or necessary to effectuate the purposes of the Act.

RH-23. **Radiation Machine Registration Forms**.

Initial ~~R~~registration and ~~renewal~~ subsequent notifications to the Department shall be made on forms ~~furnished by the Department~~ RC FORM 200 and RC FORM 201, as applicable.~~.~~ ~~The registration or renewal of registration~~ and shall ~~set forth~~ contain all ~~applicable~~ appropriate information ~~called for~~ required by the forms. The Department may request additional information as part of the registration process.

RH-25. ~~**Special Registration**.~~

~~If the reporting of each installation or other information called for is impractical, the Department, upon the request of a registrant, may approve registration in such special form as the Department may prescribe.~~

Terms and Conditions of Registrations.

a. Each registration issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

b. No registration issued under this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any registration to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

c. Each person registered by the Department pursuant to this Section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the registration.

d. The Department may incorporate in the registration at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's possession, use, and transfer of radiation machines subject to this Section as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

2. Require such reports and the keeping of such records as may be necessary or appropriate to effectuate the purposes of the Act; and

3. Prevent loss or theft of radiation machines subject to this Section.

e. The Department may request, and the registrant shall provide, additional information after the registration has been issued to enable the Department to determine whether the registration should be modified in accordance with RH-29.

RH-26. **Report of Changes**.

The registrant shall notify the Department in writing of any changes that would render the information contained in the application for registration no longer accurate, including, but not limited to, the following changes: name or mailing address of the registrant; location of the installation or an additional use location; designation of the Radiation Safety Officer; ~~and~~ the receipt, sale, or disposal of any ~~reportable source of~~ radiation machine; and placement or removal of a radiation machine into or out of storage. Notification of the Department is required within ten (10) days of a change, unless the change involves a machine use listed in RH-21.b. Changes regarding RH-21.b. uses must be reported in writing to the Department prior to the change being made.

RH-27. **Report of Discontinuance**.

Every registrant who permanently discontinues the use of~~, or permanently disposes of,~~ all his ~~reportable sources of~~ radiation machines at an installation shall notify the Department in writing within ten (10) days of such action. The notice shall be signed by the registrant or other individual duly authorized to act for and on his behalf.

RH-28. ~~Deleted.~~

Report of Termination.

Every registrant who permanently disposes or transfers all his radiation machines at an installation shall, within ten (10) days of such action:

1. Notify the Department in writing, signed by the registrant or other individual duly authorized to act for and on his behalf; and

2. Submit to the Department a record of the disposal of the radiation machines, if applicable; and if transferred, to whom they were transferred.

RH-29. ~~Reserved.~~

Modification, Suspension, and Revocation of Part C Registrations.

a. The terms and conditions of registrations issued pursuant to Part C of this Section shall be subject to revision or modification. A registration may be suspended or revoked by reason of amendments to the Act or by reason of rules or orders issued by the Department.

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules, or because of

conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a registration on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

d. Each registration revoked by the Department expires with the Department's final determination to revoke the registration, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

PART D.
REGISTRATION OF VENDOR SERVICES

RH-32. **Vendor Services Registration Forms**.

Registration and ~~renewal~~ changes to a registration shall be ~~completed~~ made on forms ~~furnished by the Department~~ RC FORM 800 or RC FORM 801, as applicable, and shall contain all information required by the Department as indicated on the forms and accompanying instructions. The Department may request additional information as part of the registration process.

RH-36. **Modification, Suspension, and Revocation of Part D Registrations**.

a. The terms and conditions of registrations issued pursuant to Part D of this Section shall be subject to revision or modification. A registration may be suspended or revoked by reason of amendments to the Act, or by reason of rules or orders issued by the Department.

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a registration on an original application, or for violation

of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

d. Each registration revoked by the Department expires with the Department's final determination to revoke the registration, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

SECTION 2.
LICENSING OF RADIOACTIVE MATERIALS

PART B.
DEFINITIONS

RH-200. **Definitions**.

~~**Authorized nuclear pharmacist** – A pharmacist who:~~

~~1. Meets the requirements in RH-8317.; or~~

~~2. Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Department, U.S. Nuclear Regulatory Commission, or Agreement State; or~~

~~3. Is identified as an authorized nuclear pharmacist on a permit issued by a Department, U.S. Nuclear Regulatory Commission, or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.~~

~~**Authorized user** – A physician, dentist, or podiatrist who:~~

~~1. Meets the requirements in RH-8318. and RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8610., RH-8615., RH-8621., or RH-8660.; or~~

~~2. Is identified as an authorized user on a license or equivalent permit issued by the Department, U.S. Nuclear Regulatory Commission, or Agreement State; or~~

~~3. Is identified as an authorized user on a permit issued by a Department, U.S. Nuclear Regulatory Commission, or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.~~

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, ~~Government agency other than the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy (except that the DOE shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity~~ agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Physician - ~~Any individual possessing a valid physician's and surgeon's certificate issued by this state~~ A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

PART D.
LICENSES

RH-405. **Special Requirements for the Issuance of Certain Specific Licenses**.

1. **Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Section 9, "Use of Radionuclides in the Healing Arts."**

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Section 9, "Use of Radionuclides in the Healing Arts," will be approved if:

   A. The applicant satisfies the general requirements specified in RH-404.;

   B. The applicant submits evidence that the applicant is at least one of the following:

      i. Registered with the U.S. Food and Drug Administration (FDA) 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)~~ Subpart B;

      ii. Registered or licensed with a state agency as a drug manufacturer;

      iii. Licensed as a pharmacy by a State Board of Pharmacy;

RH-405.l.1.B. (Cont'd)

      iv. Operating as a nuclear pharmacy within a Federal medical institution; or

      v. A Positron Emission Tomography (PET) drug production facility registered with a state agency.

   C. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

   D. The applicant ~~satisfies~~ commits to the following labeling requirements:

i. A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words

"**CAUTION, RADIOACTIVE MATERIAL**"
or
"**DANGER, RADIOACTIVE MATERIAL**";

the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a ~~half-life~~ half-life greater than 100 (one hundred) days, the time may be omitted.

ii. A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words

"**CAUTION, RADIOACTIVE MATERIAL**"
or
"**DANGER, RADIOACTIVE MATERIAL**"

and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

RH-405.l. (Cont'd)

2. A licensee described by paragraph ~~RH-405.~~l.1.B.iii. or ~~RH-405.~~l.1.B.iv. of this ~~paragraph l.~~ section:

A. May prepare radioactive drugs for medical use, as defined in RH-8100., provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph ~~RH-405.~~l.2.B. and ~~RH-405.~~l.2.D. of this ~~paragraph l.~~ section, or an individual under the supervision of an authorized nuclear pharmacist as specified in RH-8306.

B. May allow a pharmacist to work as an authorized nuclear pharmacist if:

i. This individual qualifies as an authorized nuclear pharmacist as defined in RH-8100.;

ii. This individual meets the requirements specified in RH-8317.b. and RH-8319. and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

iii. This individual is designated as an authorized nuclear pharmacist in accordance with paragraph ~~RH-405.~~l.2.D. of this ~~paragraph l~~ section.

C. The actions authorized in paragraphs ~~RH-405.~~l.2.A. and ~~RH-405.~~l.2.B. of this ~~paragraph l.~~ section are permitted in spite of more restrictive language in license conditions.

D. May designate a pharmacist (as defined in RH-8100.) as an authorized nuclear pharmacist if:

i. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

ii. 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 U.S. Nuclear Regulatory Commission.

RH-405.l.2. (Cont'd)

E. Shall provide to the Department:

i. A copy of each individual's certification by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission, the Department, or an Agreement State as specified in RH-8317.a. ~~with the written attestation signed by a preceptor as required by RH-8317.b.2.~~; or

ii. The Department, U.S. Nuclear Regulatory Commission, or Agreement State license, or

iii. U.S. Nuclear Regulatory Commission master materials licensee permit, or

iv. The permit issued by a licensee or U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

v. 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 U.S. Nuclear Regulatory Commission; and

vi. A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs ~~RH-405.~~1.2.B.i. and ~~RH-405.~~1.2.B.iii. of this section, the individual to work as an authorized nuclear pharmacist.

RH-405.l. (Cont'd)

3. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

A. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

B. Check each instrument for constancy and proper operation at the beginning of each day of use.

4. A licensee shall satisfy the labeling requirements in paragraph l.1.D. of this section.

4 5. Nothing in this paragraph l. relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs.

RH-409. **Specific Terms and Conditions of Licenses**.

a. Each license issued pursuant to these ~~Regulations~~ Rules shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules~~, regulations~~ and orders of the Department.

b. 1. No license issued or granted pursuant to these ~~Regulations~~ Rules nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

2. An application for transfer of license must include:

A. The identity, technical, and financial qualifications of the proposed transferee; and

B. Financial assurance for decommissioning information required by RH-409.h.

c. Each person licensed by the Department pursuant to these ~~Regulations~~ Rules shall confine his ~~use and~~ possession and use of the ~~material~~ licensed material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these ~~Regulations~~ Rules shall carry with it the right to receive, acquire, receive title to, own, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4 of these ~~Regulations~~ Rules.

d. The Department may incorporate, in any license issued pursuant to these ~~Regulations~~ Rules, at the time of issuance, or thereafter by appropriate rule~~, regulation,~~ or order, such additional requirements and conditions with

respect to the licensee's receipt, possession, use, and transfer of radioactive material as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

2. Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and ~~these Regulations~~ rules thereunder~~.~~; and

3. Prevent loss or theft of licensed material.

RH-409. (Cont'd)

e. Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies to all specific licenses issued under these ~~Regulations~~ Rules.

f. Licensees required to submit emergency plans by RH-403.g. shall follow the emergency plan approved by the Department. Proposed changes to the plan may not be implemented without prior application to and prior approval by the Department.

g. **Bankruptcy notification**.

1. Each general licensee that is required to register by RH-402.c.13. and each specific licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

A. The licensee;

B. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

C. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

2. This notification must indicate:

A. The bankruptcy ~~C~~court in which the petition for ~~B~~bankruptcy was filed; ~~and,~~

B. The case name and number; and

~~B~~ C. The date of the filing of the petition.

j. 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, in accordance with RH-8531. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in RH-8531.a. at the time of generator elution, in accordance with RH-8805.

SECTION 3.
STANDARDS FOR PROTECTION AGAINST RADIATION

PART B.
DEFINITIONS

RH-1100. **Definitions**.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, ~~Government agency other than the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy (except that the DOE shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity~~ agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

PART I.
LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

RH-1801. **Equipment Control**.

k. **Notifications**.

3. Any licensee or registrant conducting radiographic operations or storing radioactive material at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the Department prior to exceeding the 180 days.

SECTION 4.
TRANSPORTATION OF RADIOACTIVE MATERIALS

PART F.
OPERATING CONTROLS AND PROCEDURES

RH-3509. **Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste**.

a. 1. As specified in paragraphs b., c., and d. of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

2. As specified in paragraphs b., c., and d. of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph c.3.C of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for

transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

b. Advance notification is also required under this section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

1. The licensed material is required by this Section to be in Type B packaging for transportation;

2. The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

3. The quantity of licensed material in a single package exceeds the least of the following:

A. 3000 times the A_1 value of the radionuclides as specified in Table A-1 of Appendix A to Section 4 for special form radioactive material;

B. 3000 times the A_2 value of the radionuclides as specified in Table A-1 of Appendix A to Section 4 for normal form radioactive material; or

C. 1000 TBq (27,000 Ci).

c. **Procedures for submitting advance notification**.

1. The notification must be made in writing to:

A. The office of each appropriate governor or governor's designee;

B. The office of each appropriate Tribal official or Tribal official's designee; and

C. The Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

2. A notification delivered by mail must be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

RH-3509.c. (Cont'd)

3. A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

   A. ~~A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).~~ Reserved.

   B. Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal officials' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf.

   C. A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of ~~Material Safety, State, Tribal, and Rulemaking Programs~~ Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

4. The licensee shall retain a copy of the notification as a record for three (3) years.

d. **Information to be furnished in advance notification of shipment**.

Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

2. A description of the irradiated reactor fuel or nuclear waste shipment, as specified in the regulations of ~~DOT~~ the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;

RH-3509.d. (Cont'd)

4. The seven (7) day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven (7) day period during which arrival of the shipment is estimated to occur; and

6. A point of contact, with a telephone number, for current shipment information.

e. **Revision notice**.

A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three (3) years.

f. **Cancellation notice**.

1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

2. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three (3) years.

SECTION 5.
RULES OF PRACTICE

PART B.
ADMINISTRATION

RH-4005. **Administrative Examination of Applications**.

Applications for the issuance of a license or registration, amendment of a license or registration at the request of the holder, and renewal of a license or registration will be given a docket number or other ~~identifying number~~ identifier for administrative examination. The applicant may be required to submit additional information and may be requested to confer informally regarding the application. The Department will give to others such notice of the filing of applications as is required under the applicable provisions of these ~~Regulations~~ Rules and such additional notices as it deems appropriate.

RH-4006. **Action on Application, Hearings**.

a. The Department will, upon request of the applicant or intervener and may upon its own initiative, direct the holding of a formal hearing prior to taking action on the application. If no prior formal hearing has been held and no notice of proposed action has been served as provided in paragraph b. of this section, the Department will direct the holding of a formal hearing upon receipt of a request therefore from the applicant or intervener within thirty (30) days after the issuance of a license or registration or other approval or a notice of denial.

RH-4008. **Notice of Violation**.

a. Prior to the institution of any proceeding for the modification, suspension, or revocation of a license or registration for alleged violation of any provision of the Act, these ~~Regulations~~ Rules, ~~or~~ conditions of a license, or a registration, the licensee or registrant shall be served with a written notice calling the facts to his/her attention and requesting a written explanation or statement in reply. Within ~~fifteen (15)~~ thirty (30) days of the ~~receipt~~ date of ~~such~~ the notice or other specified time, the licensee or registrant shall send his/her reply to the Department. If the notice relates to conditions or conduct ~~which~~ that may be susceptible to correction or to being brought into full compliance by action of the licensee or registrant, he/she shall state in his/her reply the corrective steps that have been taken and the results achieved, ~~or to be instituted in achieving correction and~~

~~preventing further violations~~ the corrective steps that will be taken, and the date when ~~such correction and~~ full compliance will be achieved. Corrective actions must address methods to prevent future noncompliance.

RH-4009. **Orders**.

In any case described in RH-4008. ~~of this Regulation~~, the Department may issue to the licensee or registrant a notice to comply with the applicable provisions of the Act or the rules ~~and regulations~~ of the Arkansas State Board of Health or any order issued by the Department. The order shall apprise the licensee or registrant that he/she has the right to request a hearing within thirty (30) days by making a written request therefore to the Director. In the event a request for a hearing is received by the Director within the time specified, a notice of hearing shall be issued by the Department in accordance with RH-4028~~. of these Regulations~~.

RH-4029. **Answer**.

a. Within the time allowed by the notice of hearing for filing and serving an answer, and as required, the answer of a licensee, registrant, or applicant shall fully advise the Department and any other parties as to the nature of the defense or other position of the answering party, the issues he/she proposes to controvert and those he/she does not controvert, and whether or not he/she proposes to appear and present evidence. If facts are alleged, the answer shall admit or deny specifically each allegation of fact; or where knowledge is lacking, the answer may so state and the statement shall operate as a denial. Allegations of fact not denied shall be deemed to be admitted. Matters alleged as affirmative defenses or positions shall be separately stated and identified and, in the absence of a reply, shall be deemed to be controverted. The answer of an intervener shall fully advise the Department and other parties of his/her position and whether or not he/she proposes to appear and present evidence.

SECTION 6.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

PART B.
DEFINITIONS

RH-5100. **Definitions**.

Person –

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this ~~State~~ state, any other ~~State~~ state or political subdivision or agency thereof; and

2. ~~any~~ Any legal successor, representative, agent, or agency of the foregoing, ~~other than the~~ but not including ~~U.S. Nuclear Regulatory Commission and other federal~~ United States ~~government~~ Government agencies.

SECTION 8.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

PART E.
RECORDS AND REPORTS

RH-7083. **Reports**.

a. In addition to the reporting requirements in other Sections of these ~~Regulations~~ Rules, the licensee shall report the following events if not reported under other Sections of the Department ~~Regulations~~ rules: …

b. The report must include a telephone report within ~~24 (~~twenty-four~~)~~ (24) hours as described in RH-~~1502.g.1.~~601.c.1. and a written report within thirty (30) days as described in RH-~~1502.g.2~~601.c.2.

SECTION 9.
USE OF RADIONUCLIDES IN THE HEALING ARTS

PART A.
GENERAL

RH-8010. **Application for License, Amendment, or Renewal**.

a. An application must be signed by the applicant's or licensee's management.

b. An application for a license or renewal of a license for medical use of radioactive material as described in RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., or RH-8670. must be made by:

1. Filing an original and one (1) copy of the "Application for Radioactive Material License" ~~and~~;

2. Submitting procedures required by sections RH-8308., RH-8400., RH-8633., RH-8643., RH-8644., and RH-8645., as applicable~~.~~; and

3. Submitting the applicable fee if the application is for a new license. A renewal license application does not require a fee to be paid.

c. A request for a license amendment must be made by:

1. Submitting an original in letter format~~.~~;

2. Submitting procedures required by sections RH-8308., RH-8400., RH-8633., RH-8643., RH-8644., and RH-8645., as applicable~~.~~; and

3. Submitting ~~any~~ the applicable fee.

d. In addition to the requirements in ~~RH-8010.b. and RH-8010.c.~~ paragraphs b. and c. of this section, an application for a license, renewal of a license, or amendment of a license for medical use of radioactive material as described in RH-8670. must also include ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in Parts A – D of Section 9, as well as any specific information on~~:

1. Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, Parts A through D, M, and N of this Section;

2. Identification of and commitment to follow the applicable radiation safety program requirements in Parts E through I of this Section that are appropriate for the specific RH-8670. medical use; and

3. Any additional specific information on:

~~1~~ A. Radiation safety precautions and instructions;

~~2~~ B. Training and experience of proposed users;

~~3~~ C. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

~~4~~ D. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

e. The applicant or licensee shall also provide any other information requested by the Department in its review of the application.

f. An applicant that satisfies the requirements specified in RH-406.b. may apply for a Type A specific license of broad scope.

RH-8011. **License Amendments**.

A licensee shall apply for and must receive a license amendment:

a. Before it receives, prepares or uses radioactive material for a type of use that is permitted under Section 9, but that is not authorized on the licensee's current license issued pursuant to Section 9;

b. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist under the license, except:

1. For an authorized user, an individual who meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8621.a., and RH-8660.a.,

2. For an authorized nuclear pharmacist, an individual who meets the requirements in RH-8317.a. and RH-8319.;

3. For an authorized medical physicist, an individual who meets the requirements in RH-8316.a. and c. and RH-8319.;

4. An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or an ophthalmic physicist:

A. On a Nuclear Regulatory Commission ~~of~~ or Agreement State license or other equivalent permit or license recognized by the NRC that authorizes the use of ~~byproduct~~ radioactive material in medical use or in the practice of nuclear pharmacy;

B. On a permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the use of ~~byproduct~~ radioactive material in medical use or in the practice of nuclear pharmacy;

C. On a permit issued by an NRC master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

D. By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

5. Deleted.

c. Before it changes Radiation Safety Officers, except as provided in RH-8300.c.;

RH-8011. (Cont'd)

d. Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

e. Before it adds to or changes the areas of use identified in the application or on the license;

f. Before it changes the address(es) of use identified in the application or on the license;

g. Before it changes statements, representations, and procedures which are incorporated into the license; ~~and~~

h. Before it releases licensed facilities for unrestricted use~~.~~; and

i. Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

RH-8020. **Notifications**.

a. ~~A licensee shall provide to the Department a copy of the board certification and the written attestation(s), signed by a preceptor, the Nuclear Regulatory Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, the permit issued by an NRC master material license broad scope permittee, and for each individual no later than thirty (30) days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear~~

~~pharmacist, or an authorized medical physicist, under RH-8011.b. For individuals permitted to work under RH-8011.b.4., within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:~~

~~1. Any additional case experience required in RH-8560.b.1.B.vii. for an authorized user under RH-8550.~~

~~2. Any additional training required in RH-8660.c. for an authorized user under RH-8630.~~

~~3. Any additional training required in RH-8316.c. for an authorized medical physicist.~~

A licensee shall provide to the Department, no later than thirty (30) days after the date that the licensee permits an individual to work under the provisions of RH-8011.b. as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist:

1. A copy of the board certification and, as appropriate, verification of completion of:

   A. Training for the authorized medical physicist under RH-8316.c.;

   B. Any additional case experience required in RH-8560.b.1.B.vii. for an authorized user under RH-8550.; or

   C. Device specific training in RH-8660.c. for the authorized user under RH-8630.; or

2. A copy of the Nuclear Regulatory Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, the permit issued by an NRC master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or 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 for each individual whom the licensee permits to work under the provisions of this section.

b. A licensee shall notify the Department by letter no later than thirty (30) days after:

1. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, ~~or~~ an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

2. The licensee's mailing address changes;

~~3. The licensee's physical address changes;~~

4 3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RH-409.b. ~~of these regulations.~~; or

4. The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RH-8011.i. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

RH-8025. **Exemptions Regarding Type A Specific Licenses of Broad Scope**.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

a. The provisions of RH-8010.d. regarding the need to file an amendment to the license for medical uses of radioactive material as described in RH-8670.;

b. The provisions of RH-8011.b.;

c. The provisions of RH-8011.e. regarding additions to or changes in the areas of use at the addresses specified in the application or on the license;

d. The provisions of RH-8020.a.;

e. The provisions of RH-8020.b.1. for an authorized user, an authorized nuclear pharmacist, ~~or~~ an authorized medical physicist, or an ophthalmic physicist; and

f. The provisions of RH-8310.a.

PART B.
DEFINITIONS

RH- 8100. **Definitions**.

Associate Radiation Safety Officer means an individual who:

1. Meets the requirements in RH-8315. and RH-8319.; and

2. Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

   A. A specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; or

   B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Authorized nuclear pharmacist means a pharmacist who:

1. Meets the requirements in RH-8317.a. and RH-8319.; or

2. Is identified as an authorized nuclear pharmacist on:

   A. A specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

   B. A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

   C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

   D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use ~~committee~~ permittee that authorizes medical use or the practice of nuclear pharmacy; or

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with RH-405.l.2.D.

Authorized user means a physician, dentist, or podiatrist who:

1. Meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8615.a., RH-8621.a., or RH-8660.a.; or

2. Is identified as an authorized user on:

   A. A Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material;

   B. A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

   C. A permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

   D. A permit issued by a Nuclear Regulatory Commission master material license broad scope ~~committee~~ permittee that is authorized to permit the medical use of radioactive material.

Misadministration – An event that meets the criteria in RH-8800.a. or b.

Ophthalmic physicist means an individual who:

1. Meets the requirements in RH-8608.a.2. and RH-8319; and

2. Is identified as an ophthalmic physicist on a:

   A. Specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State;

B. Permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

C. Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

D. Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

Physician ~~(as used in this Section)~~ – A doctor of medicine or doctor of osteopathy licensed by the ~~appropriate authority~~ Arkansas State Medical Board to prescribe drugs in the practice of medicine ~~in the state in which the Department is located~~.

Preceptor – An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~or~~ a Radiation Safety Officer, or an Associate Radiation Safety Officer.

PART C.
GENERAL ADMINISTRATIVE REQUIREMENTS

RH-8300. **Authority and Responsibilities for the Radiation Protection Program**.

a. In addition to the radiation protection program requirements of RH-1004. ~~of these regulations~~, a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Department;

2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

3. Radiation protection program changes that do not require a license amendment and are permitted under RH-8301.

b. A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety

Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

c. For up to sixty (60) days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in ~~RH-8300.e.~~ paragraph e. of this section, provided the licensee takes the actions required in ~~RH-8300.b.,d.,e., and h~~ paragraphs b., d., e., and h. of this section . A licensee may simultaneously appoint more than one (1) temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

d. A licensee shall establish ~~in writing~~ the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

RH-8300. (Cont'd)

e. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and,

4. Verify implementation of corrective actions.

f. Medical institutions that are authorized for radioactive material use under RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., and RH-8670. shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license.

g. The Committee shall:

1. Include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members ~~as~~ the licensee deems appropriate;

2. Meet as necessary, but at a minimum shall meet at intervals not to exceed six (6) months; and

3. Maintain minutes of each meeting in accordance with RH-8700.

h. A licensee shall retain a record of actions taken pursuant to ~~RH-8300.a., RH-8300.b. and RH-8300.d.~~ paragraphs a., b., and d. of this section in accordance with RH-8700.

RH-8307. **Written Directives**.

a. A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 μCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

b. The written directive must contain the patient or human research subject's name and the following:

1. For any administration of quantities greater than 1.11 megabecquerels (30 μCi) of I-131 sodium iodide, the dosage;

~~1~~ 2. For an administration of a therapeutic dosage of ~~radioactive drug containing~~ radioactive material other than I-131 sodium iodide, the radioactive drug ~~containing radioactive material~~, dosage, and route of administration;

~~2~~ 3. For gamma stereotactic radiosurgery, the total dose, treatment site, and ~~number of~~ values for the target coordinate settings per treatment for each anatomically distinct treatment site;

~~3~~ 4. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

~~4~~ 5. For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

6. For permanent implant brachytherapy:

A. Prior to implantation: the treatment site, radionuclide, and total source strength; and

B. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, number of sources implanted, total source strength implanted, and the date; or

~~5~~ 7. For all other brachytherapy, including ~~LDR, MDR, and PDR~~ low, medium, and pulsed dose-rate remote afterloaders:

A. Prior to implantation: the treatment site, ~~the~~ radionuclide, and the dose; and

B. After implantation but prior to completion of the procedure: the ~~radioisotope~~ radionuclide, treatment site, number of sources, ~~and~~ total source strength and exposure time (or, the total dose), and the date.

RH-8307. (Cont'd)

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

d. The licensee shall retain the written directive in accordance with

RH-8702.

RH-8308. **Procedures for Administrations Requiring a Written Directive**.

a. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient's or human research subject's identity is verified before each administration; and

2. Each administration is in accordance with the written directive.

b. The procedures required by ~~RH-8308.a.~~ paragraph a. of this section must, at a minimum, address the following items that are applicable ~~for~~ to the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;

2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

3. Checking both manual and computer-generated dose calculations; ~~and~~

4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RH-8630. or RH-8670.;

5. Determining if a misadministration, as defined in RH-8800., has occurred; and

6. Determining, for permanent implant brachytherapy, within sixty (60) calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

c. A licensee shall retain a copy of the procedures required under paragraph a. of this section for the duration of the license.

RH-8310. **Suppliers for Sealed Sources or Devices for Medical Use**.

For medical use, a licensee ~~may~~ shall only use:

a. Sealed sources or devices ~~initially~~ manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Section 2 ~~of these regulations~~ or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; ~~or~~

b. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Section 2 ~~of these regulations~~ or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State~~.~~; or

c. Sealed sources or devices non-commercially transferred from a Section 9 licensee or a Nuclear Regulatory Commission ~~Part 35 licensee~~ or ~~an~~ Agreement State medical use licensee.

RH-8315. **Training for Radiation Safety Officer**.

Except as provided in RH-8318., the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RH-8300. to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s (d) and (e) of RH-8315~~ d. of this section. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. A. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

RH-8315.a.1. (Cont'd)

B. Have five (5) or more years of professional experience in health physics (graduate training may be substituted for no more than two (2) years of the required experience)

including at least three (3) years in applied health physics; and

C. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. A. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

B. Have two (2) years of full-time practical training and/or supervised experience in medical physics:

i. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

ii. In clinical nuclear medicine facilities providing diagnostic ~~and/~~or therapeutic services under the direction of physicians who meet the requirements for authorized users in RH-8318., RH-8540., or RH-8560.; and

iii. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. 1. Has completed a structured educational program consisting of both:

A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

RH-8315.b.1.A. (Cont'd)

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Radiation biology; and

v. Radiation dosimetry; and

B. One (1) year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material ~~involving the following:~~. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following:

i. Shipping, receiving, and performing related radiation surveys;

ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

iii. Securing and controlling radioactive material;

iv. Using administrative controls to avoid mistakes in the administration of radioactive material;

v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

vi. Using emergency procedures to control radioactive material; and

vii. Disposing of radioactive material; ~~or~~ and

2. ~~Reserved.~~ This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs b.1. and d. of this section and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

RH-8315. (Cont'd)

c. 1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RH-8316.a., ~~and~~ has experience ~~in~~ with the radiation safety aspects ~~for~~ of similar types of use of radioactive material for which the licensee ~~is seeking~~ seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and ~~who~~ meets the requirements in paragraph~~s d. and e. of RH-8315.~~ d. of this section; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ~~the licensee's license~~ a Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, ~~and~~ has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual ~~has Radiation Safety Officer responsibilities~~ as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph d. of this section; ~~and~~ or

3. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission

master material licensee. The individual must also meet the requirements in paragraph d. of this section.

~~d. Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph e. and in paragraphs a.1.A. and a.1.B. or a.2.A. and a.2.B. or b.1. or c.1 or c.2 of RH-8315., and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

~~e~~ d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

RH-8316. **Training for Authorized Medical Physicist**.

Except as provided in RH-8318., the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s b.2. and c. of RH-8316~~ c. of this section. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit webpage.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two (2) years of full-time practical training and/or supervised experience in medical physics:

A. Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Nuclear Regulatory ~~c~~Commission or an Agreement State; or

B. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in RH-8318., RH-8610., or RH-8660.; and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

RH-8316. (Cont'd)

b. 1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services and must include:

A. Performing sealed source leak tests and inventories;

B. Performing decay corrections;

C. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

D. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs ~~c. and a.1. and a.2., or~~ b.1. and c. of ~~RH-8316.~~ this section~~,~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in RH-8316., RH-8318., or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status~~; and~~.

RH-8316. (Cont'd)

c. Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

RH-8317. **Training for Authorized Nuclear Pharmacist**.

Except as provided in RH-8318, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified by a specialty board whose certification process has been recognized by ~~the Department,~~ the ~~U.S.~~ Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph b.2. of RH-8317~~. ~~(~~The names of board certifications ~~which~~ that have been recognized by the ~~Department, U.S.~~ Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Have graduated from a pharmacy program accredited by the ~~American~~ Accreditation Council ~~on~~ for ~~Pharmaceutical~~ Pharmacy Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

2. Hold a current, active license to practice pharmacy;

3. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

RH-8317. (Cont'd)

b. 1. Has completed 700 hours in a structured educational program consisting of both:

A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology; and

B. Supervised practical experience in a nuclear pharmacy involving:

i. Shipping, receiving, and performing related radiation surveys;

ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate,

instruments used to measure alpha-or beta-emitting radionuclides;

iii. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

iv. Using administrative controls to avoid ~~medical events~~ misadministrations in the administration of radioactive material; and

v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

RH-8317.b. (Cont'd)

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs ~~a.1, a.2., and a.3. or~~ b.1. of ~~RH-8317.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

RH-8318. **Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist**.

a. ~~1. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State board scope licensee or master material license permit or by a master material license permittee of broad scope before October 1, 2006, need not comply with the training requirements of RH-8315., RH-8316., or RH-8317., respectively.~~

~~2. An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 1, 2006 and October 1, 2012 need not comply~~

~~with the training requirements of RH-8315., RH-8316., or RH-8317., respectively.~~

1. An individual identified on a Nuclear Regulatory Commission or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of RH-8315., RH-8316., or RH-8317., respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RH-8315.d. or RH-8316.c., as appropriate, for any material or uses for which they were not authorized prior to this date.

2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of RH-8315. to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Nuclear Regulatory Commission or an Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in RH-8316., for those materials and uses that these individuals performed on or before October 24, 2005.

RH-8318.a. (Cont'd)

~~3~~ 4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, ~~2007~~ 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of RH-8315., RH-8316, or RH-8317., respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of ~~Section 9, "Use of Radionuclides in the Healing Arts."~~ these Rules.

b. 1. Physicians, dentist, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before ~~October 1, 2006~~ January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section).

2. Physicians, dentist, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State board scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license of broad scope ~~permittee who perform only those medical uses for which they were authorized between October 1, 2006 and October 1, 2012~~ on or before October 24, 2005, need not comply with the training requirements of RH-8510., RH-8540.,

RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section) for those materials and uses that these individuals performed on or before October 24, 2005, as follows.:

A. For uses authorized under RH-8500. or RH-8530., or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

B. For uses authorized under RH-8550., a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

C. For uses authorized under RH-8600. or RH-8630., a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

D. For uses authorized under RH-8620., a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed 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, need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section) when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of these Rules.

RH-8318. (Cont'd)

c. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

PART D:
GENERAL TECHNICAL REQUIREMENTS

RH-8404. **Authorization for Calibration, Transmission, and Reference Sources**.

a. Any person authorized by RH-8005. for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission, and reference use:

~~a~~ 1. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi) each, manufactured and distributed by a ~~persons~~ person ~~specifically~~ licensed ~~pursuant to Part C of these regulations~~ under RH-405.n. or equivalent ~~provisions of the~~ Nuclear Regulatory Commission or Agreement State regulations ~~and that do not exceed 1.11 gigabecquerels (30 mCi) each~~;

2. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi each), redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RH-405.n. or equivalent Nuclear Regulatory Commission or

Agreement State regulations, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

~~b~~ 3. Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed ~~555 megabecquerels~~ 0.56 gigabecquerels (15 mCi);

~~c~~ 4. Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

~~1~~ A. 7.4 megabecquerels (200 μCi); or

~~2~~ B. 1000 times the quantities in Schedule B ~~of~~ to Section 2 (RH-901) ~~of these regulations~~; ~~and~~ or

~~d~~ 5. Technetium-99m in amounts as needed.

b. Radioactive material in sealed sources authorized by this section shall not be:

1. Used for medical use as defined in RH-8100. except in accordance with the requirements in RH-8620.; or

2. Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph a. or b. of this section need not list these sources on a specific medical use license.

PART E:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE NOT REQUIRED

RH-8510. **Training for Uptake, Dilution, and Excretion Studies**.

Except as provided in RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8500. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement

State ~~and who meets the requirements in paragraph c.2. of RH-8510~~. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in paragraphs c.1.A. through c.1.B.vi. of ~~RH-8510.~~ this section; and

2. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under RH-8540., RH-8560. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

RH-8510. (Cont'd)

c. 1. Has completed 60 hours of training and experience, including a minimum of eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8510.,

RH-8540., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

iii. Calculating, measuring, and safely preparing patient or human research subject dosages;

iv. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed ~~byproduct~~ radioactive material;

v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

RH-8510.c.1.B. (Cont'd)

vi. Administering dosages of radioactive drugs to patients or human research subjects; and

2. Has obtained written attestation~~, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements,~~ that the individual has satisfactorily completed the requirements in paragraph ~~a.1. or~~ c.1. of ~~RH-8510.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8500. The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph c.1. of this section.

RH-8531. **Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**.

a. A licensee shall not administer to humans a radiopharmaceutical that contains:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m); or

2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

~~3. Deleted.~~

b. ~~To demonstrate compliance with RH-8531.a., the licensee preparing radiopharmaceuticals from radionuclide generators shall:~~

~~1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;~~

~~2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.~~

A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph a. of this section.

c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph a. of this section.

RH-8531. (Cont'd)

~~c~~ d. ~~A licensee who must measure radionuclide contaminant concentration~~ If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with RH-8713.

~~d~~ e. ~~A~~ The licensee shall report ~~immediately to the Department each occurrence of radionuclide contaminant concentration exceeding the limits specified in RH-8531.a.~~ any measurement that exceeds the limits in paragraph a. of this section at the time of generator elution, in accordance with RH-8805.

RH-8540. **Training for Imaging and Localization Studies**.

Except as provided in RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8530. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph c.2. of RH-8540~~. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in paragraphs c.1.A. through c.1.B.vii. of ~~RH-8540.~~ this section; and

2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

RH-8540. (Cont'd)

b. Is an authorized user under RH-8560. and meets the requirements in RH-8540.c.1.B.vii.<u>,</u> or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

c. 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Chemistry of radioactive material for medical use;

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements~~,~~ ~~involving:~~<u>. An authorized nuclear pharmacist who meets the requirements in RH-8317. or RH-8318. may provide the supervised work experience for paragraph c.1.B.vii. of this section. Work experience must involve:</u>

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Performing quality control procedures on instruments used to determine the activity of

dosages and performing checks for proper operation of survey meters;

iii. Calculating, measuring, and safely preparing patient or human research subject dosages;

iv. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed radioactive material;

RH-8540.c.1.B. (Cont'd)

v. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

vi. Administering dosages of radioactive drugs to patients or human research subjects; and

vii. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Has obtained written attestation~~, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements,~~ that the individual has satisfactorily completed the requirements in paragraph ~~a.1. or~~ c.1. of ~~RH-8540.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8500. and RH-8530. The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency

program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph c.1. of this section.

PART F:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE REQUIRED

RH-8550. **Use of Unsealed Radioactive Material for Which a Written Directive Is Required**.

A licensee may use any unsealed radioactive material identified in RH-8560.b.1.B.vii. prepared for medical use and for which a written directive is required that is:

a. Obtained from:

1. A manufacturer or preparer licensed under RH-405.l. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

2. A PET radioactive drug producer licensed under RH-403.j. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and who meets the requirements specified in RH-8540. or RH-8560.; or

3. An individual under the supervision, as specified in RH-8306., of the authorized nuclear pharmacist in paragraph b.1. of ~~RH-8550.~~

this section or the physician who is an authorized user in paragraph b.2. of ~~RH-8550.~~ this section; or

c. Obtained from and prepared by a Department, Nuclear Regulatory Commission, 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 ~~the~~ FDA ~~for use in research~~; or

d. Prepared by the licensee for use in research in accordance with ~~a Radioactive Drug Research Committee-approved application or~~ an Investigational New Drug (IND) protocol accepted by FDA ~~for use in research~~.

RH-8560. **Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required**.

Except as provided by RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8550. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in ~~paragraphs~~ paragraph b.1.B.vii. ~~and b.2.~~ of ~~RH-8560~~ this section. ~~(Specialty boards whose certification processes~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs b.1.A. through b.1.B.v. of ~~RH-8560~~ this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Post-Graduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety,

radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

RH-8560.b.1.A. (Cont'd)

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560.<u>,</u> or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user<u>,</u> who meets the requirements in RH-8560.b.<u>,</u> must also have experience in administering dosages in the same dosage category or categories (i.e., RH-8560.b.1.B.vii.) as the individual requesting authorized user status. The work experience must involve:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

iii. Calculating, measuring, and safely preparing patient or human research subject dosages;

iv. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed radioactive material;

v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

vi. Reserved.

RH-8560.b.1.B. (Cont'd)

vii. Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RH-8670. This work experience must ~~involving~~ involve a minimum of three (3) cases in each of the following categories for which the individual is requesting authorized user status:

(a). Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(b). Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(c). Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its ~~beta emitter, or a photon-emitting radionuclide with a~~ electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and~~/or~~

~~(d). Parenteral administration of any other radionuclide, for which a written directive is required; and~~

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph~~s a.1. and b.1.B.vii. or~~ b.1. of ~~RH-8560.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8550. for which the individual is requesting authorized user status. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in RH-8560.b. must have experience in administering dosages in the same dosage category or categories (i.e., RH-8560.b.1.B.vii.) as the individual requesting authorized user status.~~ The attestation must be obtained from either:

   A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

   B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph b.1. of this section.

RH-8570. **Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries) for Which a Written Directive Is Required**.

Except as provided in RH-8318., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of ~~RH-8570.~~ this section and whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph c.3. of RH-8570~~. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~; or

b. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(a). or (b)., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

c. 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity;

D. Chemistry of radioactive material for medical use; and

E. Radiation biology; and

RH-8570.c. (Cont'd)

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or

Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b). The work experience must involve:

A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

B. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

C. Calculating, measuring, and safely preparing patient or human research subject dosages;

D. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;

E. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

F. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of ~~RH-8570.~~ this section~~,~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RH-8550. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b).~~ The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent

Nuclear Regulatory Commission or Agreement State requirements, and has experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b).; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b)., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs c.1. and c.2. of this section.

RH-8580. **Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 millicuries) ~~for Which a Written Directive Is Required~~**.

Except as provided in RH-8318., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of ~~RH-8580.,~~ this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State~~, and who meets the requirements in paragraph c.3. of RH-8580~~. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~; or

b. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(b). or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

c. 1. Has successfully completed 80 hours of classroom and laboratory

training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity;

D. Chemistry of radioactive material for medical use; and

E. Radiation biology; and

RH-8580.c. (Cont'd)

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b). The work experience must involve:

A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

B. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

C. Calculating, measuring, and safely preparing patient or human research subject dosages;

D. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;

E. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

F. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of ~~RH-8580.~~ this section~~,~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RH-8550. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b).~~ The attestation must be obtained from either:

   A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in RH-8560.b.1.B.vii.(b).; or

   B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in RH-8560.b.1.B.vii.(b)., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs c.1. and c.2. of this section.

RH-8590. **Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive**.

a. Except as provided in RH-8318., the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

~~a~~ 1. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(c). ~~or RH-8560.b.1.B.vii.(d)~~, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~b~~ 2. Is an authorized user under RH-8610., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in paragraph ~~d. of RH-8590.~~ b. of this section; or

~~c~~ 3. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RH-8610. or RH-8660., and who meets the requirements in paragraph ~~d. of RH-8590.~~ b. of this section.

~~d~~ b. The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required~~ listed in RH- 8560.b.1.B.vii.(c). The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity;

D. Chemistry of radioactive material for medical use; and

E. Radiation biology; and

RH-8590.d. (Cont'd).

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH- 8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in RH-8560.b.1.B.vii.(c)~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required~~. A supervising authorized user who meets the requirements in RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages ~~as specified in RH-8560.b.1.B.vii.(c) and/or RH-8560.b.1.B.vii.(d)~~ in the same category or categories as the individual requesting authorized user status. The work experience must involve:

   A. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

   B. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

   C. Calculating, measuring, and safely preparing patient or human research subject dosages;

   D. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed radioactive material;

   E. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

   F. Administering dosages to patients or human research subjects, that include at least three (3) cases ~~involving~~ of the parenteral administrations as specified in RH-8560.b.1.B.vii.(c)~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three (3) cases involving the parenteral administration of any other radionuclide, for which a written directive is required~~; and

RH-8590.d. (Cont'd)

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs ~~b. or c.~~ b.1. and b.2. of ~~RH-8590.~~ this section~~,~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in RH-8560., must have experience in administering dosages as specified in RH-8560.b.1.B.vii.(c) and/or RH-8560.b.1.B.vii.(d).~~ The attestation must be obtained from either:

   A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

   B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

PART G:
MANUAL BRACHYTHERAPY

RH-8600. **Use of Sealed Sources for Manual Brachytherapy**.

A licensee shall use only brachytherapy sources ~~for therapeutic medical uses~~:

a. ~~As a~~Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

b. In research to deliver therapeutic doses for medical use in accordance with an ~~effective~~ active Investigational Device Exemption (IDE) application accepted by the ~~FDA~~ U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8605. **Calibration Measurements of Brachytherapy Sealed Sources**.

a. Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2006, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of RH-8635.a.;

2. Determine source positioning accuracy within applicators; and

3. Use published protocols accepted by nationally recognized bodies to meet the requirements of paragraphs ~~RH-8605.~~a.1.~~,~~ and ~~RH-8605.~~a.2. of this section.

b. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph ~~RH-8605.~~a. of this section.

c. A licensee shall mathematically correct the outputs or activities determined in paragraph ~~RH-8605.~~a. of this section for physical decay at intervals consistent with one percent (1%) physical decay.

d. An authorized medical physicist shall perform or review the calculation measurements made pursuant to paragraphs a., b., or c. of this section ~~RH-8605.a., RH-8605.b., or RH-8605.c~~.

e. Notwithstanding paragraph d. of this section, an ophthalmic physicist, as defined in RH-8100., may perform or review measurements made pursuant to paragraphs a., b., and c. of this section, in relation to strontium-90 sources for ophthalmic treatments.

~~e. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs RH-8605.a., RH-8605.b., and RH-8605.c.~~

f. A licensee shall retain a record of each calibration in accordance with RH-8718.

~~g. A licensee shall retain a record of decay calculations required by RH-8605.e. in accordance with RH-8719.~~

RH-8608. **Strontium-90 Sources for Ophthalmic Treatments.**

a. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph b. of this section are performed by either:

1. An authorized medical physicist; or

2. An individual who:

A. Is identified as an ophthalmic physicist on a specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

B. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

C. Has successfully completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

D. Has documented training in:

i. The creation, modification, and completion of written directives;

ii. Procedures for administrations requiring a written directive; and

iii. Performing the calibration measurements of brachytherapy sources as detailed in RH-8605.

b. The individuals who are identified in paragraph a. of this section must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RH-8605.; and

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph a. of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

c. Licensees must retain a record of the activity of each strontium-90 source in accordance with RH-8719.

~~RH-8608.~~ RH-8609. Reserved.

RH-8610. **Training for Use of Manual Brachytherapy Sources**.

Except as provided in RH-8318., the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RH-8600. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State~~, and who meets the requirements in paragraph b.3. of RH-8610~~. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of three (3) years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on ~~Post-Graduate~~ Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity; and

iv. Radiation biology; and

RH-8610.b.1. (Cont'd)

B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8610.~~,~~ or equivalent Nuclear Regulatory Commission

or Agreement State requirements, at a medical ~~institution~~ facility authorized to use radioactive material under RH-8600., involving:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Checking survey meters for proper operation;

iii. Preparing, implanting, and removing brachytherapy sources;

iv. Maintaining running inventories of material on hand;

v. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;

vi. Using emergency procedures to control radioactive material; and

2. Has completed three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph b.1.B. of ~~RH-8610.~~ this section; and

3. Has obtained written attestation~~, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements,~~ that the individual has satisfactorily completed the requirements in paragraphs ~~a.1., or~~ b.1. and b.2., of ~~RH-8610.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy

sources for the medical uses authorized under RH-8600. The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

RH-8615. **Training for Ophthalmic Use of Strontium-90**.

Except as provided in RH-8318., the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity; and

D. Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

   A. Examination of each individual to be treated;

   B. Calculation of the dose to be administered;

   C. Administration of the dose; and

   D. Follow up and review of each individual's case history; and

RH-8615.b. (Cont'd)

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8610., RH-8615., or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs b.1. and b.2. of ~~RH-8615.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

PART H:
SEALED SOURCES FOR DIAGNOSIS

RH-8620. **Use of Sealed Sources and Medical Devices for Diagnosis**.

~~A licensee shall use only sealed sources for diagnostic medical uses:~~

~~a. Approved in the Sealed Source and Device Registry; and~~

~~b. Handled in accordance with the manufacturer's radiation safety instructions.~~

a. A licensee shall use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with

the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

b. A licensee shall only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8621. **Training for Use of Sealed Sources and Medical Devices for Diagnosis**.

Except as provided in RH-8318., the licensee shall require the authorized user of a diagnostic sealed source ~~for use in~~ or a device authorized under RH-8620. to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in paragraphs ~~b. and~~ c. and d. of ~~RH-8621.~~ this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.~~)~~; or

b. Is an authorized user for uses listed in RH-8530. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~b~~ c. Has completed eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

~~e~~ d. Has completed training in the use of the device for the uses requested.

PART I:
PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

RH-8630. **Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit**.

~~A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:~~

~~a. As approved in the Sealed Source and Device Registry; or~~

~~b. In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RH-8310.a. are met.~~

a. A licensee shall only use sealed sources:

1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

b. A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8633. **Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

A. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

B. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

RH-8633.a.4. (Cont'd)

C. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by ~~RH-8633.a.4.~~ paragraph a.4. of this section must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by ~~RH-8633.a.4.~~ paragraph a.4. of this section; and

2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

d. 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2. A licensee shall provide operational and safety instructions~~,~~ initially and at least annually~~,~~ to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties~~, in:~~. The instructions shall include instruction in:

~~1~~ A. The procedures identified in ~~RH-8633.a.4.~~ paragraph a.4. of this section; and

~~2~~ B. The operating procedures for the unit.

e. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

f. A licensee shall retain a record of individuals receiving instruction required by ~~RH-8633.d.~~ paragraph d. of this section, in accordance with RH-8715.

g. A licensee shall retain a copy of the procedures required by paragraphs a.4. and d.2.B. of this section until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

RH-8646. **~~Five-Year Inspection~~ Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement ~~or at intervals not to exceed five (5) years, whichever comes first,~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five (5) years for each teletherapy unit and shall not exceed seven (7) years for each gamma stereotactic radiosurgery unit.

b. This inspection and servicing may only be performed by persons specifically licensed to do so by the Department, the Nuclear Regulatory Commission, or an Agreement State ~~or the Nuclear Regulatory Commission~~.

c. A licensee shall keep a record of the inspection and servicing in accordance with RH-8728.

RH-8660. **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.

Except as provided in RH-8318., the licensee shall require an authorized user of a sealed source for a use authorized under RH-8630. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s b.3. and~~ c. of ~~RH-8660~~ this section. ~~(~~The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~web page~~ Medical Uses Licensee Toolkit web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of three (3) years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on ~~Post-Graduate~~ Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and

clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

b. 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity; and

iv. Radiation biology; and

RH-8660.b.1. (Cont'd)

B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, at a medical ~~institution~~ facility that is authorized to use radioactive material in RH-8630., involving:

i. Reviewing full calibration measurements and periodic spot-checks;

ii. Preparing treatment plans and calculating treatment doses and times;

iii. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;

iv. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

v. Checking and using survey meters; and

vi. Selecting the proper dose and how it is to be administered; and

2. Has completed three (3) years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph b.1.B. of ~~RH-8660.~~ this section; and

RH-8660.b. (Cont'd)

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~paragraph a.1. or~~ paragraphs b.1. and b.2.~~,~~ and ~~paragraph~~ c. of ~~RH-8660.~~ this section~~,~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and~~ The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission

or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

c. Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

PART M:
RECORDS

RH-8700. **Records of Authority and Responsibilities for Radiation Protection Programs**.

a. A licensee shall retain a record of actions taken by the licensee's management in accordance with RH-8300.a. for five (5) years. The record must include a summary of the actions taken and a signature of licensee management.

b. The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by RH-8300.d, and a signed copy of ~~the~~ each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by RH-8300.b. The record must include the signature of the Radiation Safety Officer and licensee management.

c. For each Associate Radiation Safety Officer appointed under RH-8300.b., the licensee shall retain, for five (5) years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

c. The minutes of each Radiation Safety Committee meeting held in accordance with RH-8300.g. shall include:

1. The date of the meeting;

2. Members present;

3. Members absent; and

4. Summary of deliberations and discussions.

RH-8703. **Records of Misadministrations**.

A licensee shall retain a record of misadministrations reported in accordance with RH-8800. for three (3) years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

RH-8715. **Records of Safety Instruction and ~~Training~~ Operational Instruction**.

A licensee shall maintain a record of safety instructions ~~and training~~ required by RH-8551.~~,~~ and RH-8603.~~,~~ and the operational and safety instructions required by RH-8633. for three (3) years. The record must include a list of the topics covered, the date of the instruction ~~or training~~, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

RH-8718. **Records of Calibration Measurements on Brachytherapy Sources**.

A licensee shall maintain a record of the calibrations on brachytherapy sources required by RH-8605. for three (3) years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist, or ophthalmic physicist, as appropriate.

RH-8719. **Records of Decay of Strontium-90 Sources for Ophthalmic Treatments**.

A licensee shall maintain a record ~~of the~~ of the activity of a strontium-90 source required by RH-~~8605.~~ 8608. for the life of the source. The record must include the date and initial activity of the source as determined under RH-8605., and for each decay calculation, the date~~,~~ and the source activity as determined under RH-8608., and the signature of the authorized medical physicist, or ophthalmic physicist, as appropriate.

RH-8728. **Records of ~~Five (5) Year Inspection~~ Full-Inspection Servicing for Teletherapy and Gamma Stereotactic ~~Surgery~~ Radiosurgery Units**.

a. A licensee shall maintain a record of the ~~five (5) year inspections~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by RH-8646. for the duration of use of the unit.

b. The record must contain:

1. The inspector's radioactive materials license number;

2. The date of inspection;

3. The manufacturer's name and model number and serial number of both the treatment unit and source;

4. A list of components inspected and serviced, and the type of service; and

5. The signature of the inspector.

PART N: REPORTS

RH-8800. **Reports and Notifications of Misadministrations**.

a. ~~Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in~~ A licensee shall report any event as a misadministration, except for an event that results from patient intervention, in which:

1. The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

~~1~~ A. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and ~~either~~

~~A~~ i. The total dose delivered differs from the prescribed dose by twenty percent (20%) or more;

~~B~~ ii. The total dosage delivered differs from the prescribed dosage by twenty percent (20%) or more or falls outside the prescribed dosage range; or

~~C~~ iii. The fractionated dose delivered differs from the prescribed dose~~,~~ for a single fraction, by fifty percent (50%) or more.

~~2~~ B. A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:

~~A~~ i. An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

~~B~~ ii. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

~~C~~ iii. An administration of a dose or dosage to the wrong individual or human research subject;

~~D~~ iv. An administration of a dose or dosage delivered by the wrong mode of treatment; or

~~E~~ v. A leaking sealed source.

RH-8800.a. (Cont'd)

~~3~~ C. A dose to the skin or an organ or tissue other than the treatment site that exceeds by ~~0.5 Sievert (50 rem) to an organ or tissue and fifty percent (50%) of the dose expected from the administration defined in the written directive~~

~~(excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~:

i. 0.5 Sievert (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

ii. Fifty percent (50%) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

A. The total source strength administered differing by twenty percent (20%) or more from the total source strength documented in the post-implantation portion of the written directive;

B. The total source strength administered outside of the treatment site exceeding twenty percent (20%) of the total source strength documented in the post-implantation portion of the written directive; or

C. An administration that includes any of the following:

i. The wrong radionuclide;

ii. The wrong individual or human research subject;

iii. Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

iv. A leaking sealed source resulting in a dose that exceeds 0.5 Sievert (50 rem) to an organ or tissue.

b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

c. The licensee shall notify the Department by telephone no later than the next calendar day after discovery of the misadministration.

d. The licensee shall submit a written report to the Department within fifteen (15) days after discovery of the misadministration.

1. The written report must include:

A. The licensee's name;

B. The name of the prescribing physician;

C. A brief description of the event;

D. Why the event occurred;

E. The effect, if any, on the individual who received the administration;

F. Actions, if any, that have been taken, or are planned, to prevent recurrence; and

G. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

RH-8800. (Cont'd)

e. The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring

physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

g. A licensee shall retain a record of a misadministration in accordance with RH-8703. A copy of the record required under RH-8703. shall be provided to the referring physician, if other than the licensee, within fifteen (15) days after discovery of the misadministration.

RH-8805. **Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**.

a. The licensee shall notify by telephone the Department and the distributor of the generator within 24 hours after discovery that an eluate exceeded the permissible concentration listed in RH-8531.a. at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

b. The licensee shall submit a written report to the Department within thirty (30) calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in

the licensee's breakthrough determination; and the information in the telephone report as required by paragraph a. of this section.

RH-~~8805~~ 8806.- RH-8899. Reserved.

FOOTNOTES TO SECTION 9

1/ Experience with at least three (3) cases in category vii.(b). also satisfies the requirement in category vii.(a).

SECTION 11.
THERAPEUTIC RADIATION MACHINES

PART B.
DEFINITIONS

RH-10100. **Definitions**.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

SECTION 12.
PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

PART A.
GENERAL

RH-11005. **Definitions**.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, ~~Government agency other than the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy (except that the DOE shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88~~

~~Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity~~ agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

PART B.
BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

RH-11023. **Access Authorization Program Requirements**.

b. **Reviewing officials**.

1. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Department by an appropriate method listed in RH-11007. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RH-11025.c.

RH-11027. **Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material**.

c. **Procedures for processing of fingerprint checks**.

1. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ~~Rockville, Maryland 20852,~~ ATTN: Criminal History Program~~,~~/-Mail Stop ~~TWB-05-B32M~~ T-07D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by calling 1-630-829-9565, or by email to FORMS.Resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~https://www.nrc.gov/site-help/e-submittals.html~~ https://www.nrc.gov/security/chp.html.

RH-11027.c. (Cont'd)

2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to ''U.S. NRC.'' (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security~~ Division of Physical and Cyber Security Policy ~~at 1-301-492-3531~~ by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals~~ Licensee Criminal History Records Checks & Firearms Background Check Information page at ~~https://www.nrc.gov/site-help/e-submittals.html~~ https://www.nrc.gov/security/chp.html and see the link for ~~the Criminal History Program under Electronic Submission Systems.~~ "How do I determine how much to pay for the request?")

3. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

PART C.
PHYSICAL PROTECTION REQUIREMENTS DURING USE

RH-11043. **General Security Program Requirements**.

d. **Protection of information**.

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

2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, ~~and~~ implementing procedures, and the list of individuals that have been approved for unescorted access.

3. Before granting an individual access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

A. Evaluate an individual's need to know the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access; and

RH-11043.d.3. (Cont'd)

B. If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in RH-11025.a.2. through a.7.

4. Licensees need not subject the following individuals to the background investigation elements for protection of information:

A. The categories of individuals listed in RH-11029.a.; or

B. Security service provider employees, provided written

verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RH-11025.a.2. through a.7., has been provided by the security service provider.

5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

6. Licensees shall maintain a list of persons currently approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven (7) working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

7. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

RH-11043.d. (Cont'd)

8. The licensee shall retain as a record for three (3) years after the document is no longer needed:

   A. A copy of the information protection procedures; and

   B. The list of individuals approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

RH-11045. **LLEA Coordination**.

b. The licensee shall notify the Department as specified in RH-11007. within

three (3) business days if:

1. The LLEA has not responded to the request for coordination within sixty (60) days of the coordination request; or

2. The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

PART D.
PHYSICAL PROTECTION IN TRANSIT

RH-11077. **Advance Notification of Shipment of Category 1 Quantities of Radioactive Material**.

As specified in paragraphs a. and b. of this section, each licensee shall provide advance notification to the Department and to the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport, of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. **Procedures for submitting advance notification**.

1. The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of the Department and of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the ~~Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001~~ Department. The notification to the Department may be made by ~~fax to 1-501-280-4407~~ email to Communication.Center@arkansas.gov.

2. A notification delivered by mail must be postmarked at least seven (7) days before transport of the shipment commences at the shipping facility.

RH-11077.a. (Cont'd)

3. A notification delivered by any means other than mail must reach

the Department at least four (4) days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four (4) days before transport of a shipment within or through the State.

b. **Information to be furnished in advance notification of shipment**.

Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

2. The license numbers of the shipper and receiver;

3. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

4. The point of origin of the shipment and the estimated time and date that shipment will commence;

5. The estimated time and date that the shipment is expected to enter each State along the route;

6. The estimated time and date of arrival of the shipment at the destination; and

7. A point of contact, with a telephone number, for current shipment information.

c. **Revision notice**.

1. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor’s designee and to the Department.

RH-11077.c. (Cont’d)

2. A licensee shall promptly notify the governor of the State or the governor’s designee of any changes to the information provided in accordance with paragraphs b. and c.1. of this section. The

licensee shall also immediately notify the Department of any such changes.

d. **Cancellation notice**.

Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Department. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

e. **Records**.

The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three (3) years.

f. **Protection of information.**

State officials, State employees, and other individuals, whether or not licensees of the Department, the NRC, or of an Agreement State, who receive schedule information of the kind specified in RH-11077.b. shall protect that information against unauthorized disclosure as specified in RH-11043.d.

RH-11081. **Reporting of Events**.

g. The initial telephone notification required by paragraphs a. through d. of this section must be followed within a period of thirty (30) days by a written report submitted to the Department by an appropriate method listed in RH-11007. A written report is not required for notifications on suspicious activities required by paragraphs c. and d. of this section. The report must set forth the following information, as appropriate:

1. A description of the licensed material involved, including kind, quantity, and chemical and physical form;

2. A description of the circumstances under which the loss, theft, etc. occurred;

3. A statement of disposition, or probable disposition, of the licensed material involved;

4. Actions that have been taken, or will be taken, to recover the material; and

5. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of this type of event.