SECTION 1.
REGISTRATION OF ~~SOURCES OF~~ RADIATION MACHINE FACILITIES AND VENDOR SERVICES

PART C.
REGISTRATION OF RADIATION MACHINES

RH-21. **Initial Registration**.

b. Notwithstanding RH-21.a., each applicant for the following uses shall apply for and receive authorization from the Department prior to operation of the machine: healing arts screening; therapeutic radiation machine use pursuant to RH-10301.~~,~~ or RH-10307.~~, or~~; other use of electronically-produced radiation to deliver therapeutic radiation dose pursuant to RH-10308.; and use of radiation therapy simulation systems.

e. A prospective Authorized User physician responsible for directing the operation of therapeutic radiation machines subject to RH-10301.~~,~~ or RH-10307., or the use of electronically-produced radiation to deliver therapeutic radiation dose subject to RH-10308., as applicable, shall be designated on each ~~therapeutic radiation machine~~ application.

RH-29. **Modification, Suspension, and Revocation of Part C Registrations.**

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. A~~a~~ny material false statement in the application or any statement of fact required under provisions of the Act or of these Rules~~, or because of~~;

2. C~~c~~onditions revealed by such application or statement of fact or any report, record, or inspection or other means ~~which~~ that would warrant the Department to refuse to grant a registration on an original application~~,~~; ~~or for~~

3. V~~v~~iolation 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~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

PART D.
REGISTRATION OF VENDOR SERVICES

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

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. A~~a~~ny material false statement in the application or any statement of fact required under provisions of the Act or of these Rules~~, or because of~~ ;

2. C~~c~~onditions revealed by such application or statement of fact or any report, record, or inspection or other means ~~which~~ that would warrant the Department to refuse to grant a registration on an original application~~,~~; ~~or for~~

3. V~~v~~iolation 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~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

PART G.
PROHIBITED USES

RH-61. **X-ray Shoe-Fitting Equipment**.

~~a. **X-ray shoe-fitting equipment prohibited**.~~

No shoe-fitting device or shoe-fitting machine which uses fluoroscopic, x-ray or radiation principles shall be operated or maintained in this state.

~~b. **Penalty for use of x-ray shoe-fitting machine**.~~

~~Any person violating the provisions of these Regulations shall be guilty of a misdemeanor and upon conviction shall be punished by a fine of not less than fifty dollars ($50.00) and not more than five hundred dollars ($500.00), and each day that such violation shall continue shall constitute a separate offense.~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

SECTION 2.
LICENSING OF RADIOACTIVE MATERIALS

PART A.
GENERAL

RH-103. ~~**License** **Fees**~~.

In accordance with Act 596 of 2011, codified at Arkansas Code Annotated §20-21-217, annual fees for licensing shall be paid. Applicants shall be charged for a full calendar year regardless of the month the license is issued. Nonpayment of fees shall result in escalated enforcement action and/or revocation of license.

a. The following ~~Radioactive Material~~ Specific License Fees are based upon 15% of the U. S. Nuclear Regulatory Commission's ~~Federal~~ Fiscal Year 2012 annual fees found in 10 CFR 171.16~~.~~:

~~a. The Radioactive Material Fees are as follows:~~

CATEGORY	CODE	FEE
Academic Broad Scope	01100, 01110, 01120	$2,115~~.00~~
Academic R&D	03620	$1,215~~.00~~
Accelerator Produced Radionuclides	03210	$2,280~~.00~~
~~Consultant~~ Other Services	03225	$2,145~~.00~~
Eye Applicator (Sr-90)	02210	$1,260~~.00~~
Gamma Knife	02310	$2,625~~.00~~
Gas Chromatographs	03123	$720~~.00~~
High Dose Rate Remote Afterloader	02230	$1,260~~.00~~
Industrial Radiography	03310, 03320	$3,855~~.00~~
Instrument Calibration; Leak Testing	03221~~;~~, 03222; 03220	$720~~.00~~
In-vitro Testing	02410	$720~~.00~~
Irradiators – Activity < 10,000 Curies	03511	$2,280~~.00~~
Irradiators – Activity ≥ 10,000 Curies	03521	$20,625~~.00~~
Irradiators – Self-shielded	03510, 03520	$1,305~~.00~~
Manufacturing & Distributing	03214	$1,770~~.00~~
Measuring Systems – Analytical Devices	03122	$720~~.00~~
Measuring Systems –	03120	$720~~.00~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

Fixed Gauge		
Measuring Systems – Portable Gauge	03121	$720~~.00~~
Medical Broad Scope	02110	$6,810~~.00~~
Medical ~~Facility~~ Institution – No Written Directive Required	02121	$1,260~~.00~~
Medical ~~Facility~~ Institution – Written Directive Required	02120	$1,260~~.00~~
Medical Private Practice – No Written Directive Required	~~02200;~~ 02201	$1,260~~.00~~
Medical Private Practice – Written Directive Required	02200	$1260
Medical Therapy – Emerging Technologies	02240	$1,260~~.00~~
Mobile Medical Services	02220, 02231	$1,260~~.00~~
Nuclear Pharmacy	02500	$2,430~~.00~~
Veterinary	02400	$720~~.00~~
Well Logging – Including Tracers	03110~~;~~, 03111~~;~~, 03112	$1,500~~.00~~
~~Other Radioactive Material (non-NORM)~~ Decommissioning – All Radioactive Material	99999	$5,000~~.00~~

~~b. Deleted. See RH-5003.~~

~~c.~~ b. The Generall~~y~~ License~~d Device~~ Registration Fees are as follows:

CATEGORY	**FEE**
Certain detecting, measuring, gauging, ~~and~~ or controlling devices and certain devices for producing light or an ionized atmosphere (including certain ECDs in gas chromatographs)	$720~~.00~~
~~Generally licensed gas chromatographs~~	~~$720.00~~
~~Static elimination devices~~	~~$125.00~~
~~Source material devices~~	~~$500.00~~
~~Devices containing depleted uranium~~	~~$500.00~~
~~Public safety devices containing radioactive material~~	~~$25.00~~
~~All other general license registrations other than those specified above~~	~~$300.00~~
~~Portable and fixed gauges~~	~~$1,125.00~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

Depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device	$150
In vitro clinical or laboratory testing	$25
Naturally Occurring Radioactive Material (NORM)	$500

~~d.~~ c. Other fees are as follows:

CATEGORY	FEE
Naturally Occurring Radioactive Material (NORM) Specific License	$2,500~~.00~~
~~Naturally Occurring Radioactive Material (NORM) Site – General License~~	~~$500.00~~
Arkansas State Board of Health Rules ~~and Regulations~~ for Control of Sources of Ionizing Radiation	$0~~.00~~ for first hard copy $30~~.00~~ for each additional hard copy
Amendment to existing license	$50~~.00~~ per amendment

~~e.~~ d. Reciprocity fees are as follows:

CATEGORY	FEE
Consultant	$2,145~~.00~~
~~Other Radioactive Material (non-NORM)~~ Decommissioning – All Radioactive Material	$5,000~~.00~~
~~Naturally Occurring Radioactive Material (NORM)~~ Decommissioning – Naturally Occurring Radioactive Material (NORM) Only	$2,500~~.00~~
~~Gas Chromatograph, Lead Paint Analyzer~~	~~$720.00~~
Industrial Radiography~~, Field~~	$3,855~~.00~~
Mobile Medical Services	$1260
Nuclear Gauge, Gas Chromatograph, Lead Paint Analyzer, or other similar specifically licensed device	$720~~.00~~
~~Well Logging with Sealed Sources Only~~	~~$1,500.00~~
Well Logging ~~with~~ – Including Tracers ~~Studies~~	$1,500~~.00~~

PART C.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

EXEMPTIONS

RH-301. **Radioactive Material Other Than Source Material**.

a. **Exempt concentrations**.

1. Except as provided in RH-301.a.3. and RH-301.a.4., any person is exempt from ~~this Section~~ the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Schedule C to Section ~~3~~2, RH-902.

b. **Certain items containing radioactive material**.

1. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from ~~these Regulations~~ the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:

A. Time pieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation: ...

PART D.
LICENSES

RH-401. **General Licenses - Source Material**.

a. **Small quantities of source material**.

1. A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

Blue language is due to Medical Use of Byproduct Material NRC amendment.

2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph a. of this section:

C. Is subject to the provisions in RH-102., RH-104. through RH-107., RH-200., RH-409.a. through d., RH-416., Part E of Section 2., RH-600. through 603., ~~RH-416.,~~ and RH-700, RH-751., and Section 4.

c. **Certain industrial products or devices**.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of paragraphs c.2. through c.5. of this section, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph c.1. of this section:

C. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of Part E of Section 2 and RH-1400. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph c.1. of this section, the transferor shall furnish the transferee a copy of paragraph c. of this section and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license of the U.S. Nuclear Regulatory Commission or an Agreement State that is equivalent to paragraph c., the transferor shall furnish the transferee a copy of paragraph c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," accompanied by a note explaining that use of the product or device is regulated by the governing agency, the agency who has jurisdiction where the product or device will be in use, under requirements substantially the same as those in paragraph c.; and

D. Shall report in writing to the Department, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph c.1. of this section is exempt from the requirements of Section 3 ~~of these Regulations~~, except for RH-1216. and RH-1400., with respect to the depleted uranium covered by that general license.

6. The general license provided in paragraph c.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-409.a.-d., RH-416., RH-600. through 603., RH-700., RH-751., and Section 4.

RH-402. **General Licenses - Radioactive Material Other Than Source Material**.

NOTE: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

a. **Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere**.

NOTE: Persons possessing radioactive material in devices under a general license in RH-402.a. before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of RH-402.a. devices in effect on January 14, 1975.

A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of RH-402.b., c. and d., radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

e. The general license provided in RH-402.a. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, ~~RH-600., RH-602., RH-603.,~~ RH-600. through 603., RH-700., RH-751., and Section 4.

f. **Luminous safety devices in aircraft**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

1. A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than ten (10) curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147 and that each device has been manufactured, assembled, or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer, assembler, or initial transferor by the Department pursuant to RH-405.h.,or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

5. The general license in paragraph f.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, ~~RH-600., RH-602., RH-603.,~~ RH-600. through 603., RH-700., RH-751., and Section 4.

g. **Calibration and reference sources**.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs g.4. and g.5. of this section to any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of radioactive material.

5. The general licenses in paragraphs g.1. through g.3. of this section are subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through RH-603., RH-700., RH-751., Section 3, and Section 4. The general license in paragraph g.2. is also subject to RH-409.g. In addition, persons who own, receive, acquire, possess, use, or transfer one (1) or more calibration or reference sources pursuant to these general licenses:

A. Shall not possess at any one time, at any one location of storage or use, more than five (5) microcuries (185 kBq) of americium-241, five (5) microcuries (185 kBq) of plutonium, or five (5) microcuries (185 kBq) of radium-226 in such sources;

i. **Ice detection devices**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and that each device has been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or initial transferor by the Department pursuant to RH-405.k., or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

4. The general license in paragraph i.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, ~~RH-600., RH-602., RH-603.,~~ RH-600. through 603., RH-700., RH-751., and Section 4.

j. **Products containing radium-226**.

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of RH-402.j.2. through 4., radium-226 contained in the following products manufactured prior to November 30, 2007.

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in RH-402.j.1. are exempt from the provisions of Section 3, and RH-600.a., b., d.-f., and RH-601., to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Section.

5. The general license in RH-402.j.1. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600.c., RH-602. and 603., RH-700., RH-751., and Section 4.

k. **Use of radioactive material for certain *in vitro* clinical or laboratory testing**.[8/]

1. A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the

Blue language is due to Medical Use of Byproduct Material NRC amendment.

provisions of RH-402.k.2., 3., 4., 5. and 6. ~~of this paragraph k.~~, the following radioactive materials in prepackaged units:

6. Any person using radioactive material pursuant to the general license of RH-402.k.1. is exempt from the requirements of Section 3, ~~"Standards for Protection Against Radiation,"~~ with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in RH-402.k.1.G. shall comply with the provisions of RH-1400., RH-1501., and RH-1502.

7. The general license in RH-402.k.1. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through 603., RH-700., RH-751., and Section 4.

n. **Incidentally produced radioactive material generated by the operation of a particle accelerator**.

A general license is hereby issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is subject to the applicable provisions of this Section and Section 3. A licensee shall transfer this radioactive material in accordance with Part E of this Section and Section 4. A licensee shall dispose of this radioactive material only by way of Department approved procedures. However, license complexity may require the Department to issue a specific license, instead, regarding the incidentally produced radioactive material.

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

l. **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.;

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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~~ Permitted by the Arkansas State Board of Pharmacy as a drug manufacturer;

iii. ~~Licensed~~ Permitted as a pharmacy by ~~a State~~ the Arkansas 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~~ permitted by the Arkansas State Board of Pharmacy.

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**"

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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~~ pharmacist license, 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.

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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**.

g. **Bankruptcy notification**.

1. Each general licensee that is required to register by RH-402.c.13., each general licensee under RH-402.g.2., 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.

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.

RH-416. **Modification, Suspension, and Revocation of Licenses and ~~Sealed Source and Device~~ Registration Certificates**.

a. The terms and conditions of each license and ~~sealed source and device~~ registration certificate issued under these ~~Regulations~~ Rules shall be subject to ~~amendment,~~ revision~~,~~ or modification. ~~or the~~ A license may be suspended or revoked by reason of amendments to the Act, or by reason of rules~~, regulations, and~~ or orders issued by the Department.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

b. Any license or ~~sealed source and device~~ registration certificate may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. A~~a~~ny material false statement in the application or any statement of fact required under provisions of the Act or of these ~~Regulations~~ Rules~~,~~; ~~or because of~~

2. C~~c~~onditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application~~,~~; ~~or for~~

3. V~~v~~iolation of, or failure to observe any of, the terms and conditions of the Act or the license or of any rule~~, regulation,~~ or order of the Department~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

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

~~d. The Department may terminate a specific license upon request submitted by the licensee to the Department in writing.~~

PART F.
RECORDS, REPORTS, INSPECTIONS, AND TESTS

RH-600. **Records**.

a. **Receipt, transfer, and disposal**.

Each person who receives radioactive material pursuant to a license issued pursuant to the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 of these ~~Regulations~~ Rules shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

Blue language is due to Medical Use of Byproduct Material NRC amendment.

1. The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three (3) years following transfer or disposal of the material.

2. The licensee who transferred the material shall ~~maintain~~ retain each record of transfer for three (3) years after each transfer ~~unless a specific requirement in another part of these Regulations dictates otherwise.~~; however, persons in paragraph a. receiving source material shall retain each record of transfer for this material until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

3. The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Department terminates each license that authorizes disposal of the material.

4. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out) to make the records that are required by this Section account for 100 percent (100%) of the material received.

RH-601. **Reporting Requirements**.

c. **Preparation and submission of reports**.

Reports made by licensees in response to the requirements of this section must be made as follows:

1. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Department at 1-800-633-1735. To the extent that the information is available at the time of notification, the information provided in these reports must include:

PART H.
RECIPROCITY AND ADDITIONAL REQUIREMENTS

RH-750. **Reciprocal Recognition of Licenses**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

a. **Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass**.

2. Notwithstanding the provisions of RH-750.a.1., any person who holds a specific license issued by the NRC or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in RH-401., RH-402.a., and RH-402.h. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

A. ~~Such person shall file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~ Reserved.

B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or an Agreement State~~;~~.

C. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited~~"; and~~."

~~D. The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises the licensee installs such device a copy of the general license contained in RH-402.a. or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.~~

b. **Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material**.

2. Notwithstanding the provisions of RH-750.b.1., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in RH-401., RH-402.a., and RH-402.h. within areas subject to the jurisdiction of the licensing body is hereby granted a

Blue language is due to Medical Use of Byproduct Material NRC amendment.

general license to install, transfer, demonstrate, or service such a device in this State provided that:

A. ~~Such person shall file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~ Reserved.

B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State~~;~~.

C. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited~~"; and~~."

~~D. The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises the licensee installs such device a copy of the general license contained in RH-402.a. or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.~~

SECTION 3.
STANDARDS FOR PROTECTION AGAINST RADIATION

PART D.
PRECAUTIONARY PROCEDURES

RH-1300. **Surveys**.

c. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated ~~periodically~~ at intervals recommended by the manufacturer or approved by the Department for the radiation measured. However, a more frequent interval may be required in another applicable Part of these Rules.

RH-1301. **Personnel Monitoring**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

a. All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with RH-~~1302.a.~~ 1200., with other applicable provisions of these ~~Regulations~~ Rules, or with conditions specified in a license or a registration must be processed and evaluated by a dosimetry processor:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology ~~[formerly called National Bureau of Standards],~~; and

2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

RH-1307. **Procedures for ~~Picking Up,~~ Receiving~~,~~ and Opening Packages**.

~~a. As used in these Regulations, Special Form means any of the following physical forms of licensed material:~~

~~1. The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters; does not melt, sublime or ignite in air at a temperature of 1,000 ^{0}F (538 ^{0}C), will not shatter or crumble if subjected to the percussion test described in Section 4; and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68 ^{0}F (20 ^{0}C) or in air at 86 ^{0}F (30 ^{0}C); or~~

~~2. The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one (1) dimension greater than five (5) millimeters, which will retain its contents if subjected to the tests prescribed in Section 4; and which is constructed of materials which do not melt, sublime or ignite in air at 1,475 ^{0}F (802 ^{0}C), and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68 ^{0}F (20 ^{0}C) or in air at 86 ^{0}F (30 ^{0}C).~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~b~~ a. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a "Type A" quantity ~~specified in or determined by procedures described in~~, as defined in RH-3100. and Appendix A to Section 4, shall make arrangements:

1. To receive the package when the carrier offers it for delivery; or

2. To receive notification of the arrival of the package at the carrier's terminal and to ~~pick up the package when the carrier offers it for delivery~~ take possession of the package expeditiously.

~~c~~ b. Each licensee shall:

1. Monitor the external surfaces of a labeled[4/] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as ~~described~~ defined in RH-3100.

2. Monitor the external surfaces of a labeled[4/] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined in RH-3100. and Appendix A to Section 4; and

RH-1307.c. (Cont'd)

3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

~~d~~ c. The licensee shall perform the monitoring required by ~~RH-1307.c.~~ paragraph b. of this section as soon as practical after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three (3) hours from the beginning of the next working day if it is received after working hours.

~~e~~ d. The licensee shall immediately notify the final delivery carrier and~~, by telephone and telegram, mailgram or facsimile,~~ the Department by telephone at 1-800-633-1735, when ~~if packages, other than those transported by exclusive use vehicle, are found to have~~:

1. Removable radioactive surface contamination ~~in excess of 0.001 microcurie per 100 square centimeters on the external surfaces of the package~~ exceeds the limits of RH-3503.i.; or

Blue language is due to Medical Use of Byproduct Material NRC amendment.

2. External ~~R~~radiation levels ~~at the external surface of the package in excess of 200 mRem/hr or at one (1) meter from the external surface of the package in excess of ten (10) mRem/hr~~ exceed the limits of RH-3400.

~~f~~ e. Each licensee ~~or registrant~~ shall:

1. E~~e~~stablish, maintain, and ~~maintain~~ retain written procedures for safely opening packages in which radioactive material is received; and
2. ~~shall assure~~ Ensure that ~~such~~ the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

~~g~~ f. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of ~~RH-1307.c.~~ paragraph b. of this section, but are not exempt from the survey requirement in ~~RH-1307.c.~~ paragraph b. of this section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

PART F.
RECORDS, REPORTS, NOTIFICATIONS, AND TESTS

RH-1501. **Reports of Lost, Stolen, or Missing Licensed or Registered Sources of Radiation**.

a. **Telephone reports**.

2. Reports must be made as follows:

All licensees or registrants shall make reports to the Department at 1-800-633-1735.

RH-1502. **Notification of Incidents**.

c. Licensees or registrants shall make the reports required by this section by telephone to the Department at 1-800-633-1735 and by confirming letter to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1513. **Reports of Transactions Involving Nationally Tracked Sources**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs a. through e. of this section for each type of transaction. See Appendix D to Section 3, "Nationally Tracked Source Thresholds."

~~h. Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph f.1. through f.4. of this section. The initial inventory report must include the following information:~~

~~1. The name, address, and license number of the reporting licensee;~~

~~2. The name of the individual preparing the report;~~

~~3. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~

~~4. The radioactive material in the sealed source;~~

~~5. The initial or current source strength in becquerels (curies); and~~

~~6. The date for which the source strength is reported.~~

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

RH-1800.d.

11. **Records of Personnel Monitoring Procedures**.

Each licensee or registrant shall maintain the following exposure records specified in RH-1802.f.:

A. Direct reading dosimeter readings and yearly operability checks required by RH-1802.f.2. and f.3. for three (3) years after the record is made.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

B. Records of alarming ratemeter calibrations for three (3) years after the record is made.

C. Personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the Department terminates the license or registration.

D. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters, until the Department terminates the license or registration.

RH-1802. **Personnel Radiation Safety Requirements for Radiographers and Radiographer's Assistants**.

f. **Personnel monitoring**.

1. A licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of a direct reading pocket dosimeter, an operable alarming ratemeter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiography~~y~~ic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

A. Pocket dosimeters shall have a range from zero to 200 millirems (2 millisieverts) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

B. Each personnel dosimeter must be assigned to and worn by only one (1) individual.

C. Personnel dosimeters that ~~are processed and evaluated by the accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ require replacement must be replaced at periods not to exceed one (1) month. All personnel dosimeters must be evaluated at periods not to exceed one (1) month.

RH-1802.f.1. (Cont'd)

Blue language is due to Medical Use of Byproduct Material NRC amendment.

D. After replacement, each personnel dosimeter must be processed as soon as possible.

2. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with RH-1800.d.11.

3. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed twelve (12) months for correct response to radiation, and records must be maintained in accordance with RH-1800.d.11. Acceptable dosimeters shall be read within plus or minus twenty percent (± 20%) of the true radiation exposure.

4. If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 200 millirems (2 millisieverts), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing and evaluation within twenty-four (24) hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within twenty-four (24) hours. In addition, the individual may not resume work associated with licensed ~~material or other~~ or registered sources of radiation until a determination of the individual's radiation ~~exposure had~~ dose has been made. This determination must be made by the Radiation Safety Officer (RSO) or the RSO's designee. The results of this determination must be included in the records maintained in accordance with RH-1800.d.11.

5. Dosimetry ~~reports received from the accredited NVLAP personnel dosimeter processor~~ results must be retained in accordance with RH-1800.d.11.

6. If a personnel dosimeter that is required ~~in~~ by RH-1802.f.1. is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in RH-1802.f.1. is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with

RH-1800.d.11.

RH-1802.f. (Cont'd)

7. Each alarming ratemeter shall:

   A. Be checked ~~to ensure that the alarm functions properly (sounds) before using~~ without being exposed to radiation prior to use at the start of each work shift~~;~~, to ensure that the audible alarm is functioning properly;

   B. Have an audible alarm sufficient to be heard by the individual wearing the alarming ratemeter or have other visual or physical notification of alarming conditions;

   ~~B~~ C. Be set to give an alarm signal at a preset dose rate of 500 mrem/hr (5 mSv/hr)~~;~~ or lower with an accuracy ~~rate~~ of plus or minus twenty percent (± 20%) of the true radiation dose rate;

   ~~C~~ D. Require special means to change the preset alarm function; and

   ~~D~~ E. Be calibrated for correct response to radiation at ~~periods~~ intervals not to exceed twelve (12) months ~~for correct response to radiation~~. The licensee or registrant shall maintain records of alarming ratemeter calibrations in accordance with RH-1800.d.11.

RH-1803.

f. **Specific requirements for radiographic personnel performing industrial radiography**.

1. At a job site, the following shall be supplied by the licensee or registrant:

   A. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

   B. A current whole-body personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP)~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~processor~~ for each individual performing radiographic operations;

C. An operable, calibrated ~~pocket~~ direct reading dosimeter ~~with a range of zero to 200 milliroentgens~~ for each individual performing radiographic operations;

D. An operable, calibrated alarming ratemeter for each individual performing radiographic operations; and

E. The appropriate barrier ropes and signs.

2. Each radiographer shall have available at the job site a valid certification ID card issued by a ~~e~~Certifying ~~e~~Entity.

3. Industrial radiographic operations shall not be performed if any of the items in paragraphs f.1. and f.2. of this section are not available at the job site or are inoperable.

4. During an inspection by the Department, the ~~Department~~ inspector may terminate an operation if any of the items in paragraphs f.1. and f.2. of this section are not available and operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until ~~such~~ all required conditions are met.

PART J.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

RH-1915. **Agreement with Well Owner or Operator**.

a. A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

1 If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it.

2. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.

3. The radiation monitoring required in RH-1969.~~a.~~ will be performed. …

b. The licensee shall retain a copy of the written agreement for three (3) years after the completion of the well logging operation.

RH-1931. **Labels, Security, and Transportation Precautions**.

a. **Labels**.

1. The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in RH-1303.a.1. and 2., without the conventional color requirements, and the wording

"**DANGER (or CAUTION) RADIOACTIVE MATERIAL**."

2. The licensee may not use a container to store radioactive material unless the container has ~~a secure,~~ securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in RH-1303.a. and the wording

"**CAUTION**,*
RADIOACTIVE MATERIAL,
NOTIFY CIVIL AUTHORITIES [or name of company] ~~**IF FOUND**~~."

*or **DANGER**

3. The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with Section 4 of these ~~Regulations~~ Rules.

RH-1961. **Training**.

a. The licensee may not permit an individual to act as a logging supervisor until that person:

1. Has completed training in the subjects outlined in RH-1961.e. of this section; …

Blue language is due to Medical Use of Byproduct Material NRC amendment.

e. The licensee shall include the following subjects in the training required in RH-1961.a.1. of this section.

1. Fundamentals of radiation safety, including:

A. Characteristics of radiation;

B. Units of radiation dose and quantity of radioactivity;

C. Hazards of exposure to radiation;

D. Levels of radiation from licensed material;

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

F. Radiation safety practices, including prevention of contamination, and methods of decontamination.

2. Radiation detection instruments, including:

A. Use, operation, calibration, and limitations of radiation survey instruments;

B. Survey techniques; and

C. Use of personnel monitoring equipment.

3. Equipment to be used, including:

A. Operation of equipment, including source handling equipment and remote handling tools;

B. Storage, control, and disposal of ~~radioactive~~ licensed material; and

C. Maintenance of equipment.

4. The requirements of pertinent Department ~~regulations~~ rules; and

5. Case histories of accidents in well-logging.

RH-1965. **Personnel Monitoring**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

a. The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that ~~persons wears,~~ person wears a personnel dosimeter at all times during the handling of licensed radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one (1) individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed.~~ All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

~~RH-1992. **Subjects to be Included in Training Courses for Logging Supervisors**.~~

~~a. **Fundamentals of radiation safety**.~~

~~1. Characteristics of radiation.~~

~~2. Units of radiation dose (rem) and quantity of radioactivity (curie).~~

~~3. Significance of radiation dose.~~

~~A. Radiation protection standards.~~

~~B. Biological effects of radiation dose.~~

~~4. Levels of radiation from sources of radiation.~~

~~5. Methods of minimizing radiation dose.~~

~~A. Working time.~~

~~B. Working distances.~~

~~C. Shielding.~~

~~b. **Radiation detection instrumentation to be used**.~~

~~1. Use of radiation survey instruments.~~

~~A. Operation.~~

~~B. Calibration.~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~C. Limitations.~~

~~2. Survey techniques.~~

~~3. Use of personnel monitoring equipment.~~

~~c. **Equipment to be used**.~~

~~1. Handling equipment.~~

~~2. Sources of radiation.~~

~~3. Storage and control of equipment.~~

~~4. Operation and control of equipment.~~

~~d. The requirements of pertinent Federal and State regulations.~~

~~e. The licensee's written operating and emergency procedures.~~

~~f. The licensee's record keeping procedures.~~

RH-1993~~3~~2.- RH-1999. Reserved.

SCHEDULE C TO SECTION 3

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES ~~CONTAINING~~ OF RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

PART N.
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

RH-2802. **Posting of Notices to Workers**.

c. ~~Department Form X (Appendix I to Section 3)~~ RC FORM 100, **"**Notice to Employees,**"** shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

(Note: As shown below, Department Form X, "Notice to Employees," is being removed from the rules. At the conclusion of the rulemaking process, the current revision will be available on the ADH website and will be titled RC FORM 100.)

~~NOTICE TO EMPLOYEES~~

~~Arkansas Department of Health~~
~~STANDARDS FOR PROTECTION AGAINST RADIATION~~

~~The Arkansas Department of Health (ADH) has adopted regulations with standards to protect you from hazards associated with radioactive materials and radiation emitting machines which are licensed or registered by ADH. In particular, the following information is available for your review:~~

~~**Section 3**: Standards for Protection Against Radiation~~
~~**Part N**: Notice, Instructions, and Reports to Workers; Inspections~~
~~Any other documents your employer must provide.~~

~~These may be found at the following location:~~

~~YOUR EMPLOYER'S RESPONSIBILITY~~
~~Your employer is required to:~~

1. ~~Comply with all applicable regulations and the conditions of the license or registration.~~

2. ~~Post or otherwise make available to you a copy of the regulations, licenses, and operating procedures which apply to work in which you are engaged, and explain the provisions to you.~~

~~YOUR RESPONSIBILITY AS A WORKER~~
~~You should:~~

1. ~~Know the provisions of the ADH regulations, the precautions, the operating procedures, and the emergency procedures which apply to your work.~~

2. ~~Observe the provisions of your own protection and for the protection of your co-workers.~~

3. ~~Report unsafe working conditions or violations of the license or registration conditions or regulations to ADH.~~

~~REPORTS OF YOUR RADIATION EXPOSURE HISTORY~~
1. ~~The ADH regulations specify the occupational limits for radiation exposure including concentrations of radioactive material in air and water. These regulations require your employer to give you a written report if you receive exposure in excess of any applicable limit. The limits on your exposure are contained in RH-1200, RH-1206, and RH-1207. While these are the maximum allowable limits, your employer should keep your radiation exposure below those limits as is reasonably achievable.~~

2. ~~If you work where personnel monitoring is required and request information on your radiation exposures,~~

   a. ~~your employer must advise you annually of your exposure to radiation, and~~
   b. ~~upon termination of employment, your employer must give you a written report of your radiation exposures.~~
   c. ~~A report of any exposure in excess of a limit must be reported to you.~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~**INSPECTIONS:** All licensed or registered activities are subject to inspection by the ADH.~~

~~**INQUIRIES**~~

~~**Direct all inquiries on matters outlined above to: ADH, Radiation Control Section, 4815 West Markham Street, Mail Slot 30, Little Rock, Arkansas 72205-3867 or to (501) 661-2301. For emergencies, call (800) 633-1735.**~~

~~**POSTING REQUIREMENT:** In accordance with RH-2802, copies of this notice must be posted in every establishment where employees are engaged in activities licensed or registered by the ADH. Posting must permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.~~

~~Appendix I to Section 3~~ ~~Revised 10/01/12~~
~~Form X~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~**APPENDIX K TO SECTION 3**~~
~~Deleted.~~

~~**APPENDIX L TO SECTION 3**~~
~~Deleted.~~

SECTION 4.
TRANSPORTATION OF RADIOACTIVE MATERIALS

PART D.
GENERAL LICENSES

RH-3301. **General License for NRC-Approved Packages**.

c. Each licensee issued a general license under paragraph a. of this section shall:

3. Submit in writing before the first use of the package to the U.S. Nuclear Regulatory Commission: ATTN: Document Control Desk, Director, Division of ~~Spent~~ Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

PART F.
OPERATING CONTROLS AND PROCEDURES

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

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

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. Reserved.

PART G.
QUALITY ASSURANCE

RH-3600. **Quality Assurance Requirements**.

a. **Purpose**.

This Part, in conjunction with Subpart H of 10 CFR Part 71, describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this Part and Subpart H of 10 CFR Part 71, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each certificate holder and applicant for a package approval, entities governed by the U.S. Nuclear Regulatory Commission, is responsible for satisfying the quality assurance requirements in Subpart H of 10 CFR Part 71 that apply to design, fabrication, testing, and modification of packaging. Each Department licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this Part.

c. **Approval of program**.

Before the use of any package for the shipment of licensed material subject to this Part, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall submit to the Department a description of its quality assurance program, including a discussion of which requirements of this Part are applicable and how they will be satisfied.

APPENDIX A TO SECTION 4

DETERMINATION OF A_1 AND A_2

TABLE A-1—A_1 AND A_2 VALUES FOR RADIONUCLIDES

Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-10}$	$2.3X10^{-8}$

Blue language is due to Medical Use of Byproduct Material NRC amendment.

SECTION 6.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

PART A.
GENERAL

RH-5002. **Purpose and Scope**.

c. **Production of radioactive material**.

1. A licensee who produces radioactive material incidentally as a result of the operation of an accelerator shall comply with the ~~general~~ license requirements of RH-402.n.

2. A licensee who produces radioactive material intentionally as a result of the operation of an accelerator shall comply with the specific license requirements of Section 2~~ of these Regulations~~.

RH-5003. **Fees**.

In accordance with ~~Act 596 of 2011, codified at~~ Arkansas Code Annotated §20-21-217, annual fees for licensing shall be paid. Applicants shall be charged for a full calendar year regardless of the month the license is issued. Nonpayment of fees shall result in escalated enforcement action and/or revocation of license.

a. The Accelerator License Fees are as follows:

CATEGORY	FEE
Particle accelerator, non-medical	$200~~.00~~
~~Medical, therapy, non-hospital unit~~	~~$250.00 per unit ($175.00 for each additional unit)~~
Particle accelerator, medical, non-hospital unit	$450~~.00~~ per unit ($300~~.00~~ for each additional unit)
Cyclotron/accelerator for the production of radioactive material	$3,750~~.00~~

b. Other fees are as follows:

CATEGORY	FEE

Blue language is due to Medical Use of Byproduct Material NRC amendment.

Arkansas State Board of Health Rules ~~and Regulations~~ for Control of Sources of Ionizing Radiation	$0~~.00~~ for first hard copy $30~~.00~~ for each additional hard copy
Amendment to existing license	$50~~.00~~ per amendment

c. Reciprocity fees are as follows:

CATEGORY	FEE
Particle accelerator, industrial	$200

PART C.
LICENSES

RH-5200. **License Requirement**.

Except for persons exempt as provided in RH-5214. and RH-5600., ~~N~~no person shall receive, possess, use, transfer, own or acquire a particle accelerator except as authorized in a license issued pursuant to this Section.

RH-5211. **Modification, Suspension, and Revocation of Licenses**.

a. The terms and conditions of all licenses shall be subject to revision or modification. A license may be suspended or revoked by reason of amendments to the Act, or by reason of rules~~, regulations,~~ or orders issued by the Department.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. A~~a~~ny material false statement in the application or any statement of fact required under provisions of the Act or of these ~~Regulations~~ Rules~~,~~; ~~or because of~~

2. C~~c~~onditions revealed by such application or statement of fact or any report, record, or inspection or other means ~~which~~ that would warrant the Department to refuse to grant a license on an original application~~,~~; ~~or for~~

3. V~~v~~iolation of, or failure to observe any of, the terms and conditions of the Act, or the license, or of any rule~~, regulation,~~ or order of the Department~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

RH-5212. **Licensure of Out-of-State Particle Accelerators for Non-Industrial Use**.

a. An out-of-state particle accelerator ~~registrant~~/licensee/registrant seeking to bring a particle accelerator into the State ~~of Arkansas~~ for non-industrial use shall apply for an Arkansas particle accelerator license in accordance with Part C of this Section.

b. Annual fees for licensing shall be paid in accordance with RH-5003.

c. The licensee shall notify the Department in writing at least three (3) working days prior to the accelerator's use in the State. The notice shall include the following:

1. ~~The t~~Type of particle accelerator;

2. ~~The n~~Nature, duration, and scope of use; and

3. ~~The e~~Exact location(s) where the particle accelerator is to be used.

d. If, for a specific case, the three (3) day period would impose an undue hardship, ~~on~~ the licensee may, ~~upon application to~~ at the determination of the Department, obtain permission to proceed sooner ~~may be granted~~.

RH-5214. **Reciprocal Recognition of Out-of-State Particle Accelerator Licenses for Industrial Use**.

a. Whenever any particle accelerator is brought into the State for any temporary industrial use, the person proposing to bring such a machine into the State shall apply for and receive a notice from the Department granting reciprocal recognition prior to beginning operations. The request for reciprocity shall include the following:

1. Type of particle accelerator;

2. Nature, duration, and scope of use;

3. Exact location(s) where the particle accelerator is to be used;

4. Copy of the person's current license or equivalent document;

5. Qualifications for each radiographer who will be working in Arkansas if the reciprocity request is for industrial radiography as defined in Part I of Section 3; and

Blue language is due to Medical Use of Byproduct Material NRC amendment.

6. Applicable fee as specified in RH-5003.

b. Upon a determination that the request for reciprocity meets the requirements of the Department, the Department may issue a notice granting reciprocal recognition authorizing the proposed use.

c. Once reciprocity is granted, the out-of-state licensee shall notify the Department in writing prior to each entry into the State. This notice shall be submitted at least three (3) working days before the particle accelerator is to be used in the State. If, for a specific case, the three (3) day period would impose an undue hardship, the out-of-state licensee may, at the determination of the Department, obtain permission to proceed sooner.

d. The out-of-state licensee shall:

1. Comply with all applicable rules of the Department and with all the terms and conditions of the out-of-state license, except any such terms and conditions that may be inconsistent with applicable rules of the Department;

2. Supply the Department with such other information as the Department may reasonably request; and

3. Only operate in the State for 180 or less calendar days per year.

e. Use in excess of 180 days per calendar year requires a license in accordance with Part C of this Section.

f. If the State from which the particle accelerator is brought does not issue licenses or equivalent documents, a license shall be obtained from the Department in accordance with Part C of this Section.

g. The Department may withdraw, limit, or qualify its acceptance of any license or equivalent document issued by another State upon determining that the action is necessary to prevent undue hazard to occupational or public health and safety.

RH-~~5214~~5215.- RH-5299. Reserved.

SECTION 8.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

PART D.
RADIATION SAFETY REQUIREMENTS FOR THE OPERATION OF IRRADIATORS

RH-7055. **Personnel Monitoring**.

a. Irradiator operators shall wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter ~~processor~~ must be ~~accredited for~~ capable of detecting high-energy photons in the normal and accident dose ranges ~~(See RH-1301.a.)~~. Each personnel dosimeter must be assigned to and worn by only one (1) individual. Film badges must be ~~processed~~ replaced at least monthly, and all other personnel dosimeters must be ~~processed~~ replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

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 all appropriate information required by the form;

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.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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.~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~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

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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, issued under RH-406., 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.

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.

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**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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,

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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 paragraphs ~~(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

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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) (previously named the American Council on Pharmaceutical Education) 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 paragraph~~s 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~~ in accordance with a Nuclear Regulatory Commission master material broad scope license ~~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-8400. **Quality Control of Diagnostic Equipment**.

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or ~~procedures, which have been~~ approved by the Department. The licensee shall conduct quality control procedures in accordance with written procedures. Each licensee shall retain records of quality control of diagnostic equipment for three (3) years after the record is made.

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.

RH-8409. **Storage and Control of Volatiles and Gases**.

e. A licensee shall check the operation of collection systems ~~monthly~~ at intervals recommended by the manufacturer or approved by the Department. The records of these checks shall be maintained for three (3) years.

PART E:
UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED

RH-8500. **Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required**.

Except for quantities that require a written directive under RH-8307., a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

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-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;

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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:~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~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)

~~e~~ 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., 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:~~. 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:

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., 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 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:

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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

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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

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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.~~

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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-8634. **Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.

f. In addition to the requirements specified in ~~RH-8634.a. through RH-8634.e.~~ paragraphs a. through e. of this section, a licensee shall:

1. For ~~[~~low dose-rate~~]~~, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

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.

~~e~~d. 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-8704. **Record of a Dose to an Embryo/Fetus or a Nursing Child**.

A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with RH-8801 for three (3) years. The record must contain the licensee's name; names of all the individuals involved; social security

number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

RH-8709. **Records of Surveys for Ambient Radiation ~~Exposure~~ Dose Rate and Contamination**.

A licensee shall retain a record of each survey required by RH-8408. for three (3) years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RH-8712. **Records of Decay-in-Storage**.

A licensee shall maintain records of the disposal of licensed materials, as required by RH-8410., for three (3) years. The record must include the date the container was sealed, the date of the disposal, the radionuclides disposed, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

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**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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-8801. **Reports and Notifications of a Dose to an Embryo/Fetus or a Nursing Child**.

d. The licensee shall submit a written report to the Department within fifteen (15) days after discovery of a dose to the embryo/fetus or nursing child that requires a report in RH-8801.a. or RH-8801.b.

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 embryo/fetus or the nursing child;

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

Blue language is due to Medical Use of Byproduct Material NRC amendment.

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

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 A.
GENERAL

RH-10000. **Purpose and Scope**.

b. Therapeutic radiation machines meeting the definition of a particle accelerator are subject to Section 6, "Licenses and Radiation Safety Requirements for Particle Accelerators." Electronic brachytherapy devices and other therapeutic radiation machines not meeting the definition of a particle accelerator are subject to Section 1, "Registration of ~~Sources of~~ Radiation Machine Facilities and Vendor Services." RH-10308. devices are licensed or registered as determined by the Department.

PART D.
TECHNICAL REQUIREMENTS

RH-10308. **Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation ~~Dosage~~ Dose**.

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation ~~dosage~~ dose, and which is not appropriately regulated under any existing device category ~~of therapeutic radiation machine~~, until:

a. The applicant, licensee, or registrant has, at a minimum, provided the Department with:

1. A completed ~~RC FORM 200,~~ "Radiation Machine Facility Registration" form or "Application for Medical Particle Accelerator," as applicable;

2. A copy of the device manufacturer's U.S. Food and Drug Administration clearance or approval;

~~2~~ 3. A detailed description of the device and its intended applications;

~~3~~ 4. Facility design ~~requirements~~ information, including shielding and access control;

~~4~~ 5. Documentation of appropriate training and experience for prospective Authorized User physicians and Qualified Medical Physicists;

6. Quality management program procedures;

Blue language is due to Medical Use of Byproduct Material NRC amendment.

~~5~~ 7. Methodology for measurement of ~~dosages~~ dose to be administered to patients or human research subjects;

~~6. Radiation safety precautions instructions;~~

8. Operating and safety procedures;

~~7~~ 9. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

~~8~~ 10. Quality assurance program procedures;

11. Acceptance testing protocol to be followed;

12. A copy of any memorandums of understanding addressing radiation safety; and

~~9~~ 13. Other information requested by the Department in its review of the application; and

b. The applicant, licensee, or registrant has received written approval from the Department to utilize the device in accordance with the ~~regulations~~ rules and specific conditions the Department considers necessary for the medical use of the device.

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

PART B.
BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

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 Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop 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 emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html.

APPENDIX A TO SECTION 12
CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIALS
TABLE 1—CATEGORY 1 AND CATEGORY 2 THRESHOLDS

~~$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$~~

$$\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\cdots+\frac{R_n}{AR_n}\geq 1.0$$

Blue language is due to Medical Use of Byproduct Material NRC amendment.

"Regulation" to "Rule" Changes

RH-3. **Registration Requirement**.

Every person possessing a reportable source of radiation shall register in accordance with the provisions of these ~~Regulations~~ Rules.

RH-4. **Communications**.

All communications concerning these ~~Regulations~~ Rules shall be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-5. **Additional Requirements**.

In addition to the requirements of this Section, all registrants are subject to the applicable provisions of other Sections of these ~~Regulations~~ Rules.

RH-10. **Definitions**.

Inspection - An official examination or observation including but not limited to, tests, surveys and monitoring to determine compliance with rules, ~~regulations,~~ orders, requirements and conditions of the Department.

Registrant - Any person who is registering or who has registered with the Department pursuant to these ~~Regulations~~ Rules.

Reportable source of radiation - Any source of radiation as specified under RH-20 of these ~~Regulations~~ Rules.

RH-35. **Assembler and/or Transfer Requirement**.

c. No person shall make, sell, lease, transfer, lend, assemble or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these ~~Regulations~~ Rules.

RH-50. **Radiation Protection Standards**.

Any person possessing a radiation machine that is a reportable source of radiation or who provides radiation machine installations and/or services shall be subject to

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the requirements of Section 3 of these ~~Regulations~~ Rules, "Standards for Protection Against Radiation."

RH-51. **Records to be Maintained**.

Each person who possesses a reportable source of radiation shall keep records showing the receipt (for any source received after January 1, 1963), transfer or disposal of such source of radiation. Additional record requirements are specified elsewhere in these ~~Regulations~~ Rules.

RH-52. **Access to Premises**.

The Department or its duly authorized representatives shall for reasonable cause have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of these rules ~~and regulations~~, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.

RH-54. **Tests**.

Upon instruction from the Department, each registrant shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary in the administration of the ~~regulation~~ rule, including, but not limited to, tests of: …

RH-55. **Exemptions**.

a. The Department may, upon application therefore, or upon its own initiative, grant such exemptions or exceptions from the requirements of these ~~Regulations~~ Rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

b. U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these ~~Regulations~~ Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation: …

RH-56. **Additional Requirements**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

The Department may, by rule~~, regulation~~ or order, impose upon any registrant such requirements in addition to those established in ~~this Regulation~~ these Rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-57. **Out-of-State Registration**.

Whenever any radiation machine is brought into the state for any temporary use, the persons proposing to bring such a machine into the state shall give written notice to the Department at least two (2) days before such a machine enters the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine is to be used and state(s) in which this machine is registered.

If for a specific case, the two (2) day period would impose an undue hardship on the person, upon application to the Department, permission to proceed sooner may be granted. In addition, the out-of-state person must:

a. Comply with all applicable ~~regulations~~ rules of the Department; and

b. Supply the Department with such other information as the Department may reasonably request.

RH-70. **Violations**.

a. Any person who violates any of the provisions of the Act or rules~~,~~ ~~regulations~~ or orders in effect pursuant thereto of the Department shall, upon conviction thereof, be punished by a fine of not less than one hundred dollars ($100.00) nor more than two thousand dollars ($2,000.00), or by imprisonment for not more than six (6) months or be both fined and imprisoned.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-101. **Effective Date**.

The provisions of these ~~Regulations~~ Rules shall become operative on the effective date of an agreement executed by the State of Arkansas and the Federal Government under the provisions of Section 274 of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

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RH-102. **Purpose and Scope**.

a. Section 2, Part I of Section 3, Part J of Section 3, and Sections 7 through 9 provide for the licensing of radioactive material. Except for persons exempt as provided in Part C of Section 2 and RH-750., no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use radioactive material except as authorized in a specific or general license issued in accordance with these ~~Regulations~~ Rules.[1/]

b. In addition to the requirements of this Section, all licensees, except as otherwise noted in these ~~Regulations~~ Rules, are subject to the requirements of Section 3 and Section 4 ~~of these Regulations~~ as well as any ~~regulations~~ rules specific to the type of radioactive material or particle accelerator use. …

RH-104. **Communications**.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-105. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-106. **Completeness and Accuracy of Information.**

a. Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the Department's ~~regulations~~ rules, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

RH-107. **Deliberate Misconduct**.

a. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder, or applicant for a license or certificate

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of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, or applicant's activities subject to this Section, may not:

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

c. For purposes of paragraph a.1. of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, certificate of registration holder, or applicant to be in violation of any rule~~, regulation,~~ or order; or any term, condition, or limitation, of any license issued by the Department; or …

RH-200. **Definitions**.

Commencement of construction - Any action defined as "construction" or any other activity at the site of a facility subject to the ~~regulations~~ rules in this Section that has a reasonable nexus to radiological health and safety.

Construction - The installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the ~~regulations~~ rules in this Section that are related to radiological safety or security. The term "construction" does not include: …

Inspection - An official examination or observation including but not limited to, tests, surveys and monitoring to determine compliance with rules, ~~regulations,~~ orders, requirements and conditions of the Department.

License - Except where otherwise specified, a license issued pursuant to these ~~Regulations~~ Rules.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general license provided by ~~regulation~~ rule or a specific license issued by the Department.

Licensee - Any person who is licensed by the Department in accordance with these ~~Regulations~~ Rules and the Act.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

Radiographer - Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these ~~Regulations~~ Rules and the conditions of registration or of a license.

Registrant - Any person who is registered with Department and is legally obligated to register with the Department pursuant to these ~~Regulations~~ Rules and the Act.

Registration - Registration with the Department in accordance with these ~~Regulations~~ Rules adopted by the Department.

Research and Development -

1. Theoretical analysis, exploration or experimentation; or

2. The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, material and processes.

   Research and Development used in these ~~Regulations~~ Rules does not include the internal or external administration of radiation or radioactive material to human beings.

RH-301. **Radioactive Material Other Than Source Material**.

a. **Exempt concentrations**.

   3. A manufacturer, processor, or producer of a product or material in an Agreement State is exempt from the requirements for a license and from these ~~Regulations~~ Rules to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in RH-902. (Schedule C to Section 2) and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

d. **Gas and aerosol detectors containing radioactive material**.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in the Act and from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26, which license authorizes the initial transfer of the product for use under RH-301.d. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by an Agreement State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

e. **Self-luminous products containing radioactive material**.

1. **Tritium, krypton-85, or promethium-147**.

Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements or equivalent regulations of an Agreement State. The exemption in RH-301.e. does not apply to tritium, krypton-85 or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. **Radium-226**.

Any person is exempt from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 μCi (3.7 kBq) of radium-226 which were manufactured prior to November 30, 2007.

f. **Radioactive drug: capsules containing carbon-14 urea for "in vivo" diagnostic use for humans**.

1. Except as provided in paragraphs RH-301.f.2. and RH-301.f.3., any person is exempt from the requirements for a license and from the ~~regulations~~ rules in this Section and Section 9 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing one (1) microcurie (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

g. **Certain industrial devices.**

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in the Act and from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under RH-301.g. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

RH-302. **Carriers**.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the ~~regulations~~ rules in this Section and Part I of Section 3, Part J of Section 3, Sections 6 through 9, and Section 12 of these ~~Regulations~~ Rules and the requirements for a license set forth in the Act to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

RH-303. **U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear of Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this state is exempt from these ~~Regulations~~ Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation: …

RH-304. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-305. **Exempt Quantities**.

a. Except as provided in paragraphs c. through e. of this section, any person is exempt from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in RH-901., Schedule B to Section 2.

e. No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in RH-901. (Schedule B to Section 2), except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the ~~regulations~~ rules in this Section.

RH-400. **Types of Licenses**.

Licenses for radioactive materials are of two (2) types: general and specific.

General License - provided by ~~regulation~~ rule, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Department or the issuance of a licensing document to a particular person. However, registration with the Department may be required by the particular general license.

Specific License - issued to a named person who has filed an application with the Department for the license under the provisions of these ~~Regulations~~ Rules.

RH-401. **General Licenses - Source Material**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

a. **Small quantities of source material**.

2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph a. of this section:

B. Shall not abandon such source material. Source material may be disposed of as follows:

i. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this Section to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued pursuant to these ~~Regulations~~ Rules; or

4. Any person who receives, possesses, uses or transfers source material in accordance with the general license granted in paragraph a. of this section is exempt from the provisions of Section 3 ~~of these Regulations~~ to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of RH-1216. and RH-1400. to the extent necessary to meet the provisions of paragraphs a.2.B. and a.3. of this section. However, this exemption does not apply to any person who also holds a specific license issued pursuant to these ~~Regulations~~ Rules.

RH-402. **General Licenses - Radioactive Material Other Than Source Material**.

c. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in RH-402.a.:

9. Shall transfer the device to another general licensee only if:

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A. The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of RH-402.a.-e., RH-600., RH-1501., and RH-1502., and any safety documents identified in the label of the device. Within thirty (30) days of the transfer, the transferor shall report to: …

iv. The name, title, and phone number of the responsible individual identified by the transferee in accordance with RH-402.c.12. to have knowledge of and authority to take actions to ensure compliance with the appropriate ~~regulations~~ rules and requirements; or

10. Shall comply with the provisions of RH-1501. and RH-1502. for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Section 3~~ of these Regulations~~.

12. Shall appoint an individual responsible for having knowledge of the appropriate ~~regulations~~ rules and requirements and the authority for taking required actions to comply with appropriate ~~regulations~~ rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate ~~regulations~~ rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

h. **Ownership of byproduct material**.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of these ~~Regulations~~ Rules, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import, or export byproduct material, except as authorized in a specific license.

m. **Ownership of special nuclear material**.

A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of these ~~Regulations~~ Rules, a general licensee under this paragraph is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-403. **Application for Specific Licenses**.

j. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Section 9 ~~of these regulations~~ or equivalent Agreement State requirements shall include: …

RH-404. **General Requirements for the Issuance of Specific Licenses**.

A license application will be approved if the Department determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these ~~Regulations~~ Rules in such a manner as to minimize danger to public health and safety or property;

d. The applicant satisfies any applicable special requirements contained in Section 2, Section 3, Sections 7 through 9, and Section 12 ~~of these Regulations~~; and

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

e. **Licensing of the manufacture or initial transfer of devices to persons generally licensed under RH-402.a**.

5. **Material transfer reports and records**.

Each person licensed under RH-405.e. to initially transfer devices to generally licensed persons shall comply with the requirements of this subparagraph.

A. The person shall report to the Radiation Control Section, Attention: General License Registration Program, all transfers of such devices to persons for use under the general license in RH-402.a. and all receipts of devices from persons licensed under RH-402.a. The report must be submitted on a quarterly basis on an NRC Form 653 entitled "Transfers of Industrial Devices Report (to General Licensees)" or in a clear and legible report containing all of the data required by the form.

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i. The required information for transfers to general licensees includes: …

(b). The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate ~~regulations~~ rules and requirements; …

B. The person shall report all transfers of devices to persons for use under a general license in a U.S. Nuclear Regulatory Commission or Agreement State's regulations that are equivalent to RH-402.a. and all receipts of devices from general licensees in the NRC or Agreement State's jurisdiction to the NRC or responsible Agreement State agency. The report must be submitted on an NRC Form 653 entitled "Transfers of Industrial Devices Report (to General Licensees)" or in a clear and legible report containing all of the data required by the form.

i. The required information for transfers to general licensees includes:

(b). The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate ~~regulations~~ rules and requirements;

RH-406. **Special Requirements for Specific Licenses of Broad Scope**.

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain ~~regulations~~ rules governing holders of such licenses.

RH-407. **Special Requirements for Land Disposal of Radioactive Waste**.

b. **Content of application**.

2. The specific technical information must include the following information needed for demonstration that the performance

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objectives of RH-407.c. and the applicable technical requirements of RH-407.d. will be met:

K. A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in RH-407.c.2. and occupational radiation exposure to ensure compliance with the requirements of Section 3 ~~of these Regulations~~ and to control contamination of personnel, vehicles, equipment, buildings and the disposal site. Both routine operations and accidents must be addressed. The program description must include procedures, instrumentation, facilities and equipment.

N. **Technical analyses**.

The specific technical information must also include the following analyses needed to demonstrate that the performance objectives of RH-407.c. will be met:

iii. Analyses of the protection of individuals during operations must include assessments of expected exposures due to routine operations and likely accidents during handling, storage and disposal of waste. The analyses must provide reasonable assurance that exposures will be controlled to meet the requirements of Section 3 ~~of these Regulations~~.

c. **Performance objectives**.

4. **Protection of individuals during operations**.

Operations at the land disposal facility must be conducted in compliance with the standards for radiation protection set out in Section 3 ~~of these Regulations~~, except for releases of radioactivity in effluents from the land disposal facility which shall be governed by RH-407.c.2. Every reasonable effort shall be made to maintain radiation exposures as low as is reasonably achievable.

RH-408. **Issuance of Specific Licenses**.

Upon a determination that an application meets the requirements of the Act and these ~~Regulations~~ Rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such

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conditions and limitations as it deems appropriate and necessary to effectuate the purposes of the Act.

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

h. **Financial assurance and record keeping for decommissioning**.

7. Each person licensed under these ~~Regulations~~ Rules shall keep records of information important to decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with RH-409.b., licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated.

RH-410. **Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas**.

e. Coincident with the notification required by RH-410.d., the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to RH-409.h. in conjunction with a license issuance or renewal or as required by RH-410. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to RH-410.g.4.E.

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this ~~regulation~~ rule becomes effective July 1, 2002.

RH-413. **Department Action on Application to Renew or Amend**.

In considering an application to renew or amend a license or to amend a sealed source and device registration certificate, the Department will apply the applicable criteria set forth in RH-404., RH-405., and RH-406. and in Sections 2, 3, 4, 5, 6, 7, 8, and 9 ~~of these Regulations~~.

RH-501. **Conditions of Transfer**.

a. Except as otherwise provided in the license and subject to the provisions of paragraphs b. and c. of this section, any licensee may transfer radioactive material, subject to acceptance by the transferee, to:

3. Any person exempt from these ~~Regulations~~ Rules to the extent permitted under such exemption;

RH-502. **Preparation and Transport**.

Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section ~~4 of these Regulations~~.

RH-600. **Records**.

b. **Record retention periods**.

1. The licensee shall retain each record that is required by the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~ or by license condition for the period specified by the appropriate ~~regulation~~ rule or license condition. If a retention period is not otherwise specified by ~~regulation~~ rule or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

2. If there is a conflict between the Department's ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~ for such records shall apply unless the Department, pursuant to RH-304., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~.

c. **Record maintenance.**

Each record required by this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~ must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified

by Department ~~regulations~~ rules. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RH-601. **Reporting Requirements**.

b. **Twenty-four hour report**.

2. An event in which equipment is disabled or fails to function as designed when:

A. The equipment is required by ~~regulation~~ rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

A. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 ~~of these Regulations~~ for the material; and

c. **Preparation and submission of reports**.

Reports made by licensees in response to the requirements of this section must be made as follows:

2. **Written report**.

Each licensee that makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within thirty (30) days of the initial report. Written reports prepared pursuant to other ~~regulations~~ rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Arkansas Department of Health, Radiation Control

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Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. The reports must include the following:

RH-602. **Inspections**.

b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these ~~Regulations~~ Rules.

RH-700. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-750. **Reciprocal Recognition of Licenses**.

a. **Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass**.

1. Subject to these ~~regulations~~ rules, any person who holds a specific license from the NRC or an Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

C. The out-of-state licensee complies with all applicable ~~regulations~~ rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable ~~regulations~~ rules of the Department;

Blue language is due to Medical Use of Byproduct Material NRC amendment.

b. **Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material**.

1. Subject to these ~~regulations~~ rules and Section 7 ~~of these regulations~~, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

C. The out-of-state licensee complies with all applicable ~~regulations~~ rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable ~~regulations~~ rules of the Department;

E. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH-750.b.1. except by transfer to a person:

ii. Exempt from the requirements for a license for such material under these ~~Regulations~~ Rules.

RH-751. **Additional Requirements**.

The Department may, by rule~~, regulation~~, or order, impose upon any licensee such requirements in addition to those established in the ~~regulations~~ rules in this Section as it deems appropriate or necessary to minimize danger to public health and safety or property.

APPENDIX A TO SECTION 2

II. **Financial Test**

C. 2. If the parent company no longer meets the requirements of paragraph A. of this Appendix, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules. The notice must be sent by certified mail within ninety (90) days after the end of the fiscal year for which the yearend financial data show that the parent company no longer meets the financial test

requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. **Parent Company Guarantee**

B. If the licensee fails to provide alternate financial assurance as specified in the Department's ~~regulations~~ rules within ninety (90) days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide alternative financial assurance that meets the provisions of the Department's ~~regulations~~ rules in the name of the licensee.

D. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee, whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

APPENDIX B TO SECTION 2

II. **Financial Test**

C. If the licensee no longer meets the requirements of Section II.A. of this Appendix, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules within 120 days of such notice.

III. **Company Self-Guarantee**

B. The licensee shall provide alternate financial assurance as specified in the Department's ~~regulations~~ rules within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

G. 2. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the

issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

APPENDIX C TO SECTION 2

II. Financial Test

B. 3. If the licensee no longer meets the requirements of Section II.A. of this Appendix, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules. The notice must be sent by certified mail, return receipt requested, within ninety (90) days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

B. The licensee shall provide alternative financial assurance as specified in the Department's ~~regulations~~ rules within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

E. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Department will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

APPENDIX D TO SECTION 2

II. Financial Test

C. 3. If the licensee no longer meets the requirements of Section I of this Appendix, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules. The notice must be sent by certified mail, return receipt requested, within ninety (90) days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the

financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. **Self-Guarantee**

B. The licensee shall provide alternative financial assurance as specified in the Department's ~~regulations~~ rules within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

F. 2. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

FOOTNOTES TO SECTION 2

2/ The requirements specified in RH-300.c.1.E.i. and ii. need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "**CAUTION - RADIOACTIVE MATERIAL - URANIUM**," as previously required by these ~~Regulations~~ Rules.

9/ Sources licensed under RH-405.e., RH-105.h. or RH-405.i. prior to January 19, 1975 may bear labels authorized by the ~~regulations~~ rules in effect on January 1, 1975.

RH-1001. **Effective Date**.

The provisions of these ~~Regulations~~ Rules shall become effective on January 1, 1963, except where another effective date is specifically noted.

RH-1002. **Purpose and Scope**.

b. It is the purpose of the ~~Regulations~~ Rules in this Section to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee or registrant in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the ~~Regulations~~ rules in this Section. However, nothing in this Section shall

be construed as limiting actions that may be necessary to protect health and safety.

RH-1003. **Communications**.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1100. **Definitions**.

License - Except where otherwise specified, a license issued pursuant to these ~~Regulations~~ Rules.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred, or disposed of under a general license provided by ~~regulation~~ rule or a specific license issued by the Department.

RH-1102. **Units of Radiation Dose**.

h. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in RH-1102.g. of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the ~~Regulations~~ rules in this Section, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to RH-1102. to convert a measured tissue dose in rads to dose equivalent in rems.

RH-1104. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-1212. **Testing for Leakage and/or Contamination of Sealed Sources**.

e. Any test conducted pursuant to RH-1212. which reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination shall be considered evidence that the sealed source is leaking. The licensee shall

Blue language is due to Medical Use of Byproduct Material NRC amendment.

immediately withdraw the sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with these ~~Regulations~~ Rules.

RH-1300. **Surveys**.

a. Each licensee or registrant shall make or cause to be made, surveys of areas, including the subsurface, that:

1. May be necessary for the licensee or registrant to comply with the ~~regulations~~ rules in this Section; and

RH-1400. **General Requirements**.

A licensee shall dispose of licensed material only:

a. By transfer to an authorized recipient as provided in RH-1406. or in Section 2 ~~of these Regulations~~, or to the Department of Energy; or

RH-1401. **Method for Obtaining Approval of Proposed Disposal Procedures**.

A licensee or applicant for a license may apply to the Department for approval of proposed procedures, not otherwise authorized in these ~~Regulations~~ Rules, to dispose of licensed material generated in the licensee's activities. Each application shall include:

RH-1406. **Transfer for Disposal and Manifests**.

a. The requirements of this section and Appendix G to 10 CFR Part 20 are designed to:

1. Control transfers of low-level radioactive waste (LLW) by any waste generator, waste collector, or waste processor licensee, as defined in Section 2 ~~of these Regulations~~, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section 2 ~~of these Regulations~~;

RH-1500. **Records**.

k. **Records required at temporary jobsites**.

Each licensee or registrant conducting activities as described in the definition for temporary jobsite in RH-1100. shall have the following

records available at the temporary jobsite for inspection by the Department:

1. Current copy of appropriate license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

2. A copy of these ~~Regulations~~ Rules.

n. 1. **Record retention periods**.

A. Each licensee or registrant shall retain each record that is required by this Section or by license condition for the period specified by the appropriate ~~regulation~~ rule or license condition. If a retention period is not otherwise specified by ~~regulation~~ rule or license condition, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.

B. If there is a conflict between the Department's ~~regulations~~ rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section for such records shall apply unless the Department, pursuant to RH-2000., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section.

RH-1509. **Reports of Individual Monitoring**.

a. This section applies to each person licensed by the Department to:

2. Possess or use at any time, for processing or manufacturing for distribution pursuant to Section 2 or 9 ~~of these Regulations~~, radioactive material in quantities exceeding any one of the following quantities:

TABLE TO RH-1509.a.2.

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37

Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

[a] The Department may require as a license condition, or by rule~~,~~ ~~Regulation,~~ or order pursuant to RH-2001., reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

RH-1513. **Reports of Transactions Involving Nationally Tracked Sources**.

g. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by ~~regulation~~ rule. …

RH-1600. **Scope**.

This Part establishes requirements, for which a registrant (or licensee) is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to and not in substitution for, other applicable provisions of these ~~Regulations~~ Rules.

RH-1602. **General Requirements**. **Administrative Controls**.

a. **Registrant**.

The registrant shall be responsible for directing the operation of the x-ray systems which have been registered with the Department. The registrant or the registrant's agent shall assure that the requirements of RH-1602.a. are met in the operation of the x-ray system(s).

1. An x-ray system which does not meet the provisions of these ~~Regulations~~ Rules shall not be operated for diagnostic or therapeutic purposes.

10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH-1200.

A. When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

ii. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by Part F ~~to~~ of Section 3 ~~of these Regulations~~. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

RH-1611. **Bone Densitometry**.

a. Bone densitometry systems shall be:

2. Registered in accordance with these ~~Regulations~~ Rules; and

SCHEDULE A TO SECTION 3

Persons requesting that the Department approve a healing arts screening program shall submit the following information and evaluation:

f. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these ~~Regulations~~ Rules. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed;

RH-1612. **Scope and Purpose – Analytical X-ray Equipment**.

This Part provides special requirements for analytical x-ray equipment. The requirements of this Part are in addition to, and not in substitution for, applicable requirements in other Parts of these ~~Regulations~~ Rules.

RH-1800. **General Provisions**.

a. **Purpose and scope.**

1. The ~~regulations~~ rules in this Part prescribe requirements for the issuance of licenses for the industrial use of sealed sources in industrial radiography and establish radiation safety requirements for persons utilizing sources of radiation in industrial radiography. The ~~regulations~~ rules in this Part apply to all licensees or

registrants who use sources of radiation for industrial radiography. Except for the ~~regulations~~ rules in this Part clearly applicable only to sealed radioactive sources - radiation machines, accelerators, and sealed radioactive sources are covered by this Part. The provisions of this Part do not apply to medical uses of sources of radiation.

2. The requirements of this Part are in addition to, and not in substitution for, other applicable requirements of these ~~Regulations~~ Rules. In particular, requirements in Sections 1, 2, 3, 4, 6, and 12 ~~of these Regulations~~ apply to applicants, licensees, and registrants subject to this Part.

b. **Specific licensing provisions**.

2. **Specific licenses for industrial radiography**.

K. The applicant identifies the locations(s) where all records required by this Part and other Sections of these ~~Regulations~~ Rules will be maintained.

c. **Definitions**.

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

Radiographer - Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these ~~Regulations~~ Rules and the conditions of registration or of a license.

d. **Recordkeeping Requirements**.

14. **Location of documents and records**.

A. Each licensee or registrant shall maintain copies of records required by RH-1800.d. and other applicable ~~regulations~~ rules at the location specified in the licensee's license application.

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

ii. A current copy of the Arkansas State Board of Health Rules ~~and Regulations~~ for Control of Sources of Ionizing Radiation.

RH-1801. **Equipment Control**.

f. **Leak testing and replacement of sealed sources**.

4. Any test conducted pursuant to the requirements of RH-1801.f. which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or disposed of in accordance with ~~Regulations~~ rules of the Department. …

l. **Labeling, storage, and transportation**.

2. The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with ~~regulations~~ rules set forth in Section 4, "Transportation of Radioactive Materials."

RH-1802. **Personnel Radiation Safety Requirements for Radiographers and Radiographer's Assistants**.

b. **Training**.

2. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

A. Has received copies of and instructions in the requirements described in this Part; RH-107.; in the applicable sections of Section 3, "Standards for Protection Against Radiation," (including its Part N, "Notices, Instructions, and Reports to Workers; Inspections"); in applicable Department of Transportation (DOT) regulations as referenced in Section

4 of these ~~Regulations~~ Rules and the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 71; in the Department license(s) under which the radiographer will perform industrial radiography; and the licensee's or registrant's operating and emergency procedures;

3. The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

A. Has received copies of and instructions in the requirements described in this Part; RH-107.; in the applicable sections of Section 3, "Standards for Protection Against Radiation," (including its Part N, "Notices, Instructions, and Reports to Workers; Inspections"); in applicable Department of Transportation (DOT) regulations as referenced in Section 4 of these ~~Regulations~~ Rules and the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 71; in the Department license(s) under which the radiographer's assistant will perform industrial radiography; and the licensee's or registrant's operating and emergency procedures;

5. Except as provided in RH-1802.b.5.D., the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's ~~regulations~~ rules, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must: …

c. **Radiographer certificate card confiscation**.

The Department may confiscate any radiographer's certification card should there be serious health and safety violations relating to the ~~Regulations~~ rules, license conditions, and/or licensee operating and emergency procedures. The radiographer will be restricted from conducting radiographic operations within the State of Arkansas.

d. **Radiation Safety Officer for industrial radiography**.

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

A Establishing and overseeing all operating, emergency, and ALARA procedures as required by this Section, "Standards

for Protection Against Radiation," and reviewing them regularly to ensure that the procedures in use conform to current Section 3 procedures, conform to other Department ~~regulations~~ rules, and to the license conditions.

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

RH-1803. **Precautionary Procedures in Radiographic Operations**.

e. **Records required at temporary job sites**.

Each licensee or registrant conducting industrial radiography at temporary job sites shall have the following records available at that site for inspection by the Department:

3. Applicable ~~regulations~~ rules.

g. **Special requirements and exemptions for enclosed radiography**.

1. **Cabinet x-ray systems**.

G. **Additional controls and indicators for cabinet x-ray systems designed to admit humans**.

For cabinet x-ray systems designed to admit humans, there shall also be provided:

i. Compliance with all applicable requirements of this Part and RH-1208.~~ of these Regulations.~~ If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this Part and 21 CFR 1020.40.

4. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Department pursuant to RH-55~~ of these Regulations~~.

RH-1900. **General Provisions**.

a. **Scope**.

The ~~Regulations~~ rules in this Part apply to all licensees who use sources of radiation for wireline service operations including mineral logging, radioactive markers or subsurface tracer studies.

b. **Purpose**.

The ~~Regulations~~ rules in this Part establish radiation safety requirements for persons utilizing sources of radiation for wireline service operations including mineral logging, radioactive markers and subsurface tracer studies. The requirements of this Part are in addition to and not in substitution for other applicable requirements of these ~~Regulations~~ Rules.

c. **Definitions**.

Logging supervisor - Any individual who uses radioactive material or radiation producing machines, or provides personal supervision in the use of radioactive material or radiation producing machines at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Department's ~~Regulations~~ rules and the conditions of the license.

Radioactive material - Byproduct, source or special nuclear material received, processed, used or transferred under a license issued by the Arkansas State Board of Health, Arkansas Department of Health under the ~~regulations~~ rules of this Part.

RH-1913. **Specific Licenses for Well Logging**.

The Department will approve an application for a specific license for the use of radioactive material in well logging if the applicant meets the following requirements:

a. The application shall satisfy the general requirements specified in RH-404. ~~of these Regulations~~, and any special requirements contained in this Part.

b. The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Department a description of this program which specifies the:

4. Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Department's ~~Regulations~~ rules and licensing requirements and the applicant's operating and emergency procedures; and …

d. The applicant shall establish and submit to the Department its program for annual inspections of the job performance of each logging supervisor to ensure that the Department's ~~regulations~~ rules, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three (3) years after each annual internal inspection.

RH-1946. **Particle Accelerators**.

No licensee shall permit above-ground testing of particle accelerators that results in the production of radiation, except in areas or facilities controlled or shielded so as to meet the requirements of RH-1200. and RH-1208. ~~of these Regulations~~, as applicable.

RH-1961. **Training**.

a. The licensee may not permit an individual to act as a logging supervisor until that person:

2. Has received copies of, and instruction in:

A. The applicable Parts of Section 3 ~~of these Regulations~~;

b. The licensee may not permit an individual to act as a logging assistant until that person:

1. Has received instruction in applicable Parts of Section 3 ~~of these Regulations~~;

RH-1963. **Operating and Emergency Procedures**.

Each licensee shall develop and follow written operating and emergency procedures that cover:

o. Identifying and reporting to the Department defects and noncompliance as required by RH-1935.d.2. and RH-1977.a., b., and d. ~~of these regulations~~.

RH-1973. **Documents and Records Required at Field Stations**.

Each licensee shall maintain the following documents and records at the field station:

a. A copy of these ~~Regulations~~ Rules;

RH-1975. **Documents and Records Required at Temporary Jobsites**.

Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well-logging operation is completed:

d. The shipping papers for the transportation of radioactive materials required by Section 4 ~~of these Regulations~~;

e. When operating under reciprocity pursuant to Section 2, Part H of these ~~Regulations~~ Rules, a copy of the U.S. Nuclear Regulatory Commission license or Agreement State license authorizing use of radioactive materials.

RH-1977. **Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources**.

b. The licensee shall notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by RH-601., RH-1501., RH-1502., and RH-1504. ~~of these Regulations..~~

RH-1991. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Part as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-2000. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-2001. **Additional Requirements**.

The Department may, by rule~~, regulation,~~ or order, impose upon any licensee such requirements in addition to those established in the ~~regulations~~ rules in this Section as it deems appropriate or necessary to minimize danger to public health and safety or property.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-2110. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-2801. **Purpose and Scope**.

This Part establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in work under a license or registration; and options available to such individuals in connection with Department inspection of licensees or registrants to ascertain compliance with the provisions of the Act and the ~~regulations~~ rules, orders, and licenses issued thereunder regarding radiological working conditions. The ~~regulations~~ rules in this Part apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed by or registered with the Department pursuant to these ~~Regulations~~ Rules in Sections 1 and 2, Part I of Section 3, Part J of Section 3, and Sections 6, 7, 8, and 9.

RH-2802. **Posting of Notices to Workers**.

a. Each licensee or registrant shall post current copies of the following documents:

1. A copy of these ~~Regulations~~ Rules;

RH-2803. **Instructions to Workers**.

a. All individuals working in or frequenting any portion of a restricted area:

3. Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of Department ~~regulations~~ rules and licenses or registrations for the protection of personnel from exposures to radiation or radioactive material;

4. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of Department ~~regulations~~ rules and licenses or unnecessary exposure to radiation and/or radioactive material;

RH-2804. **Notifications and Reports to Individuals**.

a. Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Department ~~Regulations~~ rules, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to Department ~~Regulations~~ rules. Each notification and report shall:

4. Contain the following statement:

"This report is furnished to you under the provisions of Arkansas Department of Health ~~Regulations~~ rules entitled 'Standards for Protection Against Radiation.' You should preserve this report for further reference."

RH-2805. **Presence of Representatives of Licensees or Registrants and Workers During Inspections**.

a. Each licensee or registrant shall afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these ~~Regulations~~ Rules.

RH-2806. **Consultation With Workers During Inspections**.

a. Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department ~~regulations~~ rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

b. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he/she has reason to believe may have contributed to or caused any violation of the Act, these ~~Regulations~~ Rules, or license condition, or any unnecessary exposure of an individual to radiation from

Blue language is due to Medical Use of Byproduct Material NRC amendment.

licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of RH-2807.a.

RH-2807. **Requests by Workers for Inspections**.

a. Any worker or representative of workers who believes that a violation of the Act, these ~~Regulations~~ Rules or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. …

c. No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these ~~Regulations~~ Rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself/herself or others of any option afforded by this Part.

RH-2900. **Scope and Purpose**.

This Part provides special requirements for analytical x-ray equipment. The requirements of this Part are in addition to, and not in substitution for, applicable requirements in other parts of these ~~Regulations~~ Rules.

RH-3001. **Effective Date**. The provisions of these ~~Regulations~~ Rules shall become operative on the effective date of an agreement executed by the State of Arkansas and the Federal Government under the provisions of Section 274 of the Atomic Energy Act of 1954 as amended (73 STAT. 689).

RH-3002. **Purpose and Scope**.

c. The ~~regulations~~ rules in this Section apply to any licensee authorized by specific or general license issued by the Department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Department license, or transports that material on public highways. No provision of this Section authorizes the possession of licensed material.

RH-3003. **Communications and Records**.

a. Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of

Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

b. Each record required by this section must be legible throughout the retention period specified by each Department ~~regulation~~ rule. …

RH-3006. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-3100. **Definitions**.

Licensed material - Radioactive material received, possessed, used, or transferred under a general or specific license issued by the Department pursuant to ~~the regulations in this Section~~ these Rules.

RH-3200. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-3201. **Exemption of Physicians**.

Any physician, as defined in RH-200., licensed by the State of Arkansas to dispense drugs in the practice of medicine is exempt from RH-3005. with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed by the Department under Section 9 of these ~~Regulations~~ Rules, U.S. Nuclear Regulatory Commission's 10 CFR Part 35 regulations or the equivalent Agreement State regulations.

RH-3507. **Inspection and Tests**.

b. Upon instruction from the Department, each licensee shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary for the administration of these ~~Regulations~~ Rules.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-3508. **Reports**.

b. Each licensee shall submit, in accordance with RH-3003., the written report required by paragraph a. of this section within sixty (60) days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the Department to the applicable certificate holder. Written reports prepared under other ~~regulations~~ rules may be submitted to fulfill this requirement if the reports contain all the necessary information.

RH-3607. **Quality Assurance Records**.

The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by RH-3602.e.; the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities; and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable ~~regulations~~ rules and designates factors such as duration, location, and assigned responsibility. …

RH-3700. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

APPENDIX A TO SECTION 4

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these ~~regulations~~ Rules, are given in Table A-1. …

RH-4002. **Scope**.

This Section contains the requirements applicable to and governing the proceeding of any administrative hearing pertinent to these ~~Regulations~~ Rules.

RH-4003. **Communications**.

a. Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-4004. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-4010. **Emergency Orders**.

Whenever the Department finds that an emergency exists requiring immediate action to protect the public health and safety, the Department may, without notice or hearing, issue a ~~regulation~~ rule or order reciting the existence of such emergency and requiring that such action be taken as is necessary to meet the emergency. Notwithstanding any provision of the Act (Act 8 of Second Extraordinary Session of 1961), such ~~regulation~~ rule or order shall be effective immediately. Any person to whom such ~~regulation~~ rule or order is directed shall comply therewith immediately, but on application to the Department shall be afforded a hearing within ten (10) days. On the basis of such hearing, the emergency ~~regulation~~ rule or order shall be continued, modified or revoked within thirty (30) days after such hearing. Any final order entered in any proceeding under this paragraph may be appealed within twenty (20) days from the date of issuance thereof, to the Circuit Court of Pulaski County.

RH-4012. **Impounding Materials**.

The Department shall have the authority in the event of an emergency to impound or order the impounding of sources of ionizing radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of the Act or any rules ~~or regulations~~ issued thereunder. …

RH-4013. **Filing of Papers**.

Unless otherwise specified, papers required to be filed with the Department shall be filed with the Arkansas Department of Health, Radiation Control Section, 4815

West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. Papers required to be filed with the Department shall be deemed filed upon actual receipt with the Department at the place specified, accompanied by proof of service upon the parties required to be served as provided in RH-4016. ~~of these Regulations.~~ …

RH-4014. **Computation of Time**.

The time within which any Act under these ~~Regulations~~ Rules is to be accomplished shall be computed by excluding the first day and including the last, unless the last day is Sunday or is a holiday as defined or fixed by statutes now or hereafter in force in this State, and then it shall also be excluded. If the day succeeding such Sunday or holiday is also a holiday or a Sunday, then such succeeding day shall also be excluded.

RH-4019. **Effect of Intervention or Denial Thereof**.

A person permitted to intervene becomes a party to the proceeding.

b. An order denying intervention will be without prejudice to any proposed limited appearance by the petitioner as one who is not party for the purposes provided in RH-4023. ~~of these Regulations.~~

RH-4022. **Authority to Administer Oaths**.

Any oath or affirmation required by or pursuant to the provisions of these ~~Regulations~~ Rules may be administered by any person authorized to administer oaths by the laws of the State of Arkansas.

RH-4024. **Formal Hearings**.

The parties to a formal hearing shall be the Department, the licensee, registrant or applicant as the case may be and any person permitted to intervene pursuant to RH-4018. ~~of these Regulations.~~

RH-4038. **Appeals from Decision of Director**.

… Copies of the State Board of Health Order shall be served upon the parties in interest as provided in RH-4037. ~~of this Regulation.~~

RH-4040. **Public Records - Exceptions**.

Except as provided below, all records shall be deemed public records and shall be open to inspection by the public. The following are not to be considered public records which are available for public inspection:

e. Correspondence received in confidence by the Department relating to an alleged or possible violation of any statute, rule, ~~regulation,~~ order, license, registration, or permit.

RH-5002. **Purpose and Scope**.

b. In addition to the requirements of this Section, all licensees are subject to applicable requirements in Sections 3 and 4 ~~of these Regulations~~. Licensees engaged in industrial radiographic operations are subject to the applicable requirements in Part I of Section 3. Licensees engaged in well-logging operations are subject to the applicable requirements of Part J of Section 3. Licensees who use an accelerator for medical therapy are subject to the applicable requirements in Section 11 ~~of these Regulations~~.

RH-5004. **Communications**.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-5005. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-5100. **Definitions**.

Accelerator License - Except where otherwise specified, a license issued pursuant to these ~~Regulations~~ Rules.

Licensee - Any person who is licensed by the Department in accordance with these ~~Regulations~~ Rules and the Act.

Radiation - Ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, neutrons, high speed electrons, high speed protons, and other particles capable of producing ions. Radiation, as used in these ~~Regulations~~ Rules, does not include non-ionizing radiation, such as radio waves or microwaves, or visible, infrared, or ultraviolet light.

Radiation Safety Officer - An individual who has the knowledge and responsibility to apply appropriate radiation protection ~~regulations~~ rules and has been assigned such responsibility by the licensee.

Test - The process of verifying compliance with an applicable ~~regulation~~ rule.

RH-5201. **Licensing Procedures**.

g. Every person possessing a particle accelerator on the effective date of these ~~Regulations~~ Rules shall have a period of ninety (90) days in which to make application for a license.

RH-5203. **Special Requirements for the Issuance of a License for Certain Types of Particle Accelerators**.

a. **Use of particle accelerators in medical therapy**.

In addition to the requirements set forth in RH-5202., a license for use of a particle accelerator in medical therapy will be issued only if:

2. Prospective Authorized User physicians meet training and experience requirements specified in Section 11~~ of these Regulations~~; and

c. **Use of particle accelerators for the production of radioactive material**.

In addition to the requirements of RH-5202., a license for the use of a particle accelerator to produce radioactive material will be issued only if:

2. The applicant has applied for a radioactive material specific license in accordance with the requirements of Section 2~~ of these Regulations~~.

RH-5204. **Issuance of Particle Accelerator Licenses**.

Upon a determination that an application meets the requirements of the Act and these ~~Regulations~~ Rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the Act.

RH-5205. **Specific Terms and Conditions of Licenses**.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

a. Each license issued pursuant to this Section 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.

d. The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule~~, regulation~~, or order, such additional requirements and conditions with respect to the licensee's use of a particle accelerator as it deems appropriate or necessary in order to:

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

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

RH-5206. **Expiration and Termination of Licenses.**

b. Expiration of the license does not relieve the licensee of the requirements of these ~~Regulations~~ Rules.

RH-5400. **General Provisions.**

This Part establishes radiation safety requirements for the use of particle accelerators. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these ~~Regulations~~ Rules.

RH-5401. **Limitations.**

a. No licensee shall permit any individual to act as particle accelerator operator until such individual:

2. Has received copies of and instruction in this Section, the applicable requirements of Section 3 ~~of these Regulations~~, pertinent license conditions, and the licensee's operating and emergency procedures, and has demonstrated understanding thereof; and …

b. In addition to the initial training requirements in paragraph a. of this section, the training program for accelerator operators shall also include refresher training at intervals not to exceed twelve (12) months and training to be conducted when a significant change occurs in duties, ~~regulations~~ rules, or terms of the license.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-5407. **Area Monitoring and Survey Requirements.**

g. … The survey report shall include documentation of all instances where the facility, in the opinion of the Qualified Expert, is in violation of applicable ~~regulations~~ rules. Any deficiencies detected during the survey shall be corrected prior to using the accelerator.

j. Copies of the records required in RH-5407.g. and RH-5407.i. shall be submitted to the Department within thirty (30) days following completion of the action that initiated the record requirement. Annual radiation protection surveys shall not be submitted unless it is discovered that radiation levels in unrestricted and/or restricted areas exceed the dose limits specified in Section 3~~ of these Regulations~~.

k. Surveys for airborne radiation hazards shall be performed in accordance with written procedures approved by the Department to ensure that any particulate radioactivity present will not result in doses in excess of the limits specified in Section 3~~ of these Regulations~~. Records of surveys for airborne radioactivity shall be maintained for five (5) years.

RH-5408. **Ventilation Systems and Waste Disposal.**

c. For radioactive material specific licensees, waste disposal shall be in accordance with Part E of Section 3~~ of these Regulations~~ and as stated in the specific license. General licensees subject to RH-402.n. shall dispose of incidentally produced radioactive material only by way of Department approved procedures.

RH-5600. **Exemptions.**

d. Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear of Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this state is exempt from these ~~Regulations~~ Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation: …

e. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-5601. **Additional Requirements.**

Blue language is due to Medical Use of Byproduct Material NRC amendment.

The Department may, by rule~~, regulation~~ or order, impose upon any licensee such requirements in addition to those established in these ~~Regulations~~ Rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-5602. **Inspections.**

b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these ~~Regulations~~ Rules.

RH-5700. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-5801. **Record Retention Periods.**

a. Each licensee shall retain each record that is required by this Section or by license condition for the period specified by the appropriate ~~regulation~~ rule or license condition. If a retention period is not otherwise specified by ~~regulation~~ rule or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

b. If there is a conflict between the Department's ~~regulations~~ rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section for such records shall apply unless the Department, pursuant to RH-5600.e., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section.

RH-5802. **Record Maintenance.**

Each record required by this Section must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department ~~regulations~~ rules. …

RH-6003. **Scope**.

These ~~Regulations~~ Rules apply to any person who engages in the extraction, mining, beneficiating, processing, use, transfer, or disposal of NORM in such a manner as to alter the chemical properties or physical state of the NORM or its potential exposure pathway to humans.

The ~~Regulations~~ Rules in this Section address the introduction of NORM into products in which neither the NORM nor the radiation emitted from the NORM is considered to be beneficial to the products. …

RH-6004. **Definitions**.

Licensing State - Means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NORM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

RH-6005. **Exemptions**.

a. Persons who receive, possess, use, process, transfer, distribute, and dispose of NORM are exempt from the requirements of these ~~Regulations~~ Rules if: …

b. Persons who receive products or materials containing NORM distributed in accordance with a specific license issued by the Department pursuant to RH-6022.c or an equivalent license issued by another Licensing State are exempt from these ~~Regulations~~ Rules.

c. The manufacturing, distribution, use, and disposal of the following products/materials are exempt from the requirements of these ~~Regulations~~ Rules: …

Blue language is due to Medical Use of Byproduct Material NRC amendment.

d. The wholesale and retail distribution (including custom blending), possession, and use of the following products/ materials are exempt from the requirements of these ~~Regulations~~ Rules: …

e. The possession and use of natural gas and natural gas products and crude oil and crude oil products as fuel are exempt from the requirements of these ~~Regulations~~ Rules. …

RH-6010. **General License**.

d. Equipment contaminated with NORM is exempt from the requirements of these ~~Regulations~~ Rules if the maximum radiation exposure level does not exceed 50 microroentgen per hour including background at any accessible point, and radioactive contamination levels do not exceed levels set forth in Appendix A of this Section.

f. 1. The transfer of NORM not exempt from these ~~Regulations~~ Rules from one general licensee to another general licensee may be authorized by the Department if: …

2. Transfers made under RH-6010.f.1. do not relieve the general licensee who makes the transfer from the responsibilities of assessing the extent of NORM contamination or material present, evaluating the hazards of the NORM, informing the general licensee receiving the NORM of these assessments and evaluations, and maintaining records required by these ~~Regulations~~ Rules.

RH-6013. **Disposal and Transfer of Waste for Disposal**.

b. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part E of Section 3~~, Part E of these Regulations~~.

RH-6016. **Transportation of NORM**. Transportation of NORM contaminated equipment and/or waste shall be subject to the applicable parts of Section 4 ~~of these Regulations~~ and the requirements listed below.

f. **Transporters**.

1. A transporter may not accept NORM for transportation unless the NORM is accompanied by sufficient copies of a manifest properly prepared, with each copy signed and dated by the licensee and each previous transporter in accordance with these ~~Regulations~~ Rules.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-6019. **Worker Protection Plans**.

A Worker Protection Plan must be submitted to the Department which includes, but may not be limited to, the following items:

c. **Contamination control procedures**. Including:

4. **Surveying and Counting Procedures** - This section should include the proper procedure for personnel and equipment exit surveys, as well as procedures for land surveys, airborne contamination surveys (air sampling), and counting procedures. This section should also include the licensee's action levels and limits, if more conservative than the Department's outlined in Section 3 or Section 7~~ of these Regulations~~.

RH-6020. **Specific Licenses**.

a. Unless otherwise exempted under the provisions of RH-6005. or licensed under the provisions of Section 2~~ of the Regulations~~, the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this Section or pursuant to equivalent regulations of another Licensing State.

RH-6022. **Requirements for the Issuance of Specific Licenses**.

c. An application for a specific license to manufacture and/or initially transfer products or materials containing NORM to persons exempted from these ~~Regulations~~ Rules pursuant to RH-6005.b. will be approved if:
…

RH-6026. **Conditions of Specific Licenses Issued Under RH-6022**.

a. **General terms and conditions**.

1. Each specific license issued pursuant to this Section 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.

RH-6031. **Modification and Revocation of Licenses**.

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules~~, regulations,~~ and orders issued by the Department.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

b. Any license 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 because of conditions revealed by such application or statements of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule~~s, regulation,~~ or order of the Department.

RH-6033. **Financial Assurance and Recordkeeping for Decommissioning**.

Each specific licensee shall be subject to the financial assurance and recordkeeping for decommissioning under RH-409.h. ~~of these Regulations.~~

RH-6040. **Reciprocal Recognition of Licenses**.

Subject to these ~~Regulations~~ Rules, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that: …

c. The out-of-state licensee complies with all applicable ~~regulations~~ rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable ~~regulations~~ rules of the Department;

RH-7001. **Purpose and Scope**.

a. This Section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This Section also contains radiation safety requirements for operating irradiators. The requirements of this Section are in addition to and not in substitution for other requirements of these ~~Regulations~~ Rules. …

b. The ~~Regulations~~ rules in this Section apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. …

c. The ~~Regulations~~ rules in this Section do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of material for nondestructive testing purposes), gauging, or open-field (agricultural) irradiation.

RH-7002. **Definitions**.

Commencement of construction - Any action defined as "construction" or any other activity at the site of a facility subject to the ~~regulations~~ rules in this Section that has a reasonable nexus to radiological health and safety.

Construction - The installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the ~~regulations~~ rules in this Section that are related to radiological safety or security. The term "construction" does not include: …

RH-7003. **Communications**.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-7005. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-7013. **Specific Licenses for Irradiators**.

The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

a. The applicant shall satisfy the general requirements specified in RH-404.a.-d. ~~of these Regulations~~ and the requirements contained in this Section.

b. The application must describe the training provided to irradiator operators including:

4. Means employed by the applicant to test each operator's understanding of the Department's ~~Regulations~~ rules and licensing requirements and the irradiator operating and emergency procedures; and

RH-7015. **Commencement of Construction**.

… Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and having no bearing on the issuance of a license with respect to the requirements of the Act, and rules~~, regulations,~~ and orders issued under the Act.

RH-7017. **Specific Exemptions**.

a. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-7051. **Training**.

a. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

2. The requirements of Section 3 ~~of these Regulations~~ that are relevant to the irradiator;

d. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

2. Changes in ~~regulations~~ rules and license conditions since the last review, if any;

e. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that ~~Regulations~~ rules, license conditions, and operating and emergency procedures are followed. …

RH-7081. **Records and Retention Periods**.

The licensee shall maintain the following records at the irradiator for the periods specified.

k. Records of the receipt, transfer, and disposal, of all licensed sealed sources as required by Part F and RH-600. of Section 2 ~~of these Regulations~~.

RH-7091. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-8000. **Purpose and Scope**.

This Section establishes additional requirements and provisions for the specific use of radionuclides in the healing arts. These requirements and provisions provide for the protection of public health and safety. The requirements and provisions of this Section are in addition to, and not in substitution for, others in these ~~Regulations~~ Rules. The requirements and provisions of these ~~Regulations~~ Rules apply to applicants and licensees subject to this Section unless specifically exempted.

RH-8002. **Maintenance of Records**.

Each record required by Section 9 must be legible throughout the retention period specified by each Department ~~regulation~~ rule. …

RH-8005. **License Required**.

b. An individual may receive, possess, use, or transfer radioactive material in accordance with the ~~regulations~~ rules in Section 9 under the supervision of an authorized user as provided in RH-8306., unless prohibited by license condition.

c. An individual may prepare unsealed radioactive material for medical use in accordance with the ~~regulations~~ rules in Section 9 under the supervision of an authorized nuclear pharmacist or authorized user as provided in RH-8306., unless prohibited by license condition.

RH-8006. **Communications**.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-8007. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-8012. **Mobile Medical Service Administrative Requirements**.

f. A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

3. A copy of applicable sections of the Arkansas State Board of Health Rules ~~and Regulations~~ for Control of Sources of Ionizing Radiation.

g. A mobile medical service licensee shall maintain all records required by Section 3 and Section 9 ~~of these Regulations~~ at a location within the Department's jurisdiction that is: …

RH-8013. **License Issuance**.

a. The Department shall issue a license for the medical use of radioactive material if:

3. The applicant meets the requirements of Section 2 ~~of these regulations~~; and

4. The Department finds the applicant equipped and committed to observe the safety standards established by the Department in these ~~Regulations~~ Rules for the protection of the public health and safety.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-8026. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH- 8100. **Definitions**.

Unit dosage – A dosage that:

1. Is obtained or prepared in accordance with the ~~regulations~~ rules for uses described in RH-8500., RH-8530., or RH-8550.; and …

RH-8301. **Radiation Protection Program Changes**.

a. A licensee may revise its radiation protection program without Department approval if:

2. The revision is in compliance with the ~~regulations~~ rules and the license;

RH-8306. **Supervision**.

a. A licensee that permits the ~~receipts~~ receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by RH-8005.b. shall:

1. In addition to the requirements in RH-2803.~~ of these regulations~~, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, ~~regulations~~ rules of Section 9, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, ~~regulations~~ rules of Section 9, and license conditions with respect to the medical use of radioactive material.

Blue language is due to Medical Use of Byproduct Material NRC amendment.

b. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by RH-8005.c., shall:

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the ~~regulations~~ rules of Section 9, and license conditions.

RH-8402. **Calibration of Survey Instruments**.

a. A licensee shall ensure that the survey instruments used to show compliance with Section 9 and Section 3 ~~of these regulations~~ have been calibrated before first use, annually, and following any repair that will affect the calibration.

RH-8405. **Requirements for Possession of Sealed Sources and Brachytherapy Sources**.

b. A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Section 3 ~~of these regulations~~.

d. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Sections 2 and 3~~ of these regulations~~;

RH-8409. **Storage and Control of Volatiles and Gases**.

c. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Section 3~~ of these regulations~~.

RH-8425. **Mobile Medical Service Technical Requirements**.

f. Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Section 3~~ of these regulations~~;

Blue language is due to Medical Use of Byproduct Material NRC amendment.

RH-8551. **Safety Instruction**.

In addition to the requirements of RH-2803. ~~of these regulations~~:

a. A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with RH-8420. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;

2. Visitor control to include the following:

A. Routine visitation to hospitalized individuals in accordance with Section 3 ~~of these regulations~~;

RH-8650. **Radiation Surveys**.

a. In addition to the survey requirements in RH-1300.b. ~~of these regulations~~, a person licensed pursuant to Section 9 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

RH-8670. **Other Medical Uses of Radioactive Material or Radiation from Radioactive Material**.

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Section 9 if:

b. The applicant or licensee has received written approval from the Nuclear Regulatory Commission, or an Agreement State in a license and uses the material in accordance with the ~~regulations~~ rules and specific conditions the Nuclear Regulatory Commission or Agreement State considers necessary for the medical use of the material.

RH-8900. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or

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any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-10000. **Purpose and Scope**.

a. This Section establishes requirements, for which the licensee or registrant is responsible, for use of therapeutic radiation machines. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of these ~~Regulations~~ Rules.

RH-10003. **Communications**.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-10004. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-10005. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-10100. **Definitions**.

Therapeutic radiation machine - X-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these

~~Regulations~~ Rules, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

RH-10200. **General Administrative Requirements for Facilities Using Therapeutic Radiation Machines**.

b. A therapeutic radiation machine that does not meet the provisions of these ~~Regulations~~ Rules shall not be used for irradiation of patients.

d. **Training for Qualified Medical Physicists**.

2. An individual identified as a qualified expert on an Arkansas medical particle accelerator license on or before November 30, 2014 shall be considered as meeting the requirements for a Qualified Medical Physicist for the purposes of these ~~Regulations~~ Rules.

e. **Qualifications of operators**.

1. Individuals who operate therapeutic radiation machines for human use shall meet the appropriate Radiologic Technology Licensure requirements issued in accordance with the Rules ~~and Regulations~~ Pertaining to Radiologic Technology Licensure promulgated under the authority of Act 1071 of 1999, as amended – codified at Arkansas Code Annotated §§ 17-106-101 –17-106-111 and 17-106-201 – 17-106-204. The original licensure document or a notarized copy of the document shall be maintained at the location(s) where the individual is working.

i. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the licensee's or registrant's quality management program. In addition to the requirements of Section 11, these individuals are also subject to the requirements of RH-1200., RH-1302., and RH-1500.d. ~~of these Regulations.~~

m. **Record retention periods**.

1. Each licensee or registrant shall retain each record that is required by this Section or by license condition for the period specified by the appropriate ~~regulation~~ rule or license condition. If a retention period is not otherwise specified by ~~regulation~~ rule or license condition, the record must be retained until the Department

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terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.

2. If there is a conflict between the Department's ~~regulations~~ rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section for such records shall apply unless the Department, pursuant to RH-10005., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section.

RH-10300. **General Technical Requirements for Facilities Using Therapeutic Radiation Machines**.

a. **Protection surveys**.

1. The licensee or registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with RH-10304. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist and shall verify, via the use of nationally recognized shielding evaluation survey procedures, that:

A. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in RH-1200.a. ~~of these Regulations~~; and

B. Radiation levels in unrestricted areas do not exceed the limits specified in RH-1208.a. and RH-1208.b. ~~of these Regulations.~~

4. A. The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist, is in violation of applicable ~~regulations~~ rules. Any deficiencies detected during the survey shall be corrected prior to using the therapeutic radiation machine.

d. **Reports of external beam radiation therapy surveys and measurements**.

The licensee or registrant for any therapeutic radiation machine subject to RH-10301. or RH-10302. shall furnish a copy of the records required in RH-10300.a.. and RH-10300.b. to the Department within thirty (30) days following completion of the action that initiated the record requirement. Annual radiation protection surveys shall not be submitted unless it is discovered that radiation levels in unrestricted and/or restricted areas exceed the dose limits specified in Section 3~~ of these Regulations~~.

RH-10301. **Therapeutic Radiation Machines of Less Than 500 kV**.[1/]

r. **Operating procedures**.

E. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual in the treatment room, other than the patient, shall be protected by a barrier sufficient to meet the dose limit requirements specified in Section 3~~ of these Regulations~~.

RH-10302. **Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)**.

v. **Quality assurance for Intensity-Modulated Radiation Therapy**.

2. Be performed in accordance with:

A. Department ~~regulations~~ rules;

RH-10307. **Electronic Brachytherapy**.

h. **Operating procedures**.

2. Operating procedures shall include, but are not limited to, the following:

D. During operation, the Qualified Medical Physicist shall ensure that all persons in the treatment room, and all persons entering the treatment room, are prevented from exceeding the dose limits specified in Section 3~~ of these Regulations;~~

i. **Safety precautions for electronic brachytherapy devices**.

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4. A Qualified Medical Physicist shall designate shield locations or safe distances sufficient to meet the dose limit requirements of Section 3 ~~of these Regulations~~ for any individual, other than the patient, in the treatment room; and

RH-10500. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

APPENDIX A TO SECTION 11

II. **Therapeutic Radiation Machines up to 150 Kv (photons only)**

C. … If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with RH-1200. ~~of these Regulations~~;

RH-11003. **Scope**.

a. Parts B and C of this Section apply to any person who, under these ~~Regulations~~ Rules, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

b. Part D of this Section applies to any person who:

1. Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material, under these ~~Regulations~~ Rules; or

RH-11007. **Communications**.

Except where otherwise specified, all communications concerning these

~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-11009. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-11011. **Specific Exemptions**.

a. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-11031. **Protection of Information**.

d. The licensee shall make background investigation records obtained under this Part available for examination by an authorized representative of the Department to determine compliance with the ~~regulations~~ rules and laws.

RH-11200. **Form of Records**.

Each record required by this Section must be legible throughout the retention period specified by each Department ~~regulation~~ rule. …

RH-11202. **Record Retention**.

Licensees shall maintain the records that are required by the ~~regulations~~ rules in this Section for the period specified by the appropriate ~~regulation~~ rule. If a retention period is not otherwise specified, these records must be retained until the Department terminates the facility's license. All records related to this Section may be destroyed upon Department termination of the facility license.

RH-11300. **Inspections**.

b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these ~~Regulations~~ Rules.

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RH-11301. **Violations**.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.