QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Arkansas Department of Health

DIVISION Center for Health Protection

DIVISION DIRECTOR Donnie Smith

CONTACT PERSON Robert Brech

ADDRESS 4815 West Markham Street
Slot #31
Little Rock, Arkansas 72205

PHONE NO. 661-2297 **FAX NO.** 661-2357 **E-MAIL** robert.brech@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL robert.brech@arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
Room 315, State Capitol
Little Rock, AR 72201

****

1. What is the short title of this rule? Proposed Revisions to the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation

2. What is the subject of the proposed rule? Revisions and/or additions to existing regulations for the use of radioactive material in the State of Arkansas in order to maintain Agreement State compatibility with the U.S. Nuclear Regulatory Commission

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☒ No ☐

If yes, please provide the federal rule, regulation, and/or statute citation.
The majority of these Revisions are proposed in order to maintain compatibility with the U.S. Nuclear Regulatory Commission (NRC). Regulatory compatibility with the NRC is one of the basic requirements for the State of Arkansas to continue to serve the citizens of Arkansas as an "Agreement State."

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes ☐ No ☒

If yes, what is the effective date of the emergency rule? -N/A-

When does the emergency rule expire? -N/A-

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes ☐ No ☒

5. Is this a new rule? Yes ☐ No ☒

If yes, please provide a brief summary explaining the regulation.

-N/A-

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

-N/A-

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule?
If codified, please give Arkansas Code citation.
The authority for this set of regulations was given through Act 8 of the Second Extraordinary Session of 1961, as amended. ALSO, see Arkansas Code Annotated 20-21-203 through 20-21-217.

7. What is the purpose of this proposed rule? Why is it necessary?
These revisions pertaining to the use of radioactive material have been proposed in order to maintain compatibility with the U.S. Nuclear Regulatory Commission (NRC). Regulatory compatibility with the NRC is one of the basic requirements for the State of Arkansas to continue to serve the citizens of Arkansas as an "Agreement State."

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).

www.healthy.arkansas.gov "Proposed Rules & Regs" Link

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: June 12, 2012

Time: 10:00 a.m.

Place: Freeway Medical Tower
5800 West 10th Street
Room #906
Little Rock, Arkansas

10. When does the public comment period expire for permanent promulgation? (Must provide a date.) June 12, 2012

11. What is the proposed effective date of this proposed rule? October 1, 2012

(Must provide a date.)

12. Do you expect this rule to be controversial? Yes ☐ No ☒

If yes, please explain.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Hospital Medical Licensees
Industrial Radiography Licensees

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Health

DIVISION Center for Health Protection

PERSON COMPLETING THIS STATEMENT Robert Brech

TELEPHONE NO. 661-2297 **FAX NO.** 661-2357 **EMAIL:** robert.brech@arkansas.gov

To comply with Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Proposed Revisions to the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No ☒

2. Does this proposed, amended, or repealed rule affect small businesses? Yes ☒ No ☐
   If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

SEE ATTACHMENT

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

The financial impacts described are speculative. The Department has no way to determine the costs of these regulations. However, the Department believes that the proposed regulations will not create an undue financial burden and will be "Revenue Neutral."

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	-N/A-	Total	-N/A-

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 000	$ 000

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

Current Fiscal Year	**Next Fiscal Year**
$ 0	$ 0

SUMMARY OF THE PROPOSED REVISIONS TO THE RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION

The Radiation Control Section has initiated the process for the revision of the Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation. The Section regulates the possession and use of both x-ray equipment and radioactive material in the State of Arkansas. The regulatory oversight of radioactive material is performed as an Agreement State with the U.S. Nuclear Regulatory Commission (NRC). The State of Arkansas is expected to have regulations that are compatible with NRC regulations. In order to achieve this compatibility, several additions and/or changes are being proposed.

Our proposed revisions will address the following areas:

- Changes in the generally licensed industrial devices regulations to specifically address import and export requirements;
- Adoption of requirements for the transportation of radioactive material that are compatible with the International Atomic Energy Agency's Transportation Safety Standards;
- Modifications to the medical use of radioactive material requirements that address training requirements where additional medical specialty boards are recognized, authorized user clarifications, and other minor medical use regulations;
- Adoption of requirements for the Department's radioactive material users who possess Increased Control quantities of radioactive material to participate in the National Source Tracking System as part of the enhanced national homeland security;
- Modifications to occupational dose record requirements to include the relaxation of annual dose notification requirements;
- Changes to licensing and reporting requirements regarding exemptions from licensing, general licenses, and distribution of select items/devices containing radioactive material; and
- Expansion of the definition of byproduct material to include radium and to address source security matters dealing with devices containing radium.

If you have any questions, please contact Bernie Bevill, Radiation Control Section Chief. Our telephone number is (501) 661- 2301.

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SECTION 1.
REGISTRATION OF SOURCES OF RADIATION

PART A.
GENERAL

RH-4. Communications. All communications concerning these Regulations shall be addressed to the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section, ~~P.O. Box 1437 Mail Slot H-30~~, *4815 West Markham Street, Slot #30*, Little Rock, Arkansas ~~72203-1437~~ *72205-3867*.

PART B.
DEFINITIONS

RH-10. ~~General~~ Definitions. ~~As used in these Regulations. Additional definitions used only in a certain Part will be found in that Part.~~ ...

~~n. These Regulations. The Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation, Section 1.~~

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SECTION 2.
LICENSING OF RADIOACTIVE MATERIALS

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A.
GENERAL

RH-102. License Requirement.

~~a. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to these Regulations or as otherwise provided in these Regulations. However, nothing in these Regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.1/~~

a. Except for persons exempt as provided in Part C to 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.1/

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

RH-104. Communications.

All communications concerning these Regulations shall be addressed to the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section *Chief,* ~~P.O. Box 1437 Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ 72205-3867.

PART B.
DEFINITIONS

RH-200. ~~General~~ Definitions ~~as used in these Regulations: Additional definitions used in a certain part will be found in that part.~~ ...

i. Byproduct material -

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

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

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

   B. *Any material that:*

      i. *Has been made radioactive by use of a particle accelerator; and*

      ii. *Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and*

4. *Any discrete source of naturally occurring radioactive material, other than source material, that:*

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

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

m. *Consortium - An association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use*

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in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

o. *Cyclotron – A particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.*

r. *Discrete source – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.*

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

~~bd. These Regulations. The Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation, Section 2.~~

bj. Waste - Those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level *radioactive* waste ~~has the same meaning as in the Federal Low-Level Waste Policy Act that is~~ *means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in* ~~Section 11.e.(2) of the Atomic Energy Act (Uranium or Thorium tailings and waste)~~ *paragraphs 2., 3., and 4. of the definition of byproduct material set forth in RH-200.i.*

PART C.
EXEMPTIONS

RH-301. ~~Other Radioactive Materials~~ Radioactive Material Other Than Source Material.

a. Exempt concentrations.

1. Except as provided in ~~RH-301.a.2. below~~ *RH-301.a.3. and RH-301.a.4.*, any person is exempt from this ~~Part~~ Section 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 ~~Part I, RH-902. Schedule C.~~*Schedule C to Section 3, RH-902.*

2. This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

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 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 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.

4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under ~~*RH 301.a.1.*~~ *this section* or equivalent regulations of ~~the U.S. Nuclear Regulatory Commission or~~ any Agreement State, except in accordance with a license issued pursuant to ~~RH 405.g. or the general license provided in RH 402. of this Section~~ *10 CFR 32.11.*

RH-301. (Cont'd)

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, any person is exempt from these Regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:[3/]

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

i. 25 millicuries of Tritium per timepiece;

ii. 5 millicuries of Tritium per hand;

iii. 15 millicuries of Tritium per dial (bezels when used shall be considered as part of the dial);

iv. 100 microcuries of Promethium-147 per watch or 200 microcuries of Promethium-147 per other timepiece;

v. 20 microcuries of Promethium-147 per watch hand or 40 microcuries of Promethium-147 per other timepiece hand;

vi. 60 microcuries of Promethium-147 per watch dial or 120 microcuries of Promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

vii. The levels of radiation from hands and dials containing Promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a). For wrist watches, 0.1 millirad per hour at ten (10) centimeters from any surface;

(b). For ~~any other timepiece~~ *pocket watches*, 0.1 millirad per hour at one (1) centimeter from any surface;

RH-301.b.1.A.vii. (Cont'd)

(c). For any other timepiece, 0.2 millirad per hour at ten (10) centimeters from any surface.

viii. *1 microcurie (0.037 MBq) of Radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.*

~~2.~~ ~~Lock illuminators containing not more than 15 millicuries of Tritium or not more than two (2) millicuries of Promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing Promethium-147 will not exceed one (1) millirad per hour at one (1) centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~

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B. Reserved.

C. Balances of precision containing not more than one (1) millicurie of Tritium per balance or not more than 0.5 millicuries of Tritium per balance part *manufactured before December 17, 2007.*

~~4. Automobile shift quadrants containing not more than 25 millicuries of Tritium.~~

D. Reserved.

E. Marine compasses containing not more than 750 millicuries of Tritium gas and other marine navigational instruments containing not more than 250 millicuries of Tritium gas *manufactured before December 17, 2007.*

~~6. Thermostat dials and pointers containing not more than 25 millicuries of Tritium per thermostat.~~

F. Reserved.

G. Ionization chamber smoke detectors containing not more than one (1) microcurie (μCi) of Americium-241 per detector in the form of a foil and designed to protect life and property from fires.

~~8. Spark gap irradiators containing not more than one (1) microcurie of Cobalt 60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three (3) gallons per hour (11.4 liters per hour).~~

J. Reserved.

2. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in RH-301.b.1. above, or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from RH-301.b.1.

c. ~~Resins containing Scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these Regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing Scandium-46 which are designed for sand~~

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~~consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or shall have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Section 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing Scandium-46.~~
Deleted.

RH-301. (Cont'd)

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 requirement for a license and* these Regulations to the extent such person receives, possesses, uses, transfers, owns or acquires ~~byproduct~~ *radioactive* material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, ~~imported, or transferred~~ *processed, produced, or initially transferred* in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission[5/] pursuant to ~~Section 32.26 of 10 CFR Part 32~~ *10 CFR 32.26*; or ~~any~~ *an* Agreement State *pursuant to a 10 CFR 32.26 equivalent*, which license authorizes the *initial* transfer of the detectors to persons who are exempt from regulatory requirements. *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.* ...

3. Gas and aerosol detectors containing Naturally Occurring Radioactive Material (NORM) previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under RH-301.d.1., provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they *meet the requirements of RH-405.g.*

RH-301. (Cont'd)

e. Self-luminous products containing ~~Tritium, Krypton-85 or Promethium-~~

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~~147~~ *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 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 ~~Section 32.22 of 10 CFR 32~~ 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 this Paragraph e 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 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.

3. *Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to RH-301.e.1., should apply for a license pursuant to 10 CFR 32.22, which license states that the product may be transferred by the licensee to persons exempt from the regulations pursuant to RH-301.e.1. or equivalent regulations of an Agreement State.*

RH-301. (Cont'd)

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 ~~set forth in Section 5(c) of the Atomic Energy Act of 1954, as amended~~ and from the regulations 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

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(allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans. ...

RH-305. Exempt Quantities.

a. Except as provided in ~~Subparagraphs c and d of this Paragraph~~ *paragraphs c. through e. of this section,* any person is exempt from these Regulations 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.*

b. Any person who possesses radioactive material received or acquired under the general license formerly provided in RH-402.a. *or similar general license of the Nuclear Regulatory Commission or an Agreement State,* is exempt from the requirements for a license set forth in this ~~Part~~ *Section* to the extent that such person possesses, uses, transfers or owns such radioactive material.

c. This RH-305. does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

d. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B to Section 2. knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this section or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.18 of 10 CFR Part 32, which license states that the radioactive material may be transferred by the licensee to persons exempt under this RH-305 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.[5/]

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 in this Section.

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PART D.
LICENSES

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

~~a. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in a device or equipment which is listed in Part I, RH-900., Schedule A and has been manufactured pursuant to a specific license or equivalent licensing document, issued to the supplier by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State and authorizing distribution under the general license of this Paragraph or its equivalent.~~

~~The general license provided in this RH-402.a is subject to the provision of RH-56., RH-60., RH-301.a.2., RH-409., RH-416., RH-500., RH-501., RH-600., RH-601., RH-602., RH-4012., Section 36/ and Section 4 of these Regulations.~~ (moved to RH-402.b)

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.b.~~*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.b.~~*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.

b. *1.* The general license in ~~RH-402.b.1.~~*RH-402.a.* applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

A. A specific license issued under RH-405.e.; or

B. An equivalent specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State; or

C. An equivalent specific license issued by a State with provisions comparable to RH-405.e.

RH-402.b. (Cont'd)

2. The devices must have been received from one of the specific licensees described above in ~~RH-402.b.2.A.~~ *RH-402.b.1.* or through a transfer made under ~~RH-402.b.3.H.~~ *RH-402.c.9.*

c. Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in ~~RH-402.b.1.~~ *RH-402.a.*:

1. Shall assure that all labels affixed to the device at the time of receipt and bearing the statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. Shall assure that the device is tested for leakage of radioactive material and proper operations of the on-off mechanism and indicator, if any, at no longer than six (6) month intervals or at such other intervals as are specified in the label; however:

A. Devices containing only Krypton need not be tested for leakage of radioactive material, and

B. Devices containing only Tritium or not more than 100 microcuries of other beta and/or gamma emitting material or ten (10) microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

3. Shall assure that the tests required by ~~RH-402.b.3.B.~~ *RH-402.c.2.* and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment, are performed:

A. In accordance with the instructions provided by the labels; or

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B. By a person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;

RH-402.c. (Cont'd)

4. Shall maintain records showing compliance with the requirements of ~~RH-402.b.3.B. and 3.C.~~ *RH-402.c.2. and c.3.* The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

A. Each record of a test for leakage or radioactive material required by ~~RH-402.b.3.B.~~ *RH-402.c.2.* must be retained for three (3) years after the next required leak test is performed or until the sealed source is transferred or disposed of.

B. Each record of a test of the on-off mechanism and indicator required by ~~RH-402.b.3.B.~~ *RH-402.c.2.* must be retained for three (3) years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

C. Each record that is required by ~~RH-402.b.3.C.~~ *RH-402.c.3.* must be retained for three (3) years from the date of the recorded event or until the device is transferred or disposed of.

5. Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under RH-405.e. or the U.S. Nuclear Regulatory Commission or by an Agreement State.

The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable

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radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished within thirty (30) days to:

RH-402.c.5. (Cont'd)

Arkansas Department of Health ~~& Human Services~~
Radiation Control *Section*
ATTN: General License Registration Program
~~P.O. Box 1437, Mail Slot H-30~~
4815 West Markham Street, Mail Slot # 30
Little Rock, Arkansas ~~72203-1437~~ *72205-3867*

Under these circumstances, the criteria set out in RH-1216., "Radiological Criteria for Unrestricted Use," may be applicable, as determined by the Department on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

7. *Shall not export the device containing radioactive material except in accordance with U.S. Nuclear Regulatory Commission Regulations outlined in Part 110, "Export and Import of Nuclear Equipment and Material";*

8. *A.* Shall transfer or dispose of the device containing radioactive material only by *export as provided by U.S. Nuclear Regulatory Commission Regulations outlined in Part 110, "Export and Import of Nuclear Equipment and Material,"* by transfer to another general licensee as authorized by ~~RH-402.b.3.H.~~ RH-402.c.9., or to a person authorized to receive the device by a specific license issued under *Section 2, or* Section 2 that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under ~~RH-402.b.3.G.iii.~~ *RH-402.c.8.C.*

B. Shall, *within thirty (30) days after the transfer of the device to a specific licensee or export*, furnish a report to:

Arkansas Department of Health ~~& Human Services~~
Radiation Control *Section*
ATTN: General License Registration Program
~~P.O Box 1437, Mail Slot H-30~~
4815 West Markham Street, Slot 30
Little Rock, Arkansas ~~72203-1437~~ *72205-3867*

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~~within 30 days after the transfer of a device to a specific licensee.~~ The report must contain:

i. The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

ii. The name, address, and license number of the person receiving the device (license number not applicable if exported); and

iii. The date of the transfer.

C. Shall obtain written Department approval before transferring the device to any other specific licensee not specifically identified in ~~RH-402.b.3.G.i.~~ *RH-402.c.8.A.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:*

i. Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

ii. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RH-402.c.1.) so that the device is labeled in compliance with RH-1309.; however, the manufacturer, model number, and serial number must be retained;

iii. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

iv. Reports the transfer under RH-402.c.8.B.

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

A. The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of RH-402., RH-600., RH-1501., and RH-1502., and any safety documents identified in the label of the device.

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Within thirty (30) days of the transfer, the transferor shall report to:

Arkansas Department of Health ~~& Human Services~~
Radiation Control *Section*
ATTN: General License Registration Program
~~P.O. Box 1437, Mail Slot H-30~~
4815 West Markham Street, Mail Slot # 30
Little Rock, Arkansas ~~72203-1437~~ *72205-3867*

i. The manufacturer's (or initial transferor's) name;

ii. The model number and the serial number of the device transferred;

iii. The transferee's name and mailing address for the location of use; and

iv. The name, title, and phone number of the responsible individual identified by the transferee in accordance with ~~RH-402.b.3.K.~~ *RH-402.c.12.* to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

B. The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

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.*

11. Shall respond to written requests from the Department to provide information relating to the general license within thirty (30) calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the General License Registration Program a written justification for the request.

RH-402.c. (Cont'd)

12. Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for

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taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

13. *A.* Shall register, in accordance with ~~RH-402.b.3.I.ii. and iii.~~ *RH-402.c.13.B. and C.* devices containing at least ten (10) mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, one (1) mCi (37 MBq) of cobalt-60, *0.1 mCi (3.7 MBq) of radium-226*, or one (1) mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under ~~RH-402.b.3.m.iii.~~ *RH-402.c.13.C.*, represents a separate general licensee and requires a separate registration and fee.

B. If in possession of a device meeting the criteria of ~~RH-402.b.3.I.i.~~ *RH-402.c.13.A.*, shall register these devices annually with the Department and shall pay the appropriated fee. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within thirty (30) days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of ~~RH-402.b.3.I.i.~~ *RH-402.c.13.A.* is subject to the bankruptcy notification requirement in RH-409.g.

C. In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department:

i. Name and mailing address of the general licensee.

ii. Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity as indicated on label.

RH-402.c.13.C. (Cont'd)

iii. Name, title, and telephone number of the responsible person designated as a representative of

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the general licensee under ~~RH-402.b.3.K.~~ *RH-402.c.12.*

iv. Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

v. Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

vi. Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

D. Persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State with respect to devices meeting the criteria in RH-402.c.13.A. are subject to registration requirements if the devices are used in areas subject to Arkansas Department of Health jurisdiction. The Department will request registration information from such licensees.

14. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the:

Arkansas Department of Health ~~& Human Services~~
Radiation Control *Section*
Attention: General License Registration Program
~~P.O. Box 1437 Mail Slot H 30,~~
4815 West Markham Street, Mail Slot # 30
Little Rock, Arkansas ~~72203-1437~~ *72205-3867*

within thirty (30) days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

RH-402.c. (Cont'd)

15. May not hold devices that are not in use for longer than two (2) years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by ~~RH-402.b.3.B.~~ *RH-402.c.2.* need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the

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required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two (2) year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

d. The general license in ~~RH-402.b.1.~~ *RH-402.a.* does not authorize the manufacture *or import* of devices containing radioactive material.

e. The general license provided in ~~this Paragraph~~ *RH-402.a.* is subject to the provisions of ~~RH-56.~~ RH-60., RH-409., RH-416., RH-500., RH-501., RH-600., RH-601., RH-602., *RH-751.*, RH-4012., *Section 3*[6] and Section 4.

...*g.* 1. Calibration and reference sources.

A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with provisions of subparagraphs 4. and 5. of this paragraph g., Americium-241 in the form of calibration or reference sources:

A. Any person who holds a specific license issued by the Department which authorizes him to receive, possess, use and transfer radioactive material; and

B. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use and transfer special nuclear material.

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

5. The general licenses in subparagraphs 1. and 2. of this paragraph *g.* are subject to the provisions of ~~RH-56.~~ RH-60., RH-409., RH-416., RH-500., RH-501., RH-600., RH-601., RH-602., *RH-751.*, RH-4012., Section 3 and Section 4. In addition, persons who own, receive, acquire, possess, use and 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 of Americium-241, five (5) microcuries of Plutonium, or five (5) microcuries of Radium-226 in such sources;...

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i. Ice detection devices.

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 of Strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32....

4. The general license in ~~RH-402.f.~~ RH-402.i. is subject to the provisions of ~~RH-56.~~ RH-60., RH-409., RH-416., RH-500., RH-501., RH-600., RH-601., RH-602., *RH-751.*, RH-4012., and Section 4.

RH-402. (Cont'd)

l. *Certain devices and equipment.*

A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the NRC or an Agreement State for use pursuant to 10 CFR 32.14. This general license is subject to the provisions of RH-60., RH-301 a.2, RH-409., RH-416., RH-500., RH-501., RH-600., RH-601., RH-602., RH-700., RH-751., RH-4012., Section 3[6], and Section 4 of these Regulations, as applicable.

1. *Static elimination device.*

Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

2. *Ion generating tube.*

Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device

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or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

m. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this Section, a general licensee under RH-402. is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

RH-403. Specific Licenses.

a. Application for specific licenses shall be filed on forms supplied by the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section, ~~P.O. Box 1437 Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot #30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.* The application shall set forth all applicable information called for by the form. An application for a license may request a license for one or more activities.

RH-403. (Cont'd)

h. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under ~~RH-403.i.~~ *10 CFR 32.210* or with an Agreement State *or for a source or a device containing Radium-226 or accelerator-produced radioactive material with an Agreement State under provisions comparable to 10 CFR 32.210*; or

2. Contains the information identified in ~~RH-403.i.~~10 CFR 32.210(c).

3. *For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:*

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

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

i. ~~Registration of product information.~~

1. ~~Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the U.S. Nuclear Regulatory Commission (NRC) for evaluation of radiation safety information about its product and for its registration.~~

2. ~~The request for review must be made in duplicate and sent to the U.S. Nuclear Regulatory Commission; Division of Industrial and Medical Nuclear Safety; Medical, Academic, and Commercial Use Safety Branch; Washington, D.C. 20555.~~

3. ~~The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.~~

4. ~~The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.~~

5. ~~After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.~~

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~~6. The person submitting the request for evaluation and registration of safety information about the product in accordance with:~~

~~i. The statements and representations, including quality control program, contained in the request; and~~

~~ii. The provisions of the registration certificate.~~

Deleted.

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:

A. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Section or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

B. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in RH-405.l.1.B.

C. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in RH-405.l.2.B.

D. Information identified in RH-405.l.1.C. on the PET drugs to be noncommercially transferred to members of its consortium.

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

a. – d. Deleted. (in 2006 reg's)

e. ~~Manufacture and Distribution of Devices to Persons Generally Under Part D, RH-402.b.~~ *Licensing of the manufacture or initial transfer of devices to persons generally licensed under RH-402.a.*

In addition to *satisfying* the requirements set forth in Part D, RH-404., an application for a specific license to ~~distribute~~ *manufacture or initially*

transfer ~~certain~~ devices ~~of the types enumerated in Part D, RH-402.b.~~ *containing radioactive material, excluding special nuclear material,* to persons generally licensed under ~~Part D, RH-402.b.~~ *RH-402.a.* or *equivalent regulations of the NRC or an Agreement State* will be ~~issued only~~ *approved* if:

1. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that:

   A. The device can be safely operated by persons not having training in radiological protection.

RH-405. (Cont'd)

4. A. If a device containing radioactive material is to be transferred for use under the general license contained in RH-402.a., each person that is licensed under RH-405.e. shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

   i. A copy of the general license contained in RH-402.a.; if paragraphs RH-402.c.2. through c.4. or RH-402.c.13. do not apply to the particular device, those paragraphs may be omitted.

   ii. A copy of RH-402., RH-600., RH-1501., and RH-1502.,

   iii. A list of the services that can only be performed by a specific licensee;

   iv. Information on acceptable disposal options including estimated costs of disposal; and

   v. An indication that the Department's policy is to seek high civil penalties for improper disposal.

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B. If radioactive material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under RH-405.e. shall provide the information specified in this sub-subparagraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the NRC or Agreement State's regulations equivalent to ~~RH-402.b.~~ *RH-402.a.*, RH-402., RH-600., RH-1501., and RH-1502. or a copy of ~~RH-402.b.~~ *RH-402.a.*, RH-402., RH-600., RH-1501., and RH-1502. If a copy of ~~the Department a~~ *non-governing agency's regulations* is provided to a prospective general licensee in lieu of the ~~Agreement State's~~ *governing agency's* regulations, it shall be accompanied by a note explaining that use of the device is regulated by the ~~Agreement State~~ *governing agency, the agency who has jurisdiction where the device will be in use.* If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

ii. A list of the services that can only be performed by a specific licensee;

iii. Information on acceptable disposal options including estimated costs of disposal; and

iv. The name or title, address, and phone number of the contact at the Department, NRC, or Agreement State from which additional information may be obtained.

f. ~~Use of Sealed Sources in Non-medical Radiography~~ *Licensing of the use of sealed sources in industrial radiography.*

A specific license for use of sealed sources in *industrial* radiography will be issued only if:

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1. The applicant satisfies the general requirements specified in Part D, RH-404.; and…

g. Licensing of the introduction of radioactive material into products in exempt concentrations.

~~In addition to the requirements set forth in Section RH-404. above, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under RH-301.a.1. will be issued only if:~~

~~1. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material and estimated concentration of the radioactive material in the product or material at the time of transfer; and~~

~~2. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in RH-902., Schedule C, that reconcentration of the radioactive material in concentrations exceeding those in RH-902., Schedule C, is not likely, that use of lower concentrations is not feasible and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by or application to, a human being.~~

~~Each person licensed under this Paragraph g shall file an annual report with the Department which shall identify the type and quantity of each product or material into which radioactivematerial has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this Paragraph during the reporting period, the report shall so indicate.~~

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~~The report shall cover the year ending June 30 and shall be filed within thirty (30) days thereafter.~~

No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under RH-301.a., or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to 10 CFR 32.11.

RH-405. (Cont'd)

i. ~~Licensing of the Manufacture of~~ *Special requirements for license to manufacture or initially transfer* calibration sources containing americium-241, plutonium, or radium-226 for distribution to persons generally licensed under ~~RH-402.d.~~ *RH-402.g*.

1. An application for a specific license to manufacture *or initially transfer* calibration and reference sources containing americium-241, plutonium, or radium-226 *for distribution* to persons generally licensed under ~~RH-402.d.~~ *RH-402.g*. will be approved if:

A. The applicant satisfies the general requirements of ~~RH-401.~~ *RH-404*., and

B. The applicant ~~satisfies the requirements of Sections 32.57, 32.58, 32.59 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.~~ *submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:*

i. *Chemical and physical form and maximum quantity of americium 241, plutonium, or radium-226 in the source;*

ii. *Details of construction and design;*

iii. *Details of the method of incorporation and binding of the americium-241, plutonium, or radium-226 in the source;*

iv. *Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, to demonstrate that the americium-241, plutonium, or radium-226 contained in each source will not be released or be*

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removed from the source under normal conditions of use;

v. *Details of quality control procedures to be followed in manufacture of the source;*

vi. *Description of labeling to be affixed to the source or the storage container for the source;*

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

C. *Each source will contain no more than 5 microcuries (185 kBq) of americium-241, plutonium, or radium-226.*

D. *The Department determines, with respect to any type of source containing more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, that:*

i. *The method of incorporation and binding of the americium-241, plutonium, or radium-226 in the source is such that the americium-241, plutonium, or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and*

ii. *The source has been subjected to and has satisfactorily passed the prototype tests prescribed by RH-405.i.2.*

2. *Prototype tests for calibration or reference sources containing americium-241, plutonium, or radium-226.*

An applicant for a license pursuant to RH-405.i. shall, for any type of source which is designed to contain more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, as follows:

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

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

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

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

E. *Dry wipe test. On completion of the preceding test in this section, the dry wipe test described in RH-405.i.2.B. shall be repeated.*

F. *Observations. Removal of more than 0.005 microcuries (185 Bq) of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Department shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.*

RH-405.i. (Cont'd)

3. *Labeling of devices.*

Each person licensed under RH-405.i.. shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[10/]

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The receipt, possession, use and transfer of this source, Model __, Serial No. __, are subject to a general license and the regulations of the NRC or an Agreement State. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS AMERICIUM-241
[PLUTONIUM OR RADIUM-226].
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor

4. *Leak testing of each source.*

Each person licensed under RH-405.i. shall perform a dry wipe test upon each source containing more than 0.1 microcuries (3.7 kBq) of americium-241, plutonium, or radium-226 prior to transferring the source to a general licensee under RH-402.g. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226. If any such test discloses more than 0.005 microcuries (185 Bq) of radioactive material, the source shall be deemed to be leaking or losing americium-241, plutonium, or radium-226 and shall not be transferred to a general licensee under RH-402.g, or equivalent regulations of an Agreement State.

RH-405 (Cont'd)

j. Licensing of the manufacture and distribution of radioactive material for certain *in vitro* clinical or laboratory testing under general license.

An application for a specific license to manufacture or distribute radioactive material for use under the general license of RH-402.k. will be approved if:

1. The applicant satisfies the general requirements specified RH-404.; and...

3. Each prepackaged unit bears a durable, clearly visible label:

A. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries *(370 kBq)* of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries *(1.85 MBq)* of hydrogen-3 (tritium); 20 microcuries *(740 kBq)* of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcuries *(1.85 KBq)* of iodine-129 and 0.005 microcuries *(185 Bq)* of americium-241 each; and

B. Displaying the radiation caution symbol described in RH-1303.a.1. and 2. and the words, "**CAUTION, RADIOACTIVE MATERIAL**" and "**Not for Internal or External Use in Humans or Animals.**"

RH-405. (Cont'd)

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

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution ~~radiopharmaceuticals~~ *radioactive drugs* containing radioactive material for use by persons ~~licensed pursuant to RH-405.e. for the uses listed in RH-903. Schedule D Group I, Group II, Group IV or Group V of this Part~~ *authorized pursuant to Section 9, "Use of Radionuclides in the Healing Arts,"* will be approved if:

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

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

i. Registered ~~or licensed~~ with the U.S. Food and Drug Administration (FDA) as ~~a drug manufacturer~~ *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);*

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

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

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

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

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

D. The applicant satisfies 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 ~~radiopharmaceutical~~ *radioactive drug* to be transferred for commercial distribution. The label must include the radiation symbol and the words

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

the name of the ~~radiopharmaceutical~~ *radioactive drug* or its abbreviation; and the quantity of radioactivity at a specified date and time. For ~~radiopharmaceutical~~ *radioactive drugs* with a 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 ~~radiopharmaceutical~~ *radioactive drug* to be transferred for commercial distribution. The label must include the radiation symbol and the words

"CAUTION, RADIOACTIVE MATERIAL"
or

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

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

A. May prepare ~~radiopharmaceuticals~~ *radioactive drugs* for medical use, as defined in ~~RH-200.~~ *RH-8100.*, provided that the ~~radiopharmaceutical~~ *radioactive drug* is prepared by either an authorized nuclear pharmacist, as specified in RH-405.l.2.B. and RH-405.l.2.D. of this ~~Section~~ *paragraph l.*, or an individual under the supervision of an authorized nuclear pharmacist as specified in ~~RH-404.b.8.~~ *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 RH-405.l.2.D. of this paragraph l.

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

D. May designate a pharmacist (as defined in ~~RH-200.~~ *RH-8100.*) as an authorized nuclear pharmacist if ~~the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Department under this Part~~:

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

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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.*

~~D~~*E.* Shall provide to the Department ~~a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Department, the U.S. Nuclear Regulatory Commission, or other Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the State pharmacy licensure or registration, no later than thirty (30) days after the date that the licensee allows, pursuant to 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.~~:

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

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

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

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

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

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vi. *A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under RH-405.1.2.B.i. and RH-405.1.2.B.iii., the individual to work as an authorized nuclear pharmacist.*

RH-405.1. (Cont'd)

3. A licensee shall possess and use instrumentation to measure the radioactivity of ~~radiopharmaceuticals~~ *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. 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.

m. Deleted. ~~(in 2006 reg.)~~

n. Manufacture and distribution of sources or devices containing radioactive material for medical use.

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed ~~pursuant to RH-402.~~ *under Section 9, "Use of Radionuclides in the Healing Arts,"* for use as a calibration, *transmission,* or reference source or for the uses listed in RH-8600., RH-8620., ~~and~~ RH-8630., *and RH-8670.* will be approved if:

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

RH-405. (Cont'd)

o. Radioactive drug: *manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea for "in vivo" diagnostic use for humans to persons exempt from licensing: Requirements for a license.*

1. An application for a specific license to manufacture, prepare, produce, package, repackage, or transfer for commercial distribution capsules containing one (1) microcurie (37 kBq) carbon-14 urea...

p. Radioactive drug: *manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea for "in vivo" diagnostic use for humans to persons exempt from licensing: Conditions of license.*

Each license issued under RH-405.o. is subject to the following conditions:...

q. 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-405.q.2. through 4., radium-226 contained in the following products manufactured prior to November 30, 2007.

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

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

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

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

E. Small radium sources containing no more than one (1) microcurie (0.037 MBq) of radium-226. For the purposes

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of this sub-subparagraph, ''small radium sources'' means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Nuclear Regulatory Commission.

2. *Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in RH-405.q.1. are exempt from the provisions of Section 3 (including RH-1502.e. through g.), and RH-600., to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Section.*

RH-405.q. (Cont'd)

3. *Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in RH-405.q.1. shall:*

A. *Notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished within 30 days to:*

Arkansas Department of Health
Radiation Control Section
Attention: Radioactive Materials Program
4815 West Markham Street, Slot #30
Little Rock, Arkansas 72205

B. *Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to RH-1408. or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the Nuclear Regulatory Commission or an Agreement State.*

C. *Not export products containing radium-226 except in accordance with 10 CFR Part 110.*

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D. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under Section 2, or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State, or as otherwise approved by the Nuclear Regulatory Commission or an Agreement State.

RH-405.q.3. (Cont'd)

E. Respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Radiation Control Section Chief or his designee, by an appropriate method listed in 10 CFR 30.6(a), a written justification for the request.

4. The general license in RH-405.q.1. does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

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. 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(~~14~~*15*)) controlling the licensee or listing the license or licensee as property of the estate; or

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

i. Each portable gauge licensee shall use a minimum of two (2) independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee. (moved here from RH-1221.)

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.

RH-409. (Cont'd)

k. 1. Authorization under RH-403.j. to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2. Each licensee authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

A. Satisfy the labeling requirements in RH-405.l.1.D. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

B. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in RH-405.l.3.

C. A licensee that is a pharmacy authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

i. An authorized nuclear pharmacist that meets the requirements in RH-405.l.2.B., or

ii. An individual under the supervision of an authorized nuclear pharmacist as specified in RH-8306.

D. A pharmacy, authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of RH-405.l.2.E.

PART H. RECIPROCITY

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 ~~the provisions of~~ these regulations, any person who ~~possesses~~ *holds* a specific license ~~or equivalent licensing document issued by~~ *from* the ~~U.S. Nuclear Regulatory Commission~~ *NRC* or ~~any~~ *an* Agreement State, ~~other than this 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,* ~~may~~ *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 ~~twelve (12) consecutive months~~ *180 days in any calendar year* ~~without obtaining a specific license from the Department~~ provided that:

A. The licensing document does not limit the activity authorized by such document to specified installations or locations;

B. The out-of-state licensee notifies the Department in writing at least ~~two (2)~~ *three (3)* days prior to engaging in such activity. Such notification shall indicate the exact location, period, and type of proposed possession and use within this State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the ~~two (2)~~

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three (3) day period would impose an undue hardship on the out-of-state licensee, ~~he~~ *the licensee* may, upon application to the Department, obtain permission to proceed sooner;

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

D. ~~Provided further that the Department may require~~ *The out-of-state licensee* ~~to supply~~ *supplies* such other information as the Department may ~~reasonably~~ request; *and*

RH-750.a.1. (Cont'd)

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.a.1. except by transfer to a person:

i. Specifically licensed by the Department or by the NRC to receive such material, or

ii. Exempt from the requirements for a license for such material under RH-301.a.

~~b. To the extent provided in RH-300., RH-301. and RH-402., any person may transfer, receive, acquire, own, possess and use any equipment, device, commodity or other product containing radioactive material which has been manufactured, processed or produced in accordance with a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or any Agreement State.~~

2. Notwithstanding the provisions of ~~Paragraph a of this Section RH-750.~~ RH-750.a.1., any person who holds a specific license ~~or equivalent licensing document~~ issued by the ~~U.S. Nuclear Regulatory Commission~~ *NRC* or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in ~~RH-402.b.1.~~ *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,* ~~and~~ *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;

B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license ~~or equivalent licensing document~~ issued to such person by the ~~U.S. Nuclear Regulatory Commision~~ *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 ~~or equivalent licensing document~~ shall furnish to each general licensee to whom ~~he~~ *the licensee* transfers such device or on whose premises ~~he~~ *the licensee* installs such device a copy of the general license contained in ~~RH-402.b.~~ *RH-402.a. or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.*

RH-750.a. (Cont'd)

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by ~~another agency~~ *the NRC or an Agreement State*, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

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

1. *Subject to these regulations 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*

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such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

A. The licensing document does not limit the activity authorized by such document to specified installations or locations;

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

C. The out-of-state licensee complies with all applicable regulations 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 of the Department;

D. The out-of-state licensee supplies such other information as the Department may request; and

RH-750.b.1. (Cont'd)

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:

i. Specifically licensed by the Department or by another Licensing State to receive such material, or

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

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

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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;

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.

RH-750.b. (Cont'd)

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

c. Recognition of Agreement State Licenses.

1. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site shall be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

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A. In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the NRC, and

B. Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained from the NRC by either:

i. Filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or

ii. By applying for a specific NRC license.

2. Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

PART I.
SCHEDULES

~~RH-900.~~ ~~Schedule A. Generally Licensed Equipment, When Manufactured in Accordance With Specific License.~~

~~The following devices and equipment incorporating radioactive material, when manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State, are placed under a general license pursuant to Section 2, Part D, RH-402.a.~~

~~a. Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device.~~

~~b. Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device or of a total of not more than 50 millicuries of Hydrogen-3 (Tritium) per device.~~

RH-900. Schedule A to Section 2. Deleted. See RH-402.l. and RH-402.m.

RH-901. Schedule B to Section 2. "Exempt Quantities." was revised to be equivalent to NRC's § 30.71 Schedule B by correcting the microcurie amounts listed for Iridium-194, Molybdenum-99, Osmium-185, and Osmium-191.

RH-905. Schedule E to Section 2. "Quantities of Radioactive Material Requiring Consideration of the Need for an Emergency Plan for Responding to a Release." was revised to be equivalent to NRC's § 30.72 Schedule C by correcting the Curie amount listed for Silver 110-m.

FOOTNOTES TO SECTION 2...

~~10/ Deleted. Deleted when RH-405.m. was deleted.~~

10/ Sources licensed under RH-405.i. prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975. (from RH-405.i.3.)

~~14/ These reporting requirements do not supersede or release licensee of complying with the requirements under the Emergency Planning and Community Right to Know Act of 1986, Title III, Pubic Law 99-499 or other state or federal reporting requirements.~~

14/ Deleted.

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SECTION 3.
STANDARDS FOR PROTECTION AGAINST RADIATION

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A.
GENERAL

RH-1002. Purpose and Scope.

a. ~~These Regulations~~ *This Section* establishes standards for protection against *ionizing* radiation ~~hazards. Except as otherwise specifically provided, this Part applies to all licensees or registrants~~ *resulting from activities conducted pursuant to licenses or registrations issued by the Department.*

...

RH-1003. Communications.

All communications concerning these Regulations should be addressed to the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section Chief, ~~P.O. Box 1437 Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.*

PART B.
DEFINITIONS

RH-1100. Definitions ~~as used in these Regulations~~. ~~Additional definitions used only in a certain Part will be found in that Part.~~ ...

b. *Accelerator-produced material - Any material made radioactive by a particle accelerator.*

q. Byproduct material -

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

2. *The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies*

depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

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

B. Any material that:

i. Has been made radioactive by use of a particle accelerator; and

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

4. *Any discrete source of naturally occurring radioactive material, other than source material, that:*

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

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

ac. Department - The Arkansas Department of Health ~~and Human Services~~ or its duly authorized representatives.

ag. Director - Director of the Arkansas ~~Division~~ *Department* of Health.

ah. Discrete source – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

bo. Member of the public - Any individual except when that individual is receiving an occupational dose ~~or unrestricted area~~.

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RH-1100. (Cont'd)

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

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

~~dg. These Regulations, Section 3, Rules and Regulations of the State Board of Health, Standards for Protection Against Radiation.~~

dq. Waste - *Those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs 2., 3., and 4. of the definition of byproduct material set forth in RH-200.i.*

PART C.
PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

RH-1200. Occupational Dose Limits for Adults.

a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures under RH-1205, to the following dose limits.

1. An annual limit, which is the more limiting of:

A. The total effective dose equivalent being equal to 5 rems (0.05 Sv), or

B. The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

2. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

A. An lens dose equivalent of 15 rems (0.15 Sv), and

B. A shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to skin of any extremity.

b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (See RH-1205.e.1.) and during the individual's lifetime (See RH-1205.e.2.).

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

d. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix G to Section 3 and may be used to determine the individual's dose (See RH-1500.f.) and to demonstrate compliance with the occupational dose limits.

e. In addition to the annual dose limits, the licensee shall limit the soluble Uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. (See footnote c of Appendix G to Section 3.)

f. The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see RH-1500.d.5.).

RH-1207. Dose *Equivalent* to an Embryo/Fetus.

a. The licensee or registrant shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see RH-1500.f.)

PART D.
PRECAUTIONARY PROCEDURES

RH-1302. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this Section. As a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation *from licensed and unlicensed radiation sources under the control of the licensee* and shall supply and require the use of individual monitoring devices by:

1. Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of ten (10%) percent of the limits in RH-1200.a;

2. Minors ~~and declared pregnant women~~ likely to receive, in one (1) year, from sources external to the body, a ~~dose~~ *deep dose equivalent* in excess of ~~ten (10%) percent of any of the applicable limits in RH-1206. or RH-1207.~~ *0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv)*; and

3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

NOTE: **All of the occupational doses in RH-1200. continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.**

4. Individuals entering a high or very high radiation area.

5. *Individuals working with medical fluoroscopic equipment.*

   A. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to RH-1207.a., shall be located under the protective apron at the waist.

   B. An individual monitoring device used for lens dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron. If leaded eyewear is worn, the device should be clipped to the eyewear.

   C. When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation, it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

b. Each licensee or registrant shall monitor ~~(See RH-1203.)~~, *to determine compliance with RH-1203.*, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

   1. Adults likely to receive, in one (1) year, an intake in excess of ten (10%) percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix G to Section 3; and

   2. Minors ~~and declared pregnant women~~ likely to receive, in one (1) year, a committed effective dose equivalent in excess of ~~0.05~~ *0.1* rem ~~(0.5 mSv)~~ *(1 mSv)*.

   3. *Declared pregnant women likely to receive, during the entire pregnancy, a committed dose equivalent in excess of 0.1 rem (1 mSv).*

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RH-1303. Caution Signs, Labels, and Signals. ...

~~h. Containers.~~

~~1. Except as provided in RH-1303.h.3., each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents.~~

~~2. A label required pursuant to RH-1303.h.1. shall bear the radiation caution symbol and the words:~~

~~CAUTION — DANGER~~
~~— or —~~
~~RADIOACTIVE MATERIAL — RADIOACTIVE MATERIAL~~

~~It shall also provide sufficient information3/ to permit individuals handling or using the containers or working in the vicinity thereof, to take precautions to avoid or minimize exposures.~~

~~3. Notwithstanding the provisions of RH-1303.h.1., labeling is not required:~~

~~A. For containers that do not contain radioactive materials in quantities greater than the applicable quantities listed in RH-2793., Appendix H, of this Part;~~

~~B. For containers containing only natural Uranium or Thorium in quantities no greater than ten (10) times the applicable quantities listed in RH-2793., Appendix H, of this Part;~~

~~C. For containers that do not contain radioactive materials in concentrations greater than the applicable concentrations listed in Column 2, Table I, RH-2200., Appendix A, of this Part;~~

~~D. For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established by these Regulations in this Part;~~

~~E. For containers when they are in transport and packaged and labeled in accordance with regulations published by the Department of Transportation[4/];~~

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~~F. For containers which are accessible5/ only to individuals authorized to handle or use them or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record; and~~

~~G. For manufacturing and process equipment such as piping and tanks.~~

RH-1309. *Labeling Containers.*

a. *The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words:*

CAUTION ***DANGER***

or

RADIOACTIVE MATERIAL ***RADIOACTIVE MATERIAL***

The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

b. *Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.*

RH-1310. *Exemptions to Labeling Requirements.*

A licensee is not required to label:

a. *Containers holding licensed material in quantities less than the quantities listed in Appendix H entitled "Quantities of Licensed or Registered Material Requiring Labeling"; or*

b. *Containers holding licensed material in concentrations less than those specified in Table 3 of Appendix G entitled "ALIs and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."*

c. *Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Section; or*

d. *Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation.* 5/

e. *Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or*

f. *Installed manufacturing or process equipment, such as reactor components, piping, and tanks; or*

g. *Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed by the U.S. Nuclear Regulatory Commission (NRC) Part 50 (Domestic Licensing of Production and Utilization Facilities) or Part 52 (Licenses, Certifications, and Approvals for Nuclear Power Plants), not including non-power reactors, that are within an area posted under the requirements in RH-1303. if the containers are:*

1. *Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard.*

2. *Accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers; and*

3. *Subject to plant procedures to ensure they are appropriately labeled, as specified in RH-1309. before being removed from the posted area.*

RH-1311. *Location of Individual Monitoring Devices.*

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with RH-1302.a. wear individual monitoring devices as follows:

a. *An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the*

location of the individual monitoring device is typically at the neck (collar);

b. *An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to RH-1207.a., shall be located at the waist under any protective apron being worn by the woman;*

c. *An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with RH-1200.a.2.A., shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye. If leaded eyewear is worn, the device should be clipped to the eyewear;*

d. *An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with RH-1200.a.2.B., shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.*

PART E.
WASTE DISPOSAL

RH-1400. General Requirements

A licensee shall dispose of licensed material only:

a. By transfer to an authorized recipient as provided in Section 2 of these Regulations; or

b. By decay in storage; or

c. By release in effluents within the limits in RH-1210.; or

d. As authorized under *RH-1401.*, RH-1402., RH-1403., RH-1404., RH-1405., or *RH-1408.*

e. A person must be specifically licensed to receive waste containing licensed material from other persons for:

1. Treatment prior to disposal;

2. Treatment or disposal by incineration; or

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3. Decay in storage.

RH-1406. Transfer for Disposal and Manifests.

a. The requirements of this ~~Section~~ *section* and ~~Appendix F 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 wasteland disposal facility as defined in Section 2 of these Regulations;

2. Establish a manifest tracking system; and

3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

b. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.

c. Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR Part 20.

d. Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR Part 20.

e. *Any licensee shipping byproduct material as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100. intended for ultimate disposal at a land disposal facility licensed under RH-407. must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.*

RH-1408. *Disposal of RH-1100.q. 3. and 4. Byproduct Material.*

a. Licensed material as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100. may be disposed of in accordance with RH-407. of this chapter, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under RH-407., must meet the requirements of RH-1406.

b. A licensee may dispose of byproduct material, as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100., at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

PART F.
RECORDS, REPORTS, NOTIFICATIONS, AND TESTS

RH-1501. Reports of Theft or Loss of Sources of Radiation.

Each licensee or registrant shall report promptly by telephone and confirm promptly by letter to the *Arkansas* Department of Health ~~and Human Services~~, Radiation Control Section *Chief,* ~~P.O. Box 1437, Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867*, the theft or loss as soon as such theft or loss becomes known to the licensee or registrant of: ...

d. Written reports. ...

2. Reports must be made as follows:

A. All licensees or registrants shall make reports to the *Arkansas* Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section Chief, ~~P.O. Box 1437, Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.* ...

RH-1502. Notification of Incidents.

a. Immediate notification.

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Each licensee or registrant shall immediately notify the *Arkansas* Department of Health ~~and Human Services, Division of Health~~, Radiation Control Section *Chief, 4815 West Markham Street, Mail Slot # 30*, Little Rock, Arkansas ~~72203-1437,~~ *72205-3867*, by telephone and confirming letter of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause: ...

b. Twenty-four hour notification.

Each licensee or registrant shall within twenty-four (24) hours notify the *Arkansas* Department of Health ~~and Human Services, Division of Health,~~, Radiation Control *Section Chief*, ~~P.O. Box 1437 Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867*, by telephone and confirming letter of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause: ...

RH-1502. (Cont'd)

g. Preparation and submission of reports.

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

2. Written report.

Each licensee or registrant who makes a report required by RH-1502.a. and RH-1502.b. of this Section shall submit a written follow-up report within 30 (thirty) days of the initial report. Written reports prepared pursuant to other regulations 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 ~~and Human Services, Division of Health,~~ Radiation Control *Section Chief*, ~~P.O. Box 1437 Mail Slot H-30;~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867*. ...

RH-1504. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

a. Reportable events.

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In addition to the notification required by RH-1502., each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences: ...

b. Contents of reports.

1. Each report required by RH-1504.a. of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate: ...

2. Each report filed pursuant to RH-1504.a. of this ~~Section~~ *section* must include for each occupationally overexposed[9/] individual: the name, social security ~~account~~ number *or other unique identifier*, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

3. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RH-1505. Notifications and Reports to Individuals.

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part N of this Section (RH-2804).

b. Reports to individuals of exceeding dose limits.

When a licensee or registrant is required, pursuant to the provisions of RH-1504., RH-1505.b., or RH-1509., to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, licensee or registrant shall also provide ~~a copy of the report submitted to the Department to the individual~~ *the individual a report on his or her exposure data included in the report to the Department.* The report must be transmitted ~~at a time~~ no later than the transmittal to the Department.

RH-1509. Reports of Individual Monitoring.

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

1. Possess or use radioactive material for purposes of radiography pursuant to Part I of Section 3; or

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

b. Each licensee in a category listed in RH-1509.a. shall complete an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by RH-1302. during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Department Form Y (Appendix I to Section 3) or electronic media containing all the information required by Department Form Y.

c. The licensee shall complete the report required by RH-1509.b., covering the preceding year, on or before May 31 of each year. The licensee shall retain the report and submit it, if requested, to the *Arkansas* Department of Health ~~and Human Services, Division of Health~~, Radiation Control Section Chief, ~~P.O. Box 1437 Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot #30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.*

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

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 RH-1513.a. through e. for each type of transaction. See Appendix D to Section 3, "Nationally Tracked Source Thresholds."

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

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 the source;

4. The radioactive material in the source;

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

6. *The manufacture date of the source.*

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

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

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

3. *The name and license number of the recipient facility and the shipping address;*

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

5. *The radioactive material in the source;*

6. *The initial or current source strength in becquerels (curies);*

7. *The date for which the source strength is reported;*

8. *The shipping date;*

RH-1513.b. (Cont'd)

9. *The estimated arrival date; and*

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

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

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

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

3. *The name, address, and license number of the person that provided the source;*

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

5. *The radioactive material in the source;*

6. *The initial or current source strength in becquerels (curies);*

7. *The date for which the source strength is reported;*

8. *The date of receipt; and*

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

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

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 the source or, if not available, other information to uniquely identify the source;*

RH-1513.d. (Cont'd)

4. *The radioactive material in the source;*

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

6. *The date for which the source strength is reported;*

7. *The disassemble date of the source.*

e. *Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The 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 waste manifest number;*

4. *The container identification with the nationally tracked source.*

5. *The date of disposal; and*

6. *The method of disposal.*

f. The reports discussed in RH-1513.a. through RH-1513.e. must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. *The on-line National Source Tracking System;*

2. *Electronically using a computer-readable format;*

3. *By facsimile;*

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

5. *By telephone with follow-up by facsimile or mail.*

RH-1513. (Cont'd)

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. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by RH-1513.a. through RH-1513.e. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

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

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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 G.
SPECIAL REQUIREMENTS FOR THE USE OF X-RAYS IN THE HEALING ARTS

RH-1601. Definitions ~~as Used in these Regulations. Additional definitions used only in a certain Part will be found in that Part.~~

The following mammography regulations (RH-1610) have undergone revision to better clarify the title of Subchapter I, "Mammography Quality Standards Act," of Chapter 1, "Food and Drug Administration," of Title 21 of the Code of Federal Regulations.

RH-1610. Mammography Systems.

a. Definitions. ...

7. Certificate ~~means~~ - The certificate described in ~~21 CFR Part 900 the Quality Mammography Standards; Final Rule section 900.11(a)~~ *the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a) of Section 900.11.*

22. Interpreting physician ~~means~~ - A licensed physician who interprets mammograms and who meets the requirements set forth in ~~21 CFR Part 900 the Quality Mammography Standards; Final Rule section~~

~~900.12(a)(1) the~~ *"Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a)(1) of Section 900.12.*

25. Lead interpreting physician ~~means~~ - The interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements in 21 CFR Part 16 and ~~900 the Quality Mammography Standards; Final Rule section 900.12(d) through (f) the~~ *"Mammography Quality Standards Act," Subchapter I to 21 CFR, paragraphs (d) through (f) of Section 900.12. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.*

29. Mammography equipment evaluation ~~means~~ - An onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards ~~in 21 CFR part 900 the Quality Mammography Standards; Final Rule section 900.12(b) and (e)~~ *set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraphs (b) and (e) of Section 900.12.*

33. Medical physicist ~~means~~ - A person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in ~~21 CFR Part 900 the Quality Mammography Standards; Final Rule section 900.12(a)(3) the~~ *"Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a)(3) of Section 900.12.*

RH-1610 (Cont'd)

b. Accreditation.

1. All facilities performing screening or diagnostic mammography shall be accredited every three (3) years by the Arkansas Department of Health or the American College of Radiology. Such accreditation shall be in accordance with the Food and Drug Administration (FDA) ~~Mammography Quality Standards 21 CFR Parts 16 and 900 the Quality Mammography Standards; Final Rule~~ *21 CFR Part 16 and the "Mammography Quality Standards Act," Subchapter I to Chapter I of 21 CFR.*

2. No mammography shall be performed in an unaccredited facility after January 1, 1990. The owners of any unaccredited facility where in mammography is performed after January 1, 1990 shall be subject to a civil penalty imposed by the Arkansas Department of Health ~~and Human Services~~ in an amount not to exceed one hundred dollars ($100) for each day the facility operates without accreditation by the Department.

c. Quality standards.

1. Personnel.

The following requirements apply to personnel involved in any aspect of mammography, including production, processing, and interpretation of mammograms and related quality assurance activities.

A. Interpreting physicians.

Interpreting physicians shall meet the minimum requirements of 21 CFR Part 900.12(a)(1) of the Food and Drug Administration's ~~Quality Mammography Standards; Final Rule~~ *"Mammography Quality Standards Act."*

B. Radiological technologist.

i. Radiological technologists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(2) of the Food and Drug Administration's ~~Quality Mammography Standards; Final Rule~~ *"Mammography Quality Standards Act."*

ii. Licensed by the State of Arkansas as a Registered Radiologic Technologist.

RH-1610.c.1. (Cont'd)

C. Mammography imaging medical physicist.

i. Mammography imaging medical physicists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(3) of the ~~Quality Mammography Standards; Final Rule~~ *Food and Drug Administration's "Mammography Quality Standards Act."*

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ii. All mammography imaging medical physicists must be registered with the State as a vendor as required by RH-34. ...

RH-1610.c. (Cont'd)

4. Equipment.

The equipment used to perform mammography should be specifically designed for mammography and must meet the following standards:

A. Food and Drug Administration (FDA), ~~Standards Quality Mammography Standards; Final Rule.~~ *Subchapter I entitled "Mammography Quality Standards Act."*

21 CFR Part 900.12(b).

B. Food and Drug Administration (FDA) ~~Standards,~~ *Subchapter J entitled "Radiological Health."*

Certified *equipment* must meet the FDA~~;~~ performance standards for diagnostic x-ray systems and their major components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31. ...

RH-1610.c.4. (Cont'd)

E. Mammography equipment evaluations.

All variable parameters of the equipment must be evaluated and adjusted as needed to comply with ~~the Food and Drug (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(e)(10) *of the FDA's "Mammography Quality Standards Act."* This includes but is not limited to the following: ...

6. Quality assurance.

Each facility must establish and maintain a quality assurance program that meets the requirements of 21 CFR Part 900.12(d) of the ~~Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ *FDA's "Mammography Quality Standards Act."*

A. Responsibilities for the lead interpreting physician.

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The lead interpreting physician has the following responsibility:

i. Ensuring that the facility's quality assurance program meets all the requirements of 21 CFR Part 900.12(d) ~~Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ *of the FDA's "Mammography Quality Standards Act."*

B. Responsibilities for the mammography medical physicist.

The person furnishing medical physics support has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program. That individual's specific duties must include:

i. The duties outlined in 21 CFR Part 900.12 (d)(iii) of the ~~Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ *FDA's "Mammography Quality Standards Act."* ...

RH-1610.c.6.B. (Cont'd)

v. Conduct an annual survey of the facility's equipment quality assurance program as required by ~~the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(e)(~~10~~ 9) *of the FDA's "Mammography Quality Standards Act."*

vi. Submit a written report describing the results of the survey as required by ~~the Food and Drug Administration Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(e)(9)(iii) *of the FDA's "Mammography Quality Standards Act."* ...

D. Quality assurance.

The facility must ensure the quality of mammography by maintaining a quality assurance program that meets the requirements ~~of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ *found in* 21 CFR Part 900.12(e) *of the FDA's "Mammography Quality Standards Act"* and verifying that the action limits

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described in Part 900.12(e) have been met. These tests and their frequencies are as follows: ...

RH-1610.c.6.D. (Cont'd)

ix. Infection control.

Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall comply with the requirements ~~of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ *in the FDA* 21 CFR Part 900.12(e)(13).

E. Evaluation of monitoring results.

Quality assurance test results must be evaluated in a timely manner by the individual that is responsible for performing the test to ensue compliance with ~~the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(e)(8) *of the FDA "Mammography Quality Standards Act."* The responsible individuals are limited to the lead interpreting physician, the medical physicist and the quality control technologist.

F. Medical outcomes audit.

Each facility must establish and maintain a medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results to the interpreting physician's findings. This program must comply with ~~the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(f) *of the FDA "Mammography Quality Standards Act."*

G. Procedures and techniques for mammography of patients with breast implants.

Each facility must have procedures, which specify techniques, and procedures for imaging patients with breast

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implants. These procedures must comply with ~~the Food and rug Administration (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(g) *of the FDA "Mammography Quality Standards Act."*

RH-1610.c.6. (Cont'd)

H. Consumer complaint mechanism.

Each facility must have a consumer complaint mechanism. This mechanism must comply with ~~the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(h) *of the FDA "Mammography Quality Standards Act."* ...

g. Quality assurance record keeping.

All quality assurance record keeping shall meet the requirements of ~~the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule~~ 21 CFR Part 900.12(d)(2) *of the Food and Drug Administration (FDA) "Mammography Quality Standards Act."* The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, ~~and~~ protection, *and* employee qualifications to meet assigned quality assurance tasks, are properly maintained and updated. The quality control records shall be kept for each test specified in paragraphs (e) and (f) of ~~this section 21 CFR Part 900.12~~ until the next annual inspection has been completed, and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer. ...

PART I.
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

RH-1800. General Provisions. ...

c. Definitions. ~~As used in these Regulations. Additional definitions used only in a certain part will be found in that part.~~

RH-1801. Equipment Control.

a. Performance requirements for radiography equipment.

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

1. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981).

This publication has been approved for incorporation by Radiation Control. This publication may be purchased ~~from~~ *through* the American National Standards Institute, Inc., *Customer Service,* ~~1430 Broadway,~~ *25 West 43rd Street, 4th Floor,* New York, New York ~~10018~~ *10036.* (Telephone: (212) 642-~~4900~~ *4980*)(*Email: ansionline@ansi.org*).

A copy of the document is available for inspection in the office of *the* Arkansas Department of Health ~~and Human Services~~, Radiation Control, 5800 West 10th Street, Suite 100, Little Rock, Arkansas 72204.

Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Department may find this an acceptable alternative to actual testing of the component pursuant to the above referenced standard. ...

e. Radiation survey instruments.

1. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material or industrial radiographic x-ray equipment is present to make the radiation surveys as required by this Part and RH-1300.

2. Instrumentation required by this Part must be capable of measuring a range from two (2) milliroentgens (0.02 millisieverts) per hour through one (1) roentgen (0.01 sievert) per hour.

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3. The licensee or registrant shall have each radiation survey instrument required in RH-1801.e.1.calibrated:

A. At intervals not to exceed ~~three~~ *six* ~~(3)~~ *(6)* months and after each instrument servicing, except for battery changes;

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

C. So that an accuracy within plus or minus twenty percent (±20%) of the calibration source can be demonstrated at each point checked. ...

k. Notifications.

1. In addition to the reporting requirements specified in RH-1502. and under other Sections, each licensee or registrant shall provide a written report to the Arkansas Department of Health ~~and Human Services~~, Radiation Control, ~~P.O. Box 1437 Mail Slot H-30~~ *4815 West Markham Street, Mail Slot # 30*, Little Rock, Arkansas ~~72203-1437~~ *72205-3867* within thirty (30) days of the occurrence of any of the following incidents involving radiographic equipment: ...

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

RH-1900. General Provisions. ....

c. Definitions. ~~As used in this Part, the following definitions apply. Additional definitions used only in a certain Part will be found in that Part.~~ ...

13. 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 ~~and Human Services~~ under the regulations of this Part.

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

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, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to Department Regulations. Each notification and report shall:

1. Be in writing;

2. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, the individual's date of birth and the individual's social security number *or other unique identifier*;

3. Include the individual's exposure information; and

4. Contain the following statement:

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

b. Each licensee or registrant shall ~~advise each worker annually of the worker's exposure to radiation or radioactive material~~ *make dose information available to workers* as shown in records maintained by the licensee or registrant ~~pursuant to~~ *under the provisions of* ~~RH-1301~~ *RH-1500.f.* ~~This annual notification shall be dated and signed by the worker. Copies of the notification shall be retained by the licensee or registrant for inspection by the Department.~~ *The licensee or registrant shall provide an annual report to each individual monitored under RH-1302. of the dose received in that monitoring year if:*

1. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue; or

2. The individual requests his or her annual dose report. ...

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RH-2804. (Cont'd)

f. When a licensee or registrant is required pursuant to *RH-1502. or* RH-1504. to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included ~~therein~~ *in the report to the Department.* ~~Such reports shall~~ *The report must* be transmitted ~~at a time~~ ~~not~~ later than the transmittal to the Department.

REVISIONS REGARDING SECTION 3 APPENDICES

APPENDIX C TO SECTION 3

Deleted. (For "Determination of A_1 and A_2 Quantities," see Appendix A to Section 4.)

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New table due to addition of RH-1513 – equivalent to NRC's Appendix E to Part 20

APPENDIX D TO SECTION 3

NATIONALLY TRACKED SOURCE THRESHOLDS

(for use with RH-1513.)

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

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

The following appendices were inadvertently deleted as of the 2006 (current) regulations: **Appendix F to Section 3**, "List of Elements"; **Appendix G to Section 3**, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage"; and **Appendix H to Section 3**, "Quantities of Licensed or Registered Material Requiring Labeling." These Appendices are to be added back into the regulations and are revised to be equivalent to those found in 10 CFR Part 20.

Appendix I to Section 3, on the following page, has had slight formatting and type-o's addressed. Also, "in accordance with RH-2802" was added to its bottom paragraph. This change is highlighted.

Appendix J to Section 3 has been deleted. Instead, Appendix G to Part 20 of 10 CFR has been incorporated by reference into RH-1406.

Appendices K and L to Section 3 (Form Y and Form Z respectively), following Appendix I, have had slight reformatting and the addition of "other unique identifier" to their instructions. This change is highlighted on both Forms.

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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 you radiation exposures.
   c. A report of any exposure in excess of a limit must be reported to you.

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: [redacted], 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.

OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

Form Y

1. Name: Last, First, Middle Initial	2. Identification Name	3. ID Type	4. Sex – M or F	5. Date of Birth

6. Monitoring Period	7. Licensee or Registrant Name	8. Licensee or Registration Number	9B. Record or Estimate	9B. Routine or PSE

INTAKES				DOSES (in rem)	
10A. Radionuclide	10B. Class	10C. Mode	10D. Intake in µCi		
				Deep Dose Equivalent (DDE)	11.
				Eye Dose Equivalent to the lens of the eye (LDE)	12.
				Shallow Dose Equivalent, Whole Body (SDE, WB)	13.
				Shallow Dose Equivalent, Max Extremity (SDE, ME)	14.
				Committed Effective Dose Equivalent (CEDE)	15.
				Committed Dose Equivalent, Maximally Exposed Organ (CDE)	16.
				TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) (Blocks 11 & 15)	17.
				TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (TODE) (Blocks 11 & 16)	18.
				19. Comments	

20. Signature of Licensee or Registrant	21. Date Prepared

ARKANSAS DEPARTMENT OF HEALTH

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF FORM Y

1. Type or print the full name of the monitored individual in the order of last name (include Jr., Sr., III, etc.), first name, and middle name (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9 digit social security number [redacted].

3. Enter the code for the type of identification used as follows:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	Index Identification Number
OTH	Other

4. Circle the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY – MM/DD/YY.

7. Enter the name of the licensee or registrant.

8. Enter the Agency license or registration number or numbers.

9A. Circle either Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results, and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

9B. Circle either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represent the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSE's.

10.A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-###x" (for instance, Cs-137 or Tc-99m).

10.B. Enter the lung clearance class as noted in Appendix G to Section 3 (D, W, Y, V, or O for other) for all intakes by inhalation.

10.C. Enter the mode of intake. For inhalation, enter "II." For absorption through the skin, enter "B." For oral ingestion, enter "O." For injection, enter "J."

10.D. Enter the intake of each radionuclide in μCi.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).

15. Enter the committed effective dose equivalent or "NR" for "Not Required" or "NC" for "Not Calculated."

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated."

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the person designated to represent the licensee or registrant.

20. Enter the date this form was prepared.

21. In the space provided for comments, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE, ME was the result of exposure from a discrete, hot particle. Another possibility would be to indicate that an overexposure report has been sent to the Agency in reference to the exposure report.

(All doses should be stated in rem.)

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CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY						**Form Z**	
1. Name: Last, First, Middle Initial			2. Identification Name		3. ID Type	4. Sex – M or F	5. Date of Birth
6. Monitoring Period		7. Licensee or Registrant Name		8. License or Registration Number		9. Record/ Estimate/ No Record	10. Routine or PSE
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. Monitoring Period		7. Licensee or Registrant Name		8. License or Registration Number		9. Record/ Estimate/ No Record	10. Routine or PSE
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. Monitoring Period		7. Licensee or Registrant Name		8. License or Registration Number		9. Record/ Estimate/ No Record	10. Routine or PSE
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. Monitoring Period		7. Licensee or Registrant Name		8. License or Registration Number		9. Record/ Estimate/ No Record	10. Routine or PSE
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
19. Signature of Monitored Individual		20. Date Signed	21. Certifying Organization		22. Signature of Designee		23. Date Signed

ARKANSAS DEPARTMENT OF HEALTH

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF FORM Z

9. Type or print the full name of the monitored individual in the order of last name (include Jr., Sr., III, etc.), first name, and middle name (if applicable).

10. Enter the individual's identification number, including punctuation. This number should be the 9 digit social security number [redacted].

11. Enter the code for the type of identification used as follows:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	Index Identification Number
OTH	Other

12. Circle the sex of the individual being monitored.

13. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

14. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY – MM/DD/YY.

15. Enter the name of the licensee, registrant, or facility not licensed by the Agency that provided monitoring.

16. Enter the Agency license or registration number or numbers.

17. Circle either Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results, and the licensee or registrant intends to assign the record dose on the basis of TLD results that are not yet available.

18. Circle either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represent the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSE's.

19. Enter the deep dose equivalent (DDE) to the whole body.

20. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

21. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).

22. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).

23. Enter the committed effective dose equivalent (CEDE).

24. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.

25. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

26. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

27. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.

28. Enter the date this form was signed by the monitored individual.

29. (Optional) Enter the name of the licensee, registrant, or facility not licensed by the Agency providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.

30. (Optional) Signature of the person designated to represent the licensee, registrant, or employer entered in item 21. The licensee, registrant, or employer who chooses to countersign the form should have on-file documentation of all the information on the Agency Form Y being signed.

31. (Optional) Enter the date this form was signed by the designated representative.

(All doses should be stated in rem.)

SECTION 4.
TRANSPORTATION OF RADIOACTIVE MATERIALS

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A.
GENERAL ...

RH-3002. Purpose and Scope.

a. This ~~part~~ *Section* establishes:

1. Requirements for packaging, preparation for shipment, and transportation of licensed material; *and*

2. *Procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity.*

b. The packaging and transport of licensed material are also subject to the regulations of other agencies (e.g., the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission, and the U.S. Postal Service) having jurisdiction over means of transport. The requirements of this Section are in addition to, and not in substitution for, other requirements.

c. The regulations in this ~~part~~ *Section* apply to any ~~licensed authority~~ licensee authorized by specific or general license issued by the Department to receive, possess, use, or transfer licensed material ~~to a carrier for transport~~, *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 ~~part~~ *Section* authorizes the possession of licensed material.

d. *1.* Exemptions from the requirement for license in ~~RH-3200.~~ *RH-3004.* are specified in ~~RH-3300.~~ *RH-3202. General licenses for which no NRC package approval is required are issued in RH-3304. through RH-3306. The general license in RH-3301. requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license.*

2. *Application for package approval must be completed in accordance with U.S. Nuclear Regulatory Commission Regulations in Part 71, subpart D, "Application for Package Approval," demonstrating that the design of the package to*

be used satisfies the package approval standards contained in the U.S. Nuclear Regulatory Commission Regulations in Part 71, subpart E, "Package Approval Standards," as related to the tests of the U.S. Nuclear Regulatory Commission Regulations in Part 71, subpart F, "Package, Special Form, and LSA-III Tests."

3. *A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements of Part F; the quality assurance requirements of Part G; and the general provisions of Part A, including DOT regulations referenced in RH-3005.*

e. *The regulations of this Section apply to any person holding, or applying for, a certificate of compliance, issued pursuant to this section, for a package intended for the transportation of radioactive material, outside the confines of a licensee's facility or authorized place of use.*

f. The regulations of this ~~part~~ *Section* apply to any person required to obtain a certificate of compliance or an approved compliance plan *pursuant to U.S. Nuclear Regulatory Commission Part 76 regulations* if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.

g. This ~~part~~ *Section* also gives notice to all persons who knowingly provide to any licensee, certificate holder, quality assurance program approval or to a contractor, or subcontractor of any of them, components, equipment, materials, or other goods or services, that relate to a licensee's, certificate holder's, quality assurance program approval holder's or applicant's activities subject to this ~~part~~ *Section*, that they may be individually subject to Department enforcement action for violation of RH-1511., "Deliberate Misconduct." ~~The regulations in this Section establish requirements for packaging, preparation for shipment, and transportation of radioactive material in excess of Type A quantities.~~

RH-3003: Communications *and Records*.

a. All communications concerning these Regulations shall be addressed to the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section, ~~P.O. Box 1437 Mail Slot H-30,~~ *4815 West Markham Street, Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.*

b. *Each record required by this section must be legible throughout the*

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

~~(formerly RH-3200)~~

RH-3004. ~~Transportation of Radioactive Material. No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general or specific license issued by the Department or as exempted in RH-3300.~~

Requirement for License.

Except as authorized in a general license or a specific license issued by the Department, or as exempted in this ~~part~~ *Section*, no licensee may:

a. Deliver licensed material to a carrier for transport; or

b. Transport licensed material.

~~(formerly RH-3202)~~

RH-3005. Transportation of Radioactive Material.

a. Each licensee who transports licensed material outside the ~~confines~~ *site* of ~~the licensee's plant or other place of use~~ *usage, as specified in the Department license, or where transport is on public highways,* or who delivers licensed material to a carrier for transport, shall~~:~~ ~~1.~~ comply with the applicable requirements ~~appropriate to the mode of transport~~ of the *DOT* regulations ~~of DOT~~ *in* 49 CFR parts ~~170 through 189; and~~ *107, 171 through 180, and 390 through 397, appropriate to the mode of transport.*

1. The licensee shall particularly note DOT regulations in the following areas:

A. Packaging--49 CFR part 173: subparts A, B, and I.

B. Marking and labeling--49 CFR part 172: subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of subpart E.

C. *Placarding--49 CFR part 172: subpart F, especially §§ 172.500 through 172.519 and 172.556; and appendices B and C.*

D. *Accident reporting--49 CFR part 171: §§ 171.15 and 171.16.*

E. *Shipping papers and emergency information--49 CFR part 172: subparts C and G.*

F. *Hazardous material employee training--49 CFR part 172: subpart H.*

G. *Security plans--49 CFR part 172: subpart I.*

H. *Hazardous material shipper/carrier registration--49 CFR part 107: subpart G.*

2. *The licensee shall also note DOT regulations pertaining to the following modes of transportation:*

A. *Rail--49 CFR part 174: subparts A through D and K.*

B. *Air--49 CFR part 175.*

C. *Vessel--49 CFR part 176: subparts A through F and M.*

D. *Public Highway--49 CFR part 177 and parts 390 through 397.*

~~2. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.~~

b. If~~, for any reason, the~~ *DOT* regulations ~~of the U.S. Department of Transportation~~ are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of ~~those regulations~~ *the DOT specified in RH-3005.a. of this section* to the same extent as if the shipment *or transportation* ~~was~~ *were* subject to ~~*the*~~ *DOT* regulations. *A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot# 30, Little Rock, Arkansas 72205-3867.*

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PART B.
DEFINITIONS

RH-3100. ~~General~~ Definitions.

The following terms are as defined for the purpose of this Section. To ensure compatibility with international transportation standards, all limits in this Section are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents, but rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this Section, either unit may be used. ...

~~e. CFR - Code of Federal Regulations.~~

e. *Certificate of Compliance (CoC) - the certificate issued by the Nuclear Regulatory Commission which approves the design of a package for the transportation of radioactive material.*

h. *Consignment - Each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.*

k. *Criticality Safety Index (CSI) - The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in RH- 3305., RH-3306., and in NRC Regulation §71.59.*

l. *Deuterium* - For the purposes of RH-3203. and RH-3305., deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

m. *DOT* - The U.S. Department of Transportation.

o. Fissile material – ~~Plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, -~~*The radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241,* or any combination of ~~the~~ *these* radionuclides. *Fissile material means the fissile nuclides themselves, not material containing fissile nuclides.* Unirradiated natural uranium and depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. *Certain exclusions from fissile material controls are provided in RH-3203.*

p. Graphite - For the purposes of RH-3203 and RH-3305, graphite with a boron equivalent content less than five (5) parts per million and density greater than 1.5 grams per cubic centimeter.

q. 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 ~~part~~ *Section*.

r. Low Specific Activity (LSA) - Radioactive material with limited specific activity ~~that~~ *which is nonfissile or is excepted under RH-3203. and which* satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

1. LSA-I:

   A. ~~Ores~~ *Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores* containing ~~only~~ naturally occurring radioactive radionuclides ~~(e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or~~ *which are not intended to be processed for the use of these radionuclides*

   B. Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

   C. Radioactive material~~, other than fissile material,~~ for which the A_2 value is unlimited; or

   D. ~~Mill tailings, contaminated earth, concrete, rubble, other debris, and activated *material*~~ *Other radioactive material* in which the ~~radioactive material~~ *activity* is ~~essentially uniformly~~ distributed *throughout* and the *estimated* average specific activity does not exceed *30 times the value for exempt material activity concentration determined in accordance with Appendix A, "Determination of A_1 and A_2."*

2. LSA-II:

   A. Water with tritium concentration up to 20.0 Ci/liter (0.8 TBq/liter); or

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B. Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed ~~10E-4 A²/g~~ 10^{-4} A_2/g for solid and gases, and ~~10E-5 A²/g~~ 10^{-5} A_2/g for liquids.

RH-3100.r. (Cont'd)

3. LSA-III: Solids (e.g., consolidated wastes, activated materials), *excluding powders, that satisfy the requirements of 10 CFR 71.77*, in which:

A. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

B. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven (7) days, would not exceed 0.1 A_2.; and

C. The average specific activity of the solid does not exceed ~~2 x E-3 A²/g~~ 2×10^{-3} A_2/g.

s. Low toxicity alpha emitters - natural uranium, depleted uranium, natural *thorium*; uranium-235, uranium-238, thorium-232, thorium-228, or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten (10) days.

x. Package - Packaging together with its radioactive contents as presented for transport.

1. Fissile material package *or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package* - A fissile material packaging together with its fissile material contents.

2. *Type A package - A Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.*

3. Type B package - A Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascal (100 lb/in²) gauge or a pressure relief device which would allow the release of

radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments.

There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR ~~71.73~~ *71.19*.

z. Special form radioactive material - Radioactive material which satisfies the following conditions:

1. It is either a single solid piece or is contained in a selected capsule that can be opened only by destroying the capsule; and

2. The piece or capsule has at least one dimension not less than five (5) millimeters ~~(0.197 inch)~~ *(0.2 inch)*; and

3. It satisfies the test requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983, and constructed before July 1, 1985, and a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996, and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

ab. Spent nuclear fuel or Spent fuel -- Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one (1) year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

ae. Transport index - The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. ~~The transport index is determined as follows:~~

~~1. For non-fissile material packages, the number determined by~~

~~multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to maximum radiation level in millirem per hour at one meter (3.3 ft)); or~~

~~2. For fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to maximum radiation level in millirem per hour at one meter (3.3 ft)); or, for criticality control purposes, the number obtained as described in 10 CFR 71.59, whichever is larger.~~

(The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one (1) meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one (1) meter (3.3 ft)).

ah. Unirradiated uranium - Uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

~~PART C.~~
~~GENERAL REGULATORY PROVISIONS~~

PART C.
EXEMPTIONS

~~RH 3201.~~ ~~Exemptions.~~

~~a. Common and contract carriers, freight forwarders and warehousemen who are subject to the rules and regulation of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the U.S. Postal Service Domestic Mail Manual (DMM), Section C 023.9.0 and the U.S. Postal Service, are exempt from these requirements of this Section to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to RH 3200. and other applicable Sections of these Regulations.~~

~~b. Physicians, as defined in RH-200., are exempt from the requirements of RH-3202. to the extent that they transport radioactive material for use in the practice of medicine.~~

~~c. Any licensee is exempt from RH-3200. to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity in excess of 0.002 microcurie per gram (70 becquerels per gram).~~

RH-3200. *Specific Exemptions.*

On application of any interested person or on its own initiative, the Department may grant any exemption from the requirements of the regulations in this Section that it determines is authorized by law and will not endanger life or property nor the common defense and security.

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, U.S. Nuclear Regulatory Commission's 10 CFR Part 35 regulations or the equivalent Agreement State regulations.

RH-3202. *Exemption for Low-Level Radioactive Materials.*

A licensee is exempt from all the requirements of this section with respect to shipment or carriage of the following low-level materials:

a. Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table A-2 of Appendix A to this Section.

b. Materials for which the activity concentration is not greater than the activity concentration values specified in Table A-2 of Appendix A to this Section, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table A-2 of Appendix A to this Section.

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RH-3203. *Exemption from Classification as Fissile Material.*

Fissile material meeting the requirements of at least one (1) of the paragraphs RH-3203.a. through f. are exempt from classification as fissile material and from the fissile material package standards of U.S. Nuclear Regulatory Commission Regulations §§ 71.55 and 71.59, but are subject to all other requirements of this section, except as noted.

a. *Individual package containing two (2) grams or less fissile material.*

b. *Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.*

c. *1.* *Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:*

A. *There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and*

B. *There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.*

2. *Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.*

d. *Uranium enriched in uranium-235 to a maximum of one (1) percent by weight, and with total plutonium and uranium-233 content of up to one (1) percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five (5) percent of the uranium mass.*

e. *Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two (2) percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two (2). The material must be contained in at least a DOT Type A package.*

f. *Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.*

~~**PART D.**~~
~~**EXEMPTIONS AND ADDITIONAL REQUIREMENTS**~~

RH-3300. ~~Exemptions.~~

~~a. Common and contract carriers, freight forwarders and warehousemen who are subject to the rules and regulation of the U.S. Department of Transportation or the U.S. Postal Service are exempt from these Regulations to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common and contract carriers who are not subject to the rules and regulations of the U.S. Department of Transportation or U.S. Postal Service are subject to RH-3200. and other applicable Sections of these Regulations.~~

~~b. Physicians, as defined in RH-200., are exempt from the requirements of RH-3202. to the extent that they transport radioactive material for use in the practice of medicine.~~

~~c. Any licensee is exempt from RH-3200. to the extent that he/she delivers to a carrier for transport packages each of which contains no radioactive material having a specific activity in excess of 0.002 microcurie per gram.~~

~~d. Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the U.S. Postal Service, is exempt from the provisions of RH-3200.~~

Reserved.

PART D.
GENERAL LICENSES

~~RH-3301.~~ ~~General License For Carriers.~~

~~a. A general license is hereby issued to any common or contract carrier not exempt under RH-3201. to receive, possess, transport, and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of incidents shall be filed with, or made to, the Department as prescribed in 49 CFR,~~

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~~regardless of and in addition to notification made to U.S. Department of Transportation or other Agencies.~~

~~b. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to notification made to U.S. Department of Transportation or other Agencies.~~

~~c. Persons who transport radioactive material pursuant to the general licenses in RH-3301.a. and b. are exempt from the requirements of Section 3 entitled "Standards for Protection" and Section 3, Part N entitled **"Notices, Instructions, and Reports to Workers; Inspections"** of these regulations to the extent that they transport radioactive material.~~

~~(formerly RH-3302)~~

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

a. A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the U.S. Nuclear Regulatory Commission.

b. This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of RH-3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71.

c. This general license applies only to a licensee who:

1. Has a copy of the certificate of compliance (CoC), or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this Section;

3. ~~Prior to~~ *Before* the licensee's first use of the package, ~~has registered with the NRC; and~~ submits in writing to the U.S.

Nuclear Regulatory Commission: ATTN: Document Control Desk, Director, Spent Fuel Project Office, 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.

d. The general license in ~~RH-3302.a.~~ *RH-3301.a.* applies only when the package approval authorizes use of the package under this general license.

~~d. For previously-approved Type B packages which are not designated as either B(U) or B(M) in the NRC Certificate of Compliance, this general license is subject to additional restrictions of RH-3303.~~

e. For a Type B or fissile material package, the design of which was approved by the U.S. Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

~~(RH-3303 and RH-3304 were deleted.)~~

RH-3302. Reserved.

RH-3303. Reserved.

~~(formerly RH-3305.)~~

RH-3304. General License for Use of Foreign Approved Package.

a. A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

b. Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of RH-3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71.

~~b. This general license applies only international shipments.~~

c. This general license applies only to shipments made to or from locations outside the United States.

d. This general license applies only to a licensee who:

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1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

2. Complies with the terms and conditions of the certificate and revalidation and with applicable requirements of this Section.~~; and~~ *With respect to the quality assurance provisions of Part G of this Section, the licensee is exempt from design, construction, and fabrication considerations.*

~~3. Has a quality assurance program approved by the U.S. Nuclear Regulatory Commission.~~

~~RH-3306.~~ ~~General License For Fissile Material, Limited Quantity Per Package.~~

~~a. A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transfer, without complying with the package standards of this Section, if the material is shipped in accordance with this Section.~~

~~b. The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of RH-3500.~~

~~c. Except as provided in RH-3306.d., this general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:~~

~~1. Up to 40 g of uranium-235;~~

~~2. Up to 30 g of uranium-233;~~

~~3. Up to 25 g of fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or~~

~~4. A combination of fissile radionuclides in which the sum of the ratios of the amounts of each radionuclide to the corresponding maximum amounts in RH-3306.c.1., 2., and 3. does not exceed unity.~~

~~d. For packages where fissile material is mixed with substances having an average hydrogen density greater than water, this general license applies only when a package containing no more than a Type A quantity of radioactive material, including only one of the following:~~

1. Up to 29 g of uranium-235;

2. Up to 18 g of uranium-233;

3. Up to 18 g of fissile radionuclides of plutonium, or

4. A combination of fissile radionuclides in which the sum of the ratios of the amounts of each radionuclide to the corresponding maximum amounts in RH-3306.d.1, 2., and 3. does not exceed unity.

e. Except for the beryllium contained within the special form plutoniumberyllium sources authorized in RH-3306.e., this general license applies only when the beryllium, graphite, or hydrogenous material enriched in deuterium is not present in quantities not exceeding 0.1% of the fissile material mass.

f. 1. Except as specified in RH-3306.f.2. for encapsulated plutonium beryllium sources, this general license applies only when a package is labeled with a transport index not less than the number given by the following equation, where the package contains 'x' grams of uranium-235, 'y' grams of uranium-233, and 'z' grams of the fissile radionuclides of plutonium:

Minimum Transport Index = (0.25x + 0.33y + 0.4z)

2. For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.025 times the number of grams of the fissile radionuclides of plutonium.

3. Packages which have a transport index greater than ten (10) are not authorized under this general license provisions of this Section.

RH-3307. General License: Fissile Material, Limited Quantity, Controlled Shipment.

a. A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transfer, without complying with the package standards of this Section, if limited material is shipped in accordance with this Section.

b. The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of RH-3500.

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c. This general license applies only when a package contains no more than a Type A quantity of radioactive material and no more than 400 g total of the fissile radionuclides of plutonium encapsulated as plutoniumberyllium neutron sources in special form.

d. This general license applies only when:

1. The mass of fissile radionuclides in the shipment is limited such that the

$$\frac{\text{grams of uranium 235}}{X} + \frac{\text{grams of other fissile material}}{Y} < 1$$

where X and Y are the mass defined in the table following RH 3307.d.2.

2. The encapsulated plutonium-beryllium neutron sources are in special form and the total mass of fissile radionuclides in the shipment does not exceed 2500 g.

PERMISSIBLE MASS LIMITS FOR SHIPMENTS OF FISSILE MATERIAL

	Fissile material mass (g) mixed with substances having a hydrogen density less than or equal to water	Fissile material mass (g) mixed with substances having a hydrogen density greater than water
Fissile material:		
Uranium-235 (X)	500	290
Other fissile material (Y)	300	180

e. Except for the beryllium contained within the special form plutoniumberyllium sources authorized in RH 3307.c. and d., this general license applies only when the beryllium, graphite, or hydrogenous material enriched in deuterium is not present in quantities not exceeding 0.1% of the fissile material mass.

f. This general license applies only when shipment of these packages is made under procedures specifically authorized by DOT, in accordance

~~with 49 CFR Part 173 of its regulations, to prevent loading, transport, or storage of these packages with other fissile material shipments.~~

~~(formerly RH-3306)~~

RH-3305. *General License: Fissile Material.*

a. *A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of Part E of Section 4 entitled "Package Approval Standards" and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).*

b. *The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of RH-3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71.*

c. *The general license applies only when a package's contents:*

1. *Contain no more than a Type A quantity of radioactive material; and*

2. *Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.*

d. *The general license applies only to packages containing fissile material that are labeled with a CSI which:*

1. *Has been determined in accordance with paragraph (e) of this section;*

2. *Has a value less than or equal to 10; and*

3. *For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).*

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e. 1. *The value for the CSI must be greater than or equal to the number calculated by the following equation:*

$$CSI = 10 \left[\frac{\text{grams of } ^{235}U}{X} + \frac{\text{grams of } ^{233}U}{Y} + \frac{\text{grams of Pu}}{Z} \right]$$

2. *The calculated CSI must be rounded up to the first decimal place;*

3. *The values of X, Y, and Z used in the CSI equation must be taken from Tables 71-1 or 71-2, as appropriate;*

4. *If Table 71-2 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and*

5. *Table 71-1 values for X, Y, and Z must be used to determine the CSI if:*

A. Uranium-233 is present in the package;

B. The mass of plutonium exceeds one (1%) percent of the mass of uranium-235;

C. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

D. Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table 71-1. — Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per RH-3305.e.

Fissile material	*Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)*	*Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a] (grams)*
^{235}U (X)	*60*	*38*
^{233}U (Y)	*43*	*27*
^{239}Pu or ^{241}Pu (Z)	*37*	*24*

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

Table 71-2. —Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per RH-3305.e.

Uranium enrichment in weight percent of ^{235}U not exceeding	*Fissile material mass of ^{235}U (X) (grams)*
24	*60*
20	*63*
15	*67*
11	*72*
10	*76*
9.5	*78*
9	*81*
8.5	*82*
8	*85*
7.5	*88*
7	*90*
6.5	*93*
6	*97*
5.5	*102*
5	*108*
4.5	*114*
4	*120*
3.5	*132*
3	*150*
2.5	*180*
2	*246*
1.5	*408*
1.35	*480*
1	*1,020*
0.92	*1,800*

RH-3306. *General license: Plutonium-Beryllium Special Form Material.*

a. *A general license is issued to any licensee of the Department to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of Part E of Section 4 entitled "Package Approval Standards" and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).*

b. *The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of RH-3600, Part G of this Section and the provisions of Subpart H of 10 CFR Part 71.*

c. *The general license applies only when a package's contents:*

1. *Contain no more than a Type A quantity of radioactive material; and*

2. *Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.*

d. *The general license applies only to packages labeled with a CSI which:*

1. *Has been determined in accordance with paragraph (e) of this section;*

2. *Has a value less than or equal to 100; and*

3. *For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).*

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RH-3306. (Cont'd)

e. *1.* *The value for the CSI must be greater than or equal to the number calculated by the following equation:*

$$CSI = 10 \left[\frac{\text{grams of } ^{239}Pu + \text{grams of } ^{241}Pu}{24} \right] \text{; and}$$

2. *The calculated CSI must be rounded up to the first decimal place.*

~~**Part E: Enforcement**~~

PART E.
PACKAGE APPROVAL STANDARDS

RH- 3400. *External Radiation Standards for All Packages.*

a. *Except as provided in RH-3400.b., each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.*

b. *A package that exceeds the radiation level limits specified in RH-3400.a. must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:*

1. *2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):*

A. *The shipment is made in a closed transport vehicle;*

B. *The package is secured within the vehicle so that its position remains fixed during transportation; and*

C. *There are no loading or unloading operations between the beginning and end of the transportation;*

2. *2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the*

case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

3. *0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and*

RH-3400.b. (Cont'd)

4. *0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with RH-1302.*

c. *For shipments made under the provisions of RH-3400.b., the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.*

d. *The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.*

RH-3401.– RH-3499. Reserved.

PART F.
OPERATING CONTROLS AND PROCEDURES

RH-3500. *Applicability of Operating Controls and Procedures.*

A licensee subject to this part, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of this Part F, with the quality assurance requirements of Part G, and with the general provisions of Part A of these transportation regulations.

RH-3501. *Assumptions as to Unknown Properties.*

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

RH-3502. *Preliminary Determinations.*

Before the first use of any packaging for the shipment of licensed material:

a. *The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;*

b. *Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and*

c. *The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. Nuclear Regulatory Commission.*

~~(formerly RH-3401)~~

RH-3503. Routine Determinations.

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this Section and the license. The licensee shall determine that: ...

g. *For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;*

h. Any structural part of the package ~~which~~ *that* could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements ~~specified by the U.S. Nuclear Regulatory Commission~~ *of 10 CFR 71.45.*

h. 1. The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of non-fixed (removable) radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the non-fixed contamination levels. Except as provided in RH-3401.h.2., the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed ten (10) times the limits listed in Table 3.

2. In the case of packages transported as exclusive use shipments by rail or highway only, the non-fixed radioactive contamination at any time during transport must not exceed ten (10) times the levels prescribed in RH-3401.h.1. The levels at the beginning of transport must not exceed the levels in RH-3401.h.1.;

3. In the case of packages containing radioactive materials is Special Form, a leak test performed in the past six (6) months may be used as evidence that the requirements of RH-3401.h.1. has been met.

i. External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed ten (10).

j. For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in RH-3401.h.1. but shall not exceed any of the following:

1. 200 millirems per hour (2 mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1000 millirems per hour (10 mSv/h);

A. The shipment is made in a closed transport vehicle,

B. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

C. There are no loading or unloading operations between the beginning and end of the transportation.

2. 200 millirems per hour (2 mSv/h) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of an open vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load, and on the lower external surface of the vehicle;

3. 10 millirems per hour (0.1 mSv/h) at any point two (2) meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of an open vehicle, at any point two (2) meters from the vertical planes projected from the outer edges of the vehicle; and

4. 2 millirems per hour (0.02 mSv/h) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with RH-2803, **INSTRUCTIONS TO WORKERS**.

j. A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 180 degrees Fahrenheit (82 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

Table 3

Removable External Radioactive Contamination Wipe Limits

Maximum Permissible Limits

Contaminant	uCi/cm²*	dpm/cm²
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than ten days; natural uranium; natural thorium; uranium-235; uranium-238; thorium-232; thorium-228 and thorium-230 when contained in ores or physical concentrates	10^{-5}	22
All other alpha emitting radionuclides	10^{-6}	2.2

~~NOTE (*) == to convert microcuries (μCi) to SI units of megabecquerels, multiply the values by 37.~~

i. The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

j. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in RH-3400 at any time during transportation; and

k. Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

~~(formerly RH-3502.)~~

RH-3504. Air Transport of Plutonium.

a. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Section or included indirectly by citation of the U.S. Department of Transportation ~~(DOT)~~ regulations *(49 CFR Chapter 1),* as may be applicable, the licensee shall assure that plutonium in any form, *whether for import, export, or domestic shipment,* is not transported by air, or delivered to a carrier for air transport, unless:

1. The plutonium is contained in a medical device designed for individual human application; or

2. The plutonium is contained in a material in which the specific activity is ~~not greater than 0.002 microcuries per gram (74 Bq/gm) of material~~ *less than or equal to the activity concentration values for plutonium specified in Table A-2 of Appendix A to this Section,* and in which the radioactivity is essentially uniformly distributed; or

3. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with RH-3005.; or

~~d. The plutonium is shipped in a package specifically authorized in the certificate of compliance, issued by the U.S. Nuclear Regulatory Commission, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the U.S. Department of Transportation regulations~~

~~applicable to the air transport of plutonium.~~

4. *The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.*

b. *Nothing in RH-3504.a. is to be interpreted as removing or diminishing the requirements of the physical protection of plants where special nuclear materials are used as described in 10 CFR Part 73.24, "Prohibitions."*

c. *For a shipment of plutonium by air which is subject to RH-3504.a.4., the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.*

RH-3505. *Opening Instructions.*

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with RH-1307.f.

~~(formerly RH-3403)~~

RH-3506. Records.

a. Each licensee shall maintain, for a period of ~~two~~ *three* ~~(2)~~ *(3)* years after shipment, a record of each shipment of licensed material not exempt under ~~RH-3201.~~ *10 CFR 71.10, "Public Inspection of Application,"* showing where applicable:

1. Identification of the packaging by model number;

2. Verification that there were no significant defects in the packaging, as shipped;

3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package, and the total quantity of each shipment;

5. *For each item of irradiated fissile material:*

A. Identification by model number and serial number;

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B. Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

C. Any abnormal or unusual condition relevant to radiation safety;

6. Date of the shipment;

7. For fissile packages and for Type B packages, any special controls exercised;

8. Name and address of the transferee;

9. Address to which the shipment was made; and

10. Results of the determinations required by ~~RH-3401.~~ *RH-3503 and by the conditions of the package approval.*

~~b. The licensee shall make available to the Department for inspection, upon reasonable notice, all records required by this Section.~~

b. Each certificate holder shall maintain, for a period of three (3) years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.

RH-3506. (Cont'd)

c. The licensee, certificate holder, and an applicant for a CoC, shall make available to the Department for inspection, upon reasonable notice, all records required by this Section. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

d. The licensee, certificate holder, and an applicant for a CoC shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by RH-3502.; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three (3) years after the life of the packaging to which they apply.

RH-3507. *Inspection and Tests.*

a. *The licensee, certificate holder, and applicant for a CoC shall permit the U.S. Nuclear Regulatory Commission (NRC), at all reasonable times, to inspect the licensed material, packaging, premises, and facilities in which the licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.*

b. *The licensee, certificate holder, and applicant for a CoC shall perform, and permit the NRC to perform, any tests the NRC deems necessary or appropriate for the administration of these Regulations.*

c. *The certificate holder and applicant for a CoC shall notify the NRC, in accordance with 10 CFR 71.1 (RH-3003), forty-five (45) days in advance of starting fabrication of the first packaging under a CoC. This paragraph applies to any packaging used for the shipment of licensed material which has either:*

1. *A decay heat load in excess of 5 kW; or*

2. *A maximum normal operating pressure in excess of 103 kPa (15 lbf/in^2) gauge.*

~~(formerly RH-3404)~~

RH-3508. Reports.

~~The licensee shall report to the Department within thirty (30) days:~~

~~a. Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and~~

~~b. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.~~

a. *The licensee, after requesting the certificate holder's input, shall submit a written report to the Department and the U.S. Nuclear Regulatory Commission of:*

1. *Instances in which there is a significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use; or*

2. *Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.*

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3. *Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.*

b. *The licensee shall submit a written report to the Department and the U.S. Nuclear Regulatory Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.*

c. *Each licensee shall submit, in accordance with RH-3003, a written report required by RH-3508.a. or RH-3508.b. 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 and the NRC to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. Using an appropriate method listed in RH-3003.a., the licensee shall report to:*

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

and using an appropriate method listed in 10 CFR 71.1(a), the licensee shall also report to the U.S. Nuclear Regulatory Commission:

ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

These written reports must include the following:

1. *A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.*

RH-3508.c. (Cont'd)

2. *A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of Section 4 and 10 CFR Part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.*

   A. *Status of components or systems that were inoperable at the start of the event and that contributed to the event;*

B. Dates and approximate times of occurrences;

C. The cause of each component or system failure or personnel error, if known;

D. The failure mode, mechanism, and effect of each failed component, if known;

E. A list of systems or secondary functions that were also affected for failures of components with multiple functions;

F. The method of discovery of each component or system failure or procedural error;

G. For each human performance-related root cause, a discussion of the cause(s) and circumstances;

H. The manufacturer and model number (or other identification) of each component that failed during the event; and

I. For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

3. An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

4. A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

5. Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

6. The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

7. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

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d. *Report legibility.*

The reports submitted by licensees and/or certificate holders under this section must be of sufficient quality to permit reproduction and micrographic processing.

~~RH 3203.~~ ~~Advance Notification of Transport of Nuclear Waste.2/~~

~~a. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the Governor (or Governor's designee) of each State through which the waste will be transported.~~

~~b. Advance notification is required only when:~~

~~1. The nuclear waste is required to be in Type B packaging for transportation;~~

~~2. The nuclear waste is being transported to, through, or across State boundaries to a disposal site or to a collection point for transport to a disposal site;~~

~~3. The quantity of licensed material in a single package exceeds:~~

~~A. 5,000 curies of special form radionuclides;~~

~~B. 5,000 curies of uncompressed gases of Argon-41, Krypton-85m, Krypton-87, Xenon-131m, or Xenon-135;~~

~~C. 50,000 curies of Argon-37, or of uncompressed gases of Krypton-85 or Xenon-133, or of Hydrogen-3 as a gas, as luminous paint, or absorbed on solid material;~~

~~D. 20 curies of other non-special-form radionuclides for which A_2 is less than or equal to 4 curies; or~~

~~E. 200 curies of other non-special-form radionuclides for which A_2 is greater than 4 curies (148 GBq).~~

~~c. Each advance notification required by RH 3203.a. shall contain the following information:~~

~~1. The name, address and telephone number of the shipper, carrier and receiver of the shipment;~~

~~2. A description of the nuclear waste contained in the shipment as~~

required by these Regulations or the U.S. Department of Transportation in 49 CFR172.202 and 172.203.d;

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

4. The seven-day period during which arrival of the shipment at State boundaries is estimated to occur;

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

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

d. The notification required by RH-3203.a. shall be made in writing to the office of each appropriate Governor (or Governor's designee) and to the Department. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the Office of the Governor (or Governor'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 copy of the notification shall be retained by the licensee for one (1) year.

e. The licensee shall notify each appropriate Governor (or Governor's designee) and the Department of any changes to schedule information provided pursuant to RH-3203. Such notification shall be by telephone to a responsible individual in the Office of the Governor (or Governor's designee) of the appropriate state or states.

Each licensee shall maintain for one (1) year a record of the name of the individual contacted.

f. Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the Governor (or Governor's designee) of each appropriate state and to the Department. A copy of the notice shall be retained by the licensee for one year.

RH-3405. Advance Notification of Transport of Nuclear Waste.2/

a. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the Governor (or Governor's designee) of each State within or through which the waste will be

~~transported.~~

~~b. Advance notification is required only when:~~

~~1. The nuclear waste is required to be in Type B packaging for transportation;~~

~~2. The nuclear waste is being transported into, within, or through a State en route to a disposal site or to a collection point for transport to a disposal site;~~

~~3. The quantity of licensed material in a single package exceeds:~~

~~A. 3000 times the A_1 value of the radionuclides as specified in RH-2700., Table C-1 for special form radioactive material;~~

~~B. 3000 times the A_2 value of the radionuclides as specified in RH-2700., Table C-1 for normal form radioactive material; or~~

~~C. 27,000 Curies (1000 terabecquerel)~~

~~c. Each advance notification required by RH-3405.a. shall contain the following information:~~

~~1. The name, address and telephone number of the shipper, carrier and receiver of the shipment;~~

~~2. A description of the nuclear waste contained in the shipment as required by these Regulations or the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);~~

~~3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated of occur;~~

~~4. The seven-day period during which arrival of the shipment at State boundaries is estimated to occur;~~

~~5. The destination of the shipment and the seven-day period during which arrival of the shipment is estimated to occur; and~~

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

~~d. The notification required by RH-3405.a. shall be made in writing to the office of each appropriate Governor (or Governor's designee) and to the Department. A notification delivered by mail must be postmarked at least seven (7) days before the beginning of the seven-day period during which~~

~~departure of the shipment is estimated to occur. A notification delivered by messenger must reach the Office of the Governor (or Governor's designee) at least four (4) days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three (3) years.~~

~~e. The licensee shall notify each appropriate Governor (or Governor's designee) and the Department of any changes to schedule information provided pursuant to RH-3405. Such notification shall be by telephone to a responsible individual in the Office of the Governor (or Governor's designee) of the appropriate state or states. The licensee shall maintain for three (3) years a record of the name of the individual contacted.~~

~~f. Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice, identifying the advance notification that is being canceled, to the Governor (or Governor's designee) of each appropriate state and to the Department. A copy of the notice shall be retained by the licensee for three (3) years.~~

~~(formerly RH-3203, and RH-3405)~~

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

a. As specified in RH-3509 b., c., and d., each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, through, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

b. Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements as described in 10 CFR Part 73. Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

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

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

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

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

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

   C. *1000 TBq (27,000 Ci).*

c. *Procedures for submitting advance notification.*

1. *The notification must be made in writing to the office of each appropriate governor or governor's designee and to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response.*

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

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

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

   B. *The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.*

   C. *A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.*

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

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RH-3509. (Cont'd)

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

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

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

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

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

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

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

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

e. *Revision notice.*

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

f. *Cancellation notice.*

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

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RH-3509.f. (Cont'd)

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

PART G.
QUALITY ASSURANCE

~~RH-3500. Quality Assurance Requirements.~~

~~a. Unless otherwise authorized by the Department, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material are promptly identified and corrected.~~

~~b. The licensee shall identify the material and components to be covered by the quality assurance program.~~

~~c. Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.~~

~~d. Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Department of its quality assurance program.~~

~~e. The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of three (3) years after shipment.~~

(formerly RH-3500)

RH-3600. Quality Assurance Requirements.

a. Purpose.

This Part 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, "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. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this Part G or the Nuclear Regulatory Commissions' subpart H to Part 71.

b. *Establishment of program.*

Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Part G, "Quality Assurance," and U.S. Nuclear Regulatory Commission regulations 10 CFR Part 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

RH-3600. (Cont'd)

c. *Approval of program.*

Before the use of any package for the shipment of licensed material subject to this Part G, each licensee shall obtain Department and/or U.S. Nuclear Regulatory Commission approval of its quality assurance program. Using an appropriate method listed in RH-3003.a. (10 CFR Part 71.1(a)), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this Part G (subpart H of Part 71) are applicable and how they will be satisfied, by submitting the description to:

Arkansas Department of Health
Radiation Control Section

4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

and to the U.S. Nuclear Regulatory Commission:

ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

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d. *Previously approved programs.*

A Department or U.S. Nuclear Regulatory Commission approved quality assurance program that satisfies the applicable criteria of Part G of this Section, subpart H of 10 CFR Part 71, Appendix B of 10 CFR Part 50, or subpart G of 10 CFR Part 72, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of RH-3600.b. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the U.S. Nuclear Regulatory Commission in accordance with 10 CFR Part 71.1 of its intent to apply its previously approved Part G of this Section, Appendix B of Part 50, or subpart G of Part 72 quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the U.S. Nuclear Regulatory Commission, Docket Number, and date of U.S. Nuclear Regulatory Commission approval.

RH-3600. (Cont'd)

e. *Radiography containers.*

A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of RH-1801.i.2. or equivalent Nuclear Regulatory Commission or Agreement State requirement, is deemed to satisfy the requirements of RH-3301.b. and RH-3600.b.

RH-3601. *Quality Assurance Organization.*

a. *The licensee[1/], certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.*

b. *The quality assurance functions are:*

1. *Assuring that an appropriate quality assurance program is established and effectively executed; and*

2. *Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.*

c. *The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to:*

1. *Identify quality problems;*

2. *Initiate, recommend, or provide solutions; and*

3. *Verify implementation of solutions.*

d. *The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.*

RH-3601. (Cont'd)

e. *Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.*

f. *Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.*

RH-3602. Quality Assurance Program.

a. *The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the Department requirements found in Part G, "Quality Assurance," and U.S. Nuclear Regulatory Commission regulations 10 CFR Part 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall*

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identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

RH-3602. (Cont'd)

b. The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

c. The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

1. The impact of malfunction or failure of the item to safety;

2. The design and fabrication complexity or uniqueness of the item;

3. The need for special controls and surveillance over processes and equipment;

4. The degree to which functional compliance can be demonstrated by inspection or test; and

5. The quality history and degree of standardization of the item.

d. The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in

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the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

RH-3603. *Handling, Storage, and Shipping Control.*

The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

RH-3604. *Inspection, Test, and Operating Status.*

a. *The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.*

b. *The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.*

RH-3605. *Nonconforming Materials, Parts, or Components.*

The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

RH-3606. *Corrective Action.*

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the

measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

RH-3607. *Quality Assurance Records.*

The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by U.S. Nuclear Regulatory Commission regulation 10 CFR 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for three (3) years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for three (3) years after it is superseded.

RH-3608. *Audits.*

The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated.

Former Appendix C to Section 3, "Determination of A_1 and A_2 Quantities," (former RH-2700) now is revised in its entirety (to be NRC equivalent) and is designated as Appendix A to Section 4, "Determination of A_1 and A_2."

FOOTNOTES FOR SECTION 4

~~1/ Any notification of incidents referred to in those requirements shall be filed with or made to, the Department.~~

1/ *While the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.* (for RH-3601)

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SECTION 5.
RULES OF PRACTICE

PART A.
GENERAL

RH-4003. Communications.

a. All communications concerning this Regulation shall be addressed to the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section, ~~P.O. Box 1437 Mail Slot H 30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.*

b. The Director of the Arkansas ~~Division~~ *Department* of Health or a duly appointed Hearing Officer shall specify the time and place of all hearings.

PART B.
ADMINISTRATION

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 ~~and Human Services, Division of Health,~~ Radiation Control Section, ~~P.O. Box 1437, Mail Slot H 30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *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. Unless otherwise specified, the filing, when by mail or telegram, shall, upon actual receipt, be deemed complete as of the date of deposit in the mail or with the telegraph company. Papers may be filed in person at the Department's offices at Little Rock, Arkansas.

SECTION 6.
PARTICLE ACCELERATORS

PART A.
GENERAL

RH-5004. Communications.

All communications concerning this Regulation shall be addressed to the Arkansas Department of Health ~~and Human Services, Division of Health,~~ Radiation Control Section, ~~P.O. Box 1437, Mail Slot H-30,~~ *4815 West Markham Street, Mail Slot # 30,* Little Rock, Arkansas ~~72203-1437~~ *72205-3867.*

PART B.
DEFINITIONS

RH-5100. ~~General~~ Definitions. ~~Additional definitions used only in a certain Part will be found in that Part.~~ ...

e. Department - Arkansas Department of Health ~~and Human Services~~.

~~t. These Regulations - Section 6 of the Rules and Regulations for Control of Sources of Ionizing Radiation of the State Board of Health, Standards for Protection Against Radiation.~~

PART C.
LICENSES

RH-5201. Licensing Procedures.

a. Application for accelerator licenses shall be filed on forms supplied by:

Radiation Control,
Arkansas Department of Health ~~& Human Services,~~
~~P.O. Box 1437, Mail Slot H-30,~~
4815 West Markham Street, Mail Slot # 30,
Little Rock, Arkansas ~~72203-1437~~ *72205-3867.*

The application shall set forth all applicable information called for by the form. ...

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RH-5203. Special Requirements for Issuance of a License for Particle Accelerators.

a. Human use of particle accelerators in medical institutions.

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

1. Whenever deemed necessary by the Department, the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic and therapeutic use of a particle accelerator within that institution. Membership of the committee should include physicians expert in internal, hematology, therapeutic radiology and a person experienced in depth dose calculations and protection against radiation. ...

5. The applicant has appointed a Radiation Safety Officer.

RH-5205. Specific Terms and Conditions of Licenses.

d. Bankruptcy Notification.

1. Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (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(~~14~~*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. ...

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SECTION 7.
NATURALLY OCCURRING RADIOACTIVE MATERIAL (NORM)

...PART B.
DEFINITIONS

RH-6004. ~~General~~ Definitions. ~~As used in this Section, the following definitions apply:~~

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.

2. No *specific* license issued or granted under this Section and no right to possess or utilize NORM granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

3. Each person *specifically* licensed by the Department pursuant to this Section shall confine use and possession of the NORM licensed to the locations and purposes authorized in the *specific* license.

4. Each person *specifically* licensed by the Department pursuant to this Section is subject to the general license provisions of RH-6011., RH-6012., and RH-6013.

5. *Notification of* bankruptcy ~~(of Licensee)~~.

A. Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title 11 (Bankruptcy) of the United States Code (11 U.S.C.) by or against:

i. A licensee;

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ii. An entity [as that term is defined in 11 U.S.C. 101 (~~14~~15)] controlling a licensee or listing the license or licensee as property of the estate; or

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

RH-6026.a.5. (Cont'd)

B. This notification must indicate:

i. The bankruptcy court in which the petition for bankruptcy was filed; and

ii. The date of the filing of the petition.

6. *Notification of commencement of activities.*

Each licensee shall notify the Department, in writing, at least five (5) days prior to commencing decontamination or remediation activities at a customer's site. If, for a specific case, the five (5) day period would pose an undue hardship on the licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The notification shall specify the following:

A. Type of operation;

B. Mode of decontamination (if more than one mode is authorized on the license);

C. Address and physical location of the decontamination or remediation activity;

D. Dates when the activities will be conducted; and

E. Name of the person supervising the operations at the site.

7. *Notification of completion of activities.*

Each licensee shall notify the Department, in writing, within thirty (30) days following completion of NORM decontamination or remediation work. The notification shall specify the following:

A. Customer name, mailing address, and telephone number;

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B. *Quantity of contaminated material generated as a result of the decontamination or remediation process;*

C. *Disposition of contaminated material;*

D. *Type of container used for storage of the contaminated material; and*

E. *Location and description of where contaminated material is stored. (If a street address is not available, a map must be provided.)*

PART E.
RECIPROCITY

RH-6040. Reciprocal Recognition of Licenses.

Subject to 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:

a. The licensing document does not limit the activity authorized by such document to specific installations or locations;

b. The out-of-state licensee notifies the Department in writing at least ~~two (2)~~ *five (5)* days prior to engaging in such activity. Such notification shall indicate the location period and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the ~~two (2)~~ *five (5)* day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

c. The out-of-state licensee complies with all applicable regulations 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 of the Department; ...

d. The out-of-state licensee supplies such other information as the Department may request; and

e. The out-of-state licensee shall not transfer or dispose of NORM possessed or used under the general license provided in RH-6040.a. except by transfer to a person:

1. Specifically licensed by the Department or by another Licensing State to receive such NORM; or

2. Exempt from the requirements for a license for such NORM under RH-6005.

~~PART F.~~

APPENDIX A *TO* SECTION 7
ACCEPTABLE SURFACE CONTAMINATION[a] LEVELS FOR NORM

~~Nuclide~~[a]	Average[b,c,f]	Maximum[b,d,f]	Removable[b,c,e,f]
~~U-nat, U-235, & U-238 and associated products. (including Po-210) except Ra-226, Th-230, Ac-227, and Pa-231~~	~~5,000 dpm alpha/100 cm^2~~	~~15,000 dpm alpha/100 cm^2~~	~~1,000 dpm alpha/100 cm^2~~
~~Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227~~	~~100 dpm/100 cm^2~~	~~300 dpm/100 cm^2~~	~~20 dpm/100 cm^2~~
~~Th-nat, Th-232, Ra-223, Ra-224, U-232~~	~~1,000 dpm/100 cm^2~~	~~3,000 dpm/100 cm^2~~	~~200 dpm/100 cm^2~~
Alpha	5,000 dpm/100 cm^2	15,000 dpm/100 cm^2	1,000 dpm/100 cm^2
Beta-gamma ~~emitters (nuclides with decay modes other than alpha emission or spontaneous fission, including Pb-210) except others noted above.~~	5,000 dpm ~~beta, gamma~~/100 cm^2	15, 000 dpm ~~beta, gamma~~/100 cm^2	1,000 dpm ~~beta, gamma~~/100 cm^2

[a] Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[b] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[c] Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.

[d] The maximum contamination level applies to an area of not more than 100 cm^2.

e The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of ~~less~~ surface area *A (where A is less than 100 sq. cm)* is determined, ~~the pertinent levels should be reduced proportionally and~~ the entire surface should be wiped *and the contamination level multiplied by 100/A to convert to a "per 100 sq. cm" basis.*

f The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr *(2 μGy/hr)* at one (1) cm and 1.0 ~~mrad~~ *mR*/hr *(10 μGy/hr)* at 1 cm, respectively, measured through not more than seven (7) milligrams per square centimeter of total absorber.

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SECTION 8.
IRRADIATORS

PART A.
GENERAL

RH-7002. Definitions. ...

1. Sealed source - Any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the ~~byproduct~~ *radioactive* material.

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SECTION 9.
USE OF RADIONUCLIDES IN THE HEALING ARTS

PART A.
GENERAL

RH-8001. ~~Effective Date. October 1, 2006.~~ *Implementation*.

~~a. A licensee shall implement the provisions in Section 9 on October 1, 2006.~~

a. Deleted.

b. When a requirement in Section 9 differs from the requirement in an existing license condition, the requirement in this Section shall govern.

c. Any existing license condition that is not affected by a requirement in Section 9 remains in effect until there is a license amendment or license renewal.

d. If a license condition exempted a licensee from a provision of Section 9 on October 1, 2006, it will continue to exempt a licensee from the corresponding provision in Section 9.

e. Licensees shall continue to comply with any license condition that requires it to implement procedures required by RH-8633., RH-8643., RH-8644., and RH-8645. until there is a license amendment or renewal that modifies the license condition.

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 under the license, except ~~an individual who is~~:

1. For an authorized user, an individual who meets the requirements in ~~RH-8318., and RH-8510., RH-8540., RH-8560., RH-8570.,~~

~~RH-8580., RH-8610., RH-8621., RH-8660.~~ *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-8318.~~ *RH-8319.*;

RH-8011.b. (Cont'd)

3. For an authorized medical physicist, an individual who meets the requirements in RH-8316.a. and c. and ~~RH-8318.~~ *RH-8319.*;

~~4. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or~~

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

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

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

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

~~5. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.~~

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5. *Deleted.*

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

RH-8020. Notifications.

~~a. A licensee shall provide to the Department a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope 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, pursuant to RH-8011.b.~~

a. A licensee shall provide to the Department a copy of the board certification and the written attestation(s), signed by a preceptor, the Nuclear Regulatory Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, the permit issued by an NRC master material license broad scope permittee, and for each individual no later than thirty (30) days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under RH-8011.b. For individuals permitted to work under RH-8011.b.4., within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:

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

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

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

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

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

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

RH-8670.;

b. The provisions of RH-8011.b. ~~regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license~~;

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. ~~regarding notification to the Department for new authorized users new authorized nuclear pharmacists and new authorized medical physicist~~;

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

f. The provisions of RH-8310.a. ~~regarding suppliers for sealed sources.~~

PART B.
DEFINITIONS

RH- 8100. Definitions ~~as used in these Regulations. Additional definitions used only in a certain Part will be found in that Part~~. …

d. Authorized medical physicist *means* an individual who:

1. Meets the requirements in ~~RH-8316.~~ *RH-8316.a. and RH-8319.*; or

~~2. Is identified as an authorized medical physicist on a specific medical use license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or~~

2. Is identified as an authorized medical physicist or teletherapy physicist on:

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

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

C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use committee.

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

e. Authorized nuclear pharmacist *means* a pharmacist who:

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

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

2. Is identified as an authorized nuclear pharmacist on:

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

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

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

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

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

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

4. *Is designated as an authorized nuclear pharmacist in accordance with RH-405.1.2.D.*

f. Authorized user *means* a physician, dentist, or podiatrist who:

1. Meets the requirements in ~~RH-8318. and RH-8510., RH-8540., RH-8560., Rh-8570., RH-8580., RH-8610., RH-8615., RH-8621., or RH-8660.~~*RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8615.a., RH-8621.a., or RH-8660.a.*; or

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

2. *Is identified as an authorized user on:*

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

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

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

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

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

j. Cyclotron – A particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged

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particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

n. High dose-rate remote afterloader ~~(HDR)~~ – A *brachytherapy* device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface ~~near treatment site~~ *where the dose is prescribed.*

o. Low dose-rate remote afterloader ~~(LDR)~~ – A *brachytherapy* device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point ~~of treatment site~~ *or surface where the dose is prescribed.*

t. Medium dose-rate remote afterloader ~~(MDR)~~ – A *brachytherapy* device that remotely delivers a dose rate of greater than 2 gray (200 rads) *per hour*, but less than or equal to 12 gray (1200 rads) per hour ~~at the treatment site~~ *at the point or surface where the dose is prescribed.*

y. *Positron Emission Tomography (PET) radionuclide production facility – A facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.*

ag. Radiation Safety Officer ~~(as used in this Section)~~ *means* an individual who:

1. Meets the requirements in ~~RH-8315.~~ *RH-8315.a. or RH-8315.c.l. and RH-8319.*; or

~~2. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Department for similar types and uses of radioactive material.~~

2. Is identified as a Radiation Safety Officer on:

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

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

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PART C.
GENERAL ADMINISTRATIVE REQUIREMENTS

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. must, at a minimum, address the following items that are applicable for 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.*

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

For medical use, a licensee may 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~~*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.

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c. *Sealed sources or devices non-commercially transferred from 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 (RSO) as provided in RH-8300. to be an individual who:~~

~~a. Is certified by the:~~

~~1. American Board of Health Physics in Comprehensive Health Physics;~~

~~2. American Board of Radiology;~~

~~3. American Board of Nuclear Medicine;~~

~~4. American Board of Science in Nuclear Medicine;~~

~~5. Board of Pharmaceutical Specialties in Nuclear Pharmacy;~~

~~6. American Board of Medical Physics in radiation oncology physics;~~

~~7. Royal College of Physicians and Surgeons of Canada in nuclear medicine;~~

~~8. American Osteopathic Board of Radiology; or~~

~~9. American Osteopathic Board of Nuclear Medicine; or~~

~~b. Has had classroom and laboratory training and experience as follows:~~

~~1. 200 hours of classroom and laboratory training that includes:~~

~~A. Radiation physics and instrumentation;~~

~~B. Radiation protection;~~

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

~~D. Radiation biology;~~

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~~E. Radiation Dosimetry;~~

~~F. Radiopharmaceutical chemistry; and~~

~~2. One (1) year of full time experience as a radiation safety technologist at a medical facility under the supervision of the individual identified as the Radiation Safety Officer of a Department, Nuclear Regulatory Commission, or Agreement State license that authorized the medical use of radioactive material; or~~

~~c. Is an authorized user identified on the licensee's license.~~

Except as provided in RH-8318., the licensee shall require an individual fulfilling the responsibilities of the 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. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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.;*

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*

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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:

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

2. Reserved.

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 radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs d. and e. of RH-8315.; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and

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. *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, 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.

~~The licensee shall require the authorized medical physicist to be an individual who:~~

~~a. Is certified by the American Board of Radiology in:~~

~~1. Therapeutic radiological physics;~~

~~2. Roentgen ray and gamma ray physics;~~

~~3. X ray and radium physics, or~~

~~4. Radiological physics; or~~

~~b. Is certified by the American Board of Medical Physics in radiation oncology physics; or~~

~~c. Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one (1) year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of an authorized medical physicist at a medical facility that includes the tasks listed in RH-8405., RH-8505.e., RH-8640., RH-8641., RH-8642., RH-8643., RH-8644., RH-8645., and RH-8650., as applicable.~~

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

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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 b.2. and c. of RH-8316. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) 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 recognized by the Nuclear Regulatory 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

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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., and has achieved a level of competency sufficient to function independently 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 ~~an~~ Authorized Nuclear Pharmacist.

~~The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:~~

~~a. Has current board certification as a nuclear pharmacist by the Board of~~

~~Pharmaceutical Specialties, or~~

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

~~A. Didactic 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.~~

~~B. Supervised experience in a nuclear pharmacy involving the following:~~

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

~~ii. Using and performing checks for proper operation of dose calibrators, 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 mistakes in the administration of radioactive material;~~

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

~~2. Has obtained written certification signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.~~

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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 have been recognized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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 Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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

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

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

RH-8317. (Cont'd)

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

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

i. Radiation physics and instrumentation;

ii. Radiation protection;

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

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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 in the administration of radioactive material; and*

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

RH-8317.b. (Cont'd)

2. *Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of RH-8317. and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.*

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

~~a. An individual identified as a Radiation Safety Officer, a medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes~~

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~~medical use or the practice of nuclear pharmacy, before October 1, 2006 need not comply with the training requirements of RH-8315., RH-8316., and RH-8317., respectively.~~

~~b. Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, issued before October 1, 2006 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8610., RH-8615., RH-8621., and RH-8660.~~

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 [redacted] need not comply with the training requirements of RH-8315., RH-8316., or RH-8317., respectively.*

RH-8318.a. (Cont'd)

3. *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 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.*

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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 purposes of Section 9, "Use of Radionuclides in the Healing Arts."

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 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 broad scope permittee before October 1, 2006, who perform only those medical uses for which they were authorized on 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 identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State board scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 1, 2006 and [redacted] need not comply with the training requirements 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).

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.

RH-8319. Recentness of Training.

~~The training and experience specified in Section 9 must have been obtained within the seven (7) years preceding the date of application or the individual must~~

~~have had related continuing education and experience since the required training and experience was completed.~~

The training and experience specified in Section 9's Part C (General Administrative Requirements), Part E (Unsealed Radioactive Material – Written Directive Not Required), Part F (Unsealed Radioactive Material – Written Directive Required), Part G (Manual Brachytherapy), Part H (Sealed Sources for Diagnosis), and Part I (Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units) must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

PART D: GENERAL TECHNICAL REQUIREMENTS

RH-8400. ...

~~**Specific Requirements For The Use of Sources For Brachytherapy**~~

RH-8401. Possession, Use, *Checking*, and Testing of Instruments *Used* to Measure the Activity of Unsealed Radioactive Materials~~.~~

a. For direct measurements performed in accordance with RH-8403., a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

~~b. A licensee shall test the instrumentation required in RH-8401.a. in accordance with nationally recognized standards or the manufacturer's instructions.~~

~~c. The tests required in RH-8401.b. shall at a minimum include tests for constancy, linearity, accuracy, and geometry dependence, as appropriate to demonstrate proper operation of the instrument.~~

b. A licensee shall:

1. Check each instrument for constancy with a dedicated check source before use each day of use. The check shall be performed on a frequently used setting with a sealed source of not less than 50 microcuries (1.85 MBq) of any photon-emitting radionuclide with a half-life greater than 90 days.

2. *Test each instrument for accuracy at the time of installation and at least every 12 months thereafter. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology (NIST) or by the manufacturer who has compared their source to a source calibrated by the NIST. The sources shall have a minimum activity of 50 microcuries (1.85 MBq) of any photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 keV and 500 keV.*

3. *Test each instrument for linearity at the time of installation and at least every three months thereafter over the range of its use between the highest and lowest dosage that will be administered.*

RH-8401.b. (Cont'd)

4. *Test each instrument for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used.*

c. *A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds manufacturer's instructions, not to exceed 10 percent, if the dosage is greater than 30 microcuries (1.11 MBq) and shall repair or replace the instrument if the accuracy or constancy error exceeds manufacturer's instructions, not to exceed 10 percent.*

d. *Prior to medical use, a licensee shall also perform checks and tests required by RH-8401. following adjustment, repair, or relocation of the instrument.*

e. *Quality control methods not in accordance with RH-8401. must be authorized by the Department prior to use.*

f. A licensee shall retain a record of each instrument *check or* test required by RH-8401. in accordance with RH-8705.

RH-8403. Determination of Dosages of Radioactive Material for Medical Use.

a. A licensee shall determine and record the activity of each dosage prior to medical use. ~~For photon-emitting radioactive material, this determination shall be within thirty (30) minutes prior to medical use. For all other radioactive material, this determination shall be within the period before~~

~~medical use that is no greater than ten (10%) percent of the physical half-life of the radioactive material.~~

b. For all ~~photon-emitting~~ radionuclides, this determination must be made by direct measurement.

~~c. For other than photon-emitting radionuclides, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to Part C of these regulations or equivalent provisions of the Nuclear Regulatory Commission or Agreement State.~~

c. Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage *does not fall within the prescribed dosage range or if the dosage* differs from the prescribed dosage by more than twenty ~~(20%)~~ percent.

d. *Dosage determination methods other than by direct measurement must be authorized by the Department prior to use.*

e. A licensee shall retain a record of the dosage determination required by Section 9 in accordance with RH-8707.

RH-8410. Decay-in-Storage.

a. A licensee may hold radioactive material with a physical half-life of less than ~~65~~ *or equal to 120* days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and …

RH-8420. Release of Individuals Containing Radioactive Drugs or Implants.

a. A licensee may authorize the release from its control of any individual who has been administered Iodine-131 as Sodium Iodide if:

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1. The total patient concentration has been determined to be 1.22 gigabecquerels (33 millicuries) or less; or

2. If the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five (5) millisievert (0.5 rem) *per year* and criteria outlined in Arkansas' **Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide** have been met.

b. A licensee may authorize the release from its control of any individual who has been administered ~~radioactive drugs~~ *unsealed radioactive material* (other than Iodine-131 as Sodium Iodide) or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five (5) millisievert (0.5 rem) *per year*.

NOTE: ***The current revision of NUREG-1556, Vol.9, "Consolidated Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).***

c. A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, of failure to follow the guidance.

d. Release of the patient must be approved by an ~~individual~~ authorized user listed ~~as an authorized user~~ on ~~a~~ the Department license ~~and who is~~. *This individual must be* approved for the *use of the* type of radioactive material ~~use~~ for which the patient being released has received.

e. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with RH-8710. ...

PART E: UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED

~~**Specific Requirements for the Use of Radioactive Material for Uptake, Dilution, or Excretion Studies**~~

RH-8500. Use of Unsealed Radioactive Material for Uptake, Dilution, ~~or~~*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 ~~, in quantities that do not require a written directive, for a diagnostic use involving measurements of~~ *prepared for medical use for* uptake, dilution, or excretion *studies* that is:

~~a. Obtained from a manufacturer or preparer licensed pursuant to Section 2 of these regulations or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or~~

~~b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RH-8510., RH-8540., or an individual under the supervision of either as specified in RH-8306.; or~~

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. and RH-8540.c.1.B.vii.; or

3. An individual under the supervision, as specified in RH-8306.; of the authorized nuclear pharmacist in paragraph b.1. of RH-8500. or the physician who is an authorized user in paragraph b.2. of RH-8500.; or

c. Obtained from and prepared by a Department, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance

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with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee 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 in:~~

~~1. Nuclear medicine by the American Board of Nuclear Medicine;~~

~~2. Diagnostic radiology by the American Board of Radiology;~~

~~3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~

~~4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~5. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or~~

~~b. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:~~

~~1. Forty (40) hours of classroom and laboratory training that includes:~~

~~A. Radiation physics and instrumentation;~~

~~B. Radiation protection;~~

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

~~D. Radiation biology; and~~

~~E. Radiopharmaceutical chemistry; and~~

~~2. Twenty (20) hours of supervised clinical experience, under the supervision of an authorized user of an unsealed radioactive material for the uses authorized under RH-8500. that includes:~~

~~A. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;~~

~~B. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~C. Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~D. Collaborating with the authorized user in the interpretation of radioisotope test results; and~~

~~E. Patient or human research subject follow-up; or~~

~~c. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in RH-8510.b.~~

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 have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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.; 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

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

A. *Classroom and laboratory training in the following areas:*

i. *Radiation physics and instrumentation;*

ii. *Radiation protection;*

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

iv. *Chemistry of radioactive material for medical use; and*

v. *Radiation biology; and*

B. *Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:*

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

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

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

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

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

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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. and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500.

~~**Specific Requirements or the Use of Unsealed Radioactive Material-Written Directive Not Required**~~

RH-8530. Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

Except for quantities that require a written directive under RH-8307., a licensee may use ~~for imaging and localization studies~~ any *unsealed* radioactive material prepared for medical use *for imaging and localization* studies ~~in quantities that do not require a written directive as described in RH-8307.~~ that is:

~~a. Obtained from a manufacturer or preparer licensed pursuant to Section 2 of these regulations or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or~~

~~b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RH-8540., or an individual under the supervision of either as specified in RH-8306.; or~~

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 the requirements in RH-8540, or RH-8560 and RH-8540.c.1.B.vii., or*

RH-8530.b. (Cont'd)

3. *An individual under the supervision, as specified in RH-8306, of the authorized nuclear pharmacist in paragraph (b)(1) of RH-8530. or the physician who is an authorized user in paragraph (b)(2) of RH-8530.;*

c. Obtained from and prepared by a Department, NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

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.

~~e. Provided the conditions of RH-8409. are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Department.~~

e. Deleted.

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

a. A licensee shall not administer to humans a ~~radioactive drug containing~~ *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);

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. 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).~~

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

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

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

c. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with RH-8713.

RH-8531. (Cont'd)

d. A licensee shall report immediately to the Department each occurrence of radionuclide contaminant concentration exceeding the limits specified in RH-8531.a.

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 in:~~

~~1. Nuclear medicine by the American Board of Nuclear Medicine;~~

~~2. Diagnostic radiology by the American Board of Radiology RH-8540.;~~

~~3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~

~~4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~5. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or~~

~~b. Has had classroom and laboratory training in basic radioisotope handling~~

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~~techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:~~

~~1. 200 hours of classroom and laboratory training that includes:~~

~~A. Radiation physics and instrumentation;~~

~~B. Radiation protection.~~

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

~~D. Radiation biology; and~~

~~E. Radiopharmaceutical chemistry; and~~

~~2. 500 hours of supervised work experience, under the supervision of an authorized user who meets the requirements of RH 8540., RH 8560. or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:~~

~~A. Ordering, receiving, and unpacking radioactive materials safely and performing 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 and safely preparing patient or human research subject dosages;~~

~~D. Using administrative controls to prevent the misadministration of radioactive material;~~

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

~~F. Eluting technetium-99m from generator systems, measuring and testing the elute for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and~~

~~3. 500 hours of supervised clinical experience, under the supervision of an authorized user who meets the requirements of RH 8540., RH 8560., or equivalent Agreement State, or Nuclear Regulatory~~

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~~Commission requirements, involving:~~

~~A. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;~~

~~B. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~C. Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~D. Collaborating with the authorized user in the interpretation of radioisotope test results; and~~

~~E. Patient or human research subject follow up; or~~

~~c. Has successfully completed a six month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in RH-8540.b.~~

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 have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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.; 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

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

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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:

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 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;

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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. and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500. and RH-8530.*

PART F:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE REQUIRED

~~**Specific Requirements for the Use of 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 ~~for diagnostic or therapeutic~~ *prepared for* medical use *and* for which a written directive is required that ~~has been~~ *is*:

~~a. Obtained from a manufacturer or preparer licensed in accordance with Section 2 of these regulations; or~~

~~b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RH-8540 or RH-8560; or~~

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

c. Obtained from and prepared by a Department, Nuclear Regulatory Commission, or Agreement State licensee 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 in accordance with a Radioactive Drug Research Committee-approved application or an 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 radioactive material for the uses authorized under RH-8550. to be a physician who:

~~a. Is certified by:~~

~~1. The American Board of Nuclear Medicine;~~

~~2. The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;~~

~~3. The American Osteopathic Board of Radiology after 1984;~~

~~4. The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or~~

~~b. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use therapeutic radiopharmaceuticals, and supervised clinical experience as follow:~~

~~1. 80 hours of classroom and laboratory training that includes:~~

~~A. Radiation physics and instrumentation;~~

~~B. Radiation protection;~~

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

~~D. Radiation biology; and~~

~~2. Supervised clinical experience under the supervision of an authorized user who meets the requirements in RH-8560. or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of RH-8560.b. must have experience in administering dosages in the same dosage category or categories listed in RH-8560.b.2.A. as the individual requesting authorized user status. The supervised clinical experience must involve administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three 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 beta emitter or photonemitting radionuclide with a photon energy 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.~~

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 b.1.B.vii. and b.2. of RH-8560. (Specialty boards whose certification processes have been

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recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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. 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 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

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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:

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 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 involving a minimum of three 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;*

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(c). Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy 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 paragraphs a.1. and b.1.B.vii. or b.1. of RH-8560. and has achieved a level of competency sufficient to function independently as an authorized user for the 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., 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.

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 an authorized user under RH-8560.a., RH-8560.b. for uses listed in RH-8560.b.2.A.i.or ii., RH-8580., or equivalent Agreement State or Nuclear Regulatory Commission requirements; or~~

~~b. 1. Be a physician with special experience in thyroid disease that has completed 80 hours 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. Radiation biology; and~~

~~2. Has supervised clinical experience, under the supervision of an authorized user who is an authorized user under RH-8570. or who meets the requirements listed in RH-8570.a., or equivalent Agreement State, or Nuclear Regulatory Commission requirements. The clinical experience must include 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.~~

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. 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 have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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

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

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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 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., and has achieved a level of competency sufficient to function independently as an authorized user 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).

RH-8580. Training for the Oral Administration of Sodium Iodide I-131 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 an authorized user under RH-8560.a., RH-8560.b. for the uses listed in RH-8560.b.2.A.ii., or equivalent Agreement State or Nuclear Regulatory Commission requirements; or~~

~~b. 1. Be a physician with special experience in thyroid disease that has completed 80 hours 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. Radiation biology; and~~

~~2. Has supervised clinical experience, under the supervision of an authorized user who is an authorized use under RH-8580. or who meets the requirements listed in RH-8580.a., or equivalent Agreement State, or Nuclear Regulatory Commission requirements. The clinical experience must include 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.~~

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., 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 have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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

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 inRH-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 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., and has achieved a level of competency sufficient to function independently as an authorized user 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

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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).

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

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. *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. *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.; or*

c. *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.*

d. *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. 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*

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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 administration, 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. 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 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 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 3 cases involving the parenteral administration, 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 paragraph b. or c. of RH-8590., and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a*

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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).

PART G: MANUAL BRACHYTHERAPY

~~**Manual Brachytherapy**~~

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 in:~~

~~1. Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;~~

~~2. Radiation oncology by the American Osteopathic Board of Radiology;~~

~~3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or~~

~~4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~

~~b. Has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:~~

~~1. 200 hours of classroom and laboratory training, that includes:~~

~~A. Radiation physics and instrumentation;~~

~~B. Radiation protection;~~

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

D. Radiation biology; and

2. 500 hours of supervised work experience, under the supervision of an authorized user who meets the requirements of RH 8610. or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

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

B. Check survey meters for proper operation;

C. Preparing, implanting, and removing sealed sources;

D. Maintaining running inventories of material on hand;

E. Using administrative controls to prevent the misadministration of radioactive material;

F. Using emergency procedures to control radioactive material; and

3. Three (3) years of supervised clinical experience that includes one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user who meets the requirements of RH 8610. This experience may be obtained concurrently with the supervised work experience required by RH 8610.b.2. The supervised clinical experience must include:

A. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindictions;

B. Selecting the proper brachytherapy sources and dose and method of administration;

C. Calculating the dose; and

D. Post-administration follow-up and review of case histories

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~~in collaboration with the authorized user.~~

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 have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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 on Post-Graduate Training of the American Osteopathic Association; and*

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

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

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

i. Radiation physics and instrumentation;

ii. Radiation protection;

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

iv. Radiation biology; and

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

B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

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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 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 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 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.; 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. and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RH-8600.

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

Except as provided in RH-8318., the licensee shall require ~~an~~ *the* authorized user of ~~a~~ strontium-90 ~~source~~ for ophthalmic ~~uses authorized under RH-8600.~~ *radiotherapy* to be a physician who:

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

~~b. 1. Has completed twenty-four (24) hours of classroom and laboratory training applicable to the medical use of strontium-90 for 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 supervision of an authorized user who meets the requirements of RH-8610. or RH-8615. and that includes the use of strontium-90 for the ophthalmic treatment of five (5) individuals that includes:~~

~~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.~~

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

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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 paragraph b. of RH-8615. and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.*

PART H:
SEALED SOURCES FOR DIAGNOSIS

~~**Sealed Sources For Diagnosis**~~

RH-8621. Training for Use of Sealed Sources for Diagnosis.

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

~~a. Is certified in:~~

~~1. Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;~~

~~2. Nuclear medicine by the American Board of Nuclear Medicine;~~

~~3. Diagnostic radiology or radiology by the American Osteopathic~~

~~Board of Radiology; or~~

~~4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~b. Has had eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:~~

~~1. Radiation physics and instrumentation;~~

~~2. Radiation protection;~~

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

~~4. Radiation biology; and~~

~~5. Training in the use of he device for the uses requested.~~

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

b. 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

c. 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

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~~Photon Emitting Remote Afterloader Units, Teletherapy Units, And Gamma Stereotactic Radiosurgery Units~~

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 in:~~

~~1. Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;~~

~~2. Radiation oncology by the American Osteopathic Board of Radiology;~~

~~3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Facility of Radiology" or "Fellow of the Royal College of Radiology", or~~

~~4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~

~~b. Has had classroom and laboratory training in radioisotope handling techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows:~~

~~1. 200 hours of classroom and laboratory training that includes:~~

~~A. Radiation physics and instrumentation;~~

~~B. Radiation protection;~~

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

~~D. Radiation biology; and~~

~~2. 500 hours of supervised work experience, under the supervision of and authorized user who meets the requirements of RH-8610. or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:~~

A. Review of the full calibration measurements and periodic spot checks;

B. Preparing treatment plans and calculating treatment times;

C. Using administrative controls to prevent the is administration of radioactive material;

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

E. Checking and using survey meters; and

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

3. Three (3) years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user who meets the requirements of RH 8610. This experience may be obtained concurrently with the supervised work experience required by RH 8610.b.2. The supervised clinical experience must include:

A. Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

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

C. Calculating the doses and collaborating with the authorized user in the review of the patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

D. Post-administration follow up and review of case histories. The licensee shall require an authorized user of a sealed source for a use authorized under RH 8630. to be a physician who has met the training and experience requirements outlined in 10 CFR Part 35 Subpart J 35.960.

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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 b.3. and c. of RH-8660. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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 on Post-Graduate 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, involving:*

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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 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 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.; 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., and has achieved a level of competency sufficient to function independently 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*

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*

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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.

PARTS J – K
[RESERVED]

PART L:
OTHER MEDICAL USES OF RADIOACTIVE MATERIAL
OR RADIATION FROM RADIOACTIVE MATERIAL

~~**Other Medical Uses of Radioactive Material or Radiation from Radioactive Material**~~

PART M:
RECORDS

~~**Records**~~

RH-8705. Records of ~~Calibrations~~ *Checks and Tests* of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

A licensee shall maintain a record of instrument ~~calibrations~~ *checks and tests* required by RH-8401. for three (3) years, *excluding geometry test records where only the most current record must be maintained.* The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

RH-8713. Records of ~~Radionuclide Purity~~ *Molybdenum-99, Strontium-82, and Strontium-85 Concentrations*.

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by RH-8531. for three (3) years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicuries), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicuries), the time and date of the measurement, and the name of the individual who made the measurement.

PART N:
REPORTS