EXHIBIT H

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Required for NRC Compatibility

- NRC RAT ID #2001-1

  Generally Licensed Industrial Devices Containing Byproduct Material Regulations addressing "Import" and "Export" Requirements and other minor changes; (RH-402.a., b., c. & d.)

- NRC RAT ID #2004-1

  Requirements for 'Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments' (Section 4 "Transportation of Radioactive Material") (RH-3000- 3999)

- MEDICAL

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Required for NRC Compatibility (con't)

Housekeeping

RATS ID
#2001-1

RH-402. General Licenses - Other Radioactive Materials.

~~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 3., and Section 4 of these Regulations~~

~~b.~~ ~~1. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere. *~~

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

a. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere. * [31.5]

* Persons possessing radioactive material in devices under a general license in RH-402 [31.5] before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of RH-402. [31.5] 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., [31.5 (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.

~~2.~~ b 1. The general license in ~~RH-402.b.1~~. RH-402.a. [31.5 (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. [32.51] or

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

C. **An equivalent specific license issued by a State with provisions comparable to RH-405.e. [32.51]**

2. The devices must have been received from one of the specific licensees described in above in ~~RH-402.b.2.A~~. RH-402.b.1. [31.5 (b) (1)] or through a transfer made under ~~RH-402.b.3.H~~. RH-402.c.9. [31.5 (c) (9)]

~~3.~~ 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. [31.5 (a)]:

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

~~B.~~ 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;

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

~~ii.~~ 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;

~~C.~~ 3. Shall assure that the tests required by ~~RH-402.b.3.B~~ RH-402.c.2 **[31.5 (c)(2)]** and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment, are performed;

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

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

~~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.** **[31.5 (c)(2) & (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:

i. Each record of a test for leakage or radioactive material required by ~~RH-402.b.3.B.~~ RH-402.c.2. **[31.5 (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.

ii. Each record of a test of the on-off mechanism and indicator required by ~~RH-402.b.3.B.~~ RH-402.c.3. **[31.5 (c)(2)]** ~~section~~ 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.

iii. Each record that is required by ~~RH-402.b.3.B~~ RH-402.c.2. **[31.5 (c)(2)]** ~~section~~ must be retained for three (3) years from the date of the recorded event or until the device is transferred or disposed of.

~~E.~~ 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 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:

Arkansas Department of Health ~~& Human Services~~
Radiation Control
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**

Under these circumstances, the criteria set out in RH-1218., **[20.1402]** ''Radiological criteria for unrestricted use,'' may be applicable, as determined by the Department on a case-by-case basis;

~~F.~~ 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 (NRC) Regulations outlined in Part 110 – "Export and Import of Nuclear Equipment and Material";

RH-402.c. (Cont'd)

~~G.~~ **8.** ~~i.~~ Shall transfer or dispose of the device containing radioactive material only **by export as provided by U.S. Nuclear Regulatory Commission (NRC) Regulations outlined in Part 110 – "Export and Import of Nuclear Equipment and Material"** by transfer to another general licensee as authorized by **RH-402.c.2 [31.5 (c)(2)]** ,or to a person authorized to receive the device by a specific license issued under 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.c.8.iii [31.5 (c)(8)(iii)]**

ii. ~~Shall furnish a report to~~:

~~Arkansas Department of Health & Human Services~~
~~Radiation Control~~
~~ATTN: General License Registration Program~~
~~P.O. Box 1437, Mail Slot H-30~~
~~Little Rock, Arkansas 72203-1437~~

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

Shall within thirty (30) day after the transfer of the device to a specific licensee or export furnish a report to:

Arkansas Department of Health
Radiation Control
ATTN: General License Registration Program
4815 West Markham Street
Mail Slot #30
Little Rock, Arkansas 72205

The report must contain:

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

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

RH-402.c. (Cont'd)

(c). The date of the transfer.

iii. Shall obtain written Department approval before transferring the device to any other specific licensee not specifically identified in RH-402.c.8.i. [31.5 (c)(8)(i)] 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:

(A) 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;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RH-402.c.1.) [31.5 (c)(1)]; so that the device is labeled in compliance with RH-1303.h. [20.1904]; however the manufacturer, model number, and serial number must be retained;

(C) 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

(D) Reports the transfer under RH-402.c.8.ii [31.5 (c)(8)(ii)]

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

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

Arkansas Department of Health ~~& Human Services~~
Radiation Control
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**

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

(b). The model number and the serial number of the device transferred;

(c). The transferee's name and mailing address for the location of use; and

(d) 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. [31.5 (c)(12)]**to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

ii. 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 [20.2201]and RH-1502 [220.2202] for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from other requirements of Section 3 of these Regulations.

~~J.~~ 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.

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

~~L.~~13. i. Shall register, in accordance with ~~RH-402.b.3.L.ii. and iii.~~ **RH-402.c.13.ii and iii. [31.5 (c)(13)(ii) and (iii)]** 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, 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 l location of use, as described under ~~RH-402.b.3.m.iii.~~, **RH-402.c.13.iii. [31.5 (c)(13)(iii)(D)],** represents a separate general licensee and requires a separate registration and fee.

ii. If in possession of a device meeting the criteria of ~~RH-402.b.3.L.i.~~ **RH-402.c.13.i. [31.5 (c)(13)(i)],** 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.L.i.~~ **RH-402.c.13.i. [31.5 (c)(13)(i)],** is subject to the bankruptcy notification requirement in RH-409.g.

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

(a). Name and mailing address of the general licensee.

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

(c). Name, title, and telephone number of the responsible person designated as a representative of the general licensee under ~~RH-402.b.3.K~~. **RH-402.c.12. [31.5 (c)(12)]**

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

(e). 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.

(f). Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

iv. Persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State with respect to devices meeting the criteria in ~~RH-402.b.3.L.i~~. **RH-402.c.12. [31.5 (c)(12)]**are subject to registration requirements if the devices are used in areas subject to Arkansas Department of Health ~~and Human Services~~ jurisdiction. The Department will request registration information from such licensees

~~M~~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
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

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.

~~N.~~ 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. 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 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.

~~4.~~d. The general license in ~~RH-402.b.1~~. **RH-402.b.1 [31.5 (a)]** does not authorize the manufacture **or import** of devices containing radioactive material.

5. The general license provided in this Paragraph 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-4012. and Section 4.

RATS ID #2004-1

SECTION 4.

TRANSPORTATION OF RADIOACTIVE MATERIALS
(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A.

GENERAL

RH-3000. Authority. Act 8 of Second Extraordinary Session of 1961, as amended.

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

RH-3002 [§ 71.0]. Purpose and Scope.

a This part 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 part are in addition to, and not in substitution for, other requirements.

c. The regulations in this part apply to any licensed authority by specific or general license issued by the Department to receive, possess, use, or transfer licensed material to a carrier for transport, transports the material outside the site of usage as specified in the Department's license, or transports that material on public highways. No provision of this part authorizes the possession of licensed material.

~~d. Exemptions from the requirement for license in RH-3200. are specified in RH-3300.~~

d. 1. Exemptions from the requirement for license in RH-3304 [§ 71.3] are specified in RH-3301 [§ 71.14]. General licenses for which no NRC package approval is required are issued in RH-3304 [§ 71.20] through RH-3306). [§ 71.23] The general license in RH-3301 [§ 71.17] 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 70, subpart D 'Application for Package Approval', demonstrating that the design of the package to be used satisfies the package approval standards contained in with U.S. Nuclear Regulatory Commission Regulations in Part 70, subpart E 'Package Approval Standards', as related to the tests of with U.S. Nuclear Regulatory Commission Regulations in Part 70, 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 'Operating Controls and Procedures'; the quality assurance requirements of Part G 'Quality Assurance'; and the general provisions of Part A 'General Provisions', including DOT regulations referenced in RH-3005 [§ 71.5].

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

RH-3002. (Cont'd)

e. f. The regulations of this part 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.

~~f.~~g. This part 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, 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. [§ 71.1]. 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 Little Rock, Arkansas 72203-1437~~. **4815 West Markham Street, Slot H-30, Little Rock, Arkansas 72205.**

b. **Each record required by this part must be legible throughout the retention period specified by each Department regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of 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**

RH-3004 [§ 71.3]. Requirement for license. Except as authorized in a general license or a specific license e issued by the Department, or as exempted in this part, no licensee may:

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

b. Transport licensed material.

RH-3005 [§ 71.5]. Transportation of Radioactive Material

a. Each licensee who transports licensed material outside the site of 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 comply with the applicable requirements of the DOT regulations in 49 CFR parts 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:

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

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

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

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

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

vi. Hazardous material employee training--49 CFR part 172 subpart H.

vii. Security plans--49 CFR part 172: subpart I.

viii. 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:

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

ii. Air--49 CFR part 175.

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

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

b. If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in RH-3005.a. of this section to the same extent as if the shipment or transportation were subject to 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.

~~RH-3004~~. RH-3006 - RH-3099. Reserved.

PART B. DEFINITIONS

RH-3100. **[§ 71.4].** 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 part 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 part, either unit may be used.

RH-3100. **[§ 71.4].** General Definitions. (con't)

a. A_1 - Maximum activity of special form of radioactive material permitted in a Type A package. These values are either listed in RH-2700., Table C-1 or may be derived in accordance with the procedure prescribed in RH-2700., Appendix C.

b. A_2 - Maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in RH-2700., Table C-1 or may be derived in accordance with the procedure prescribed in RH-2700., Appendix C.

c. Carrier - A person engaged in the transportation passengers or property by land or water as a common, or contract, or private carrier, or by civil aircraft.

d. Certificate Holder - a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

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.**

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

~~f.~~g. Close reflection by water - immediate contact by water of sufficient thickness for maximum reflection of neutrons.

h. Consignment means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

~~g.~~i. Containment system - the assembly of components of the packaging intended to retain the radioactive material during transport.

RH-3100. **[§ 71.4].** General Definitions. (con't)

~~h.~~**j.** Conveyance –

1. 'For transport by public highway or rail' any transport vehicle or large freight container;

2. 'For transport by water' any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

3. 'For transport by aircraft' any aircraft.

k. **Criticality Safety Index (CSI) - means 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. [§§ 71.22, 71.23, and 71.59]**

l. **Deuterium means, for the purposes of RH-3302 and RH-3305, [§§ 71.15 and 71.22] (deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.**

m. **DOT means the U.S. Department of Transportation.**

~~i.~~**n.** Exclusive use (also referred to in other regulations as "sole"). The sole use of a conveyance by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must-issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided by the consignor.

RH-3100. **[§ 71.4].** General Definitions. (con't)

~~j.~~o. Fissile material - ~~Plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of the radionuclides.~~

the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of 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-3302. [§71.15]**

p. Graphite means, for the purposes of RH-3302 and RH-3305, [§§ 71.15 and 71.22] graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

~~k.~~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.

~~l.~~r. Low Specific Activity (LSA) - radioactive material with limited specific activity **which is nonfissile or is excepted under RH-3302 [71.15] and which** ~~that~~ 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 containing only naturally occurring radioactive radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or~~

Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides 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; ~~or~~

C. ~~Radioactive material, other than fissile material, for which the A_2 value is unlimited; or, contaminated earth, concrete, rubble, other debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10 E-6 A_2/g.~~ **Radioactive material for which the A_2 value is unlimited or**

D. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with RH-2700 APPENDIX C '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

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

3. LSA-III. Solids (e.g., consolidated wastes, activated materials) **excluding powders, that satisfy the requirements of the NRC Regulation § 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 A_2/g~~ **2 X 10^{-3} A_2/g**.

~~r.~~**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.

~~s.~~**t.** Maximum normal operating pressure - the maximum gauge pressure that would develop in the containment system in a period of one (1) year under the heat condition specified in 10 CFR 71.71(c)(1) in the absence of venting, external cooling by an ancillary system or operational controls during transport.

~~t.~~**u.** Natural thorium - Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

~~u.~~**v.** Normal form radioactive material - Radioactive material that has not been demonstrated to qualify as "special form radioactive material".

~~v.~~**x.** Optimum interspersed hydrogenous moderation - The presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

RH-3100. **[§ 71.4].** General Definitions. (con't)

~~r.~~**y.** 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.**

~~2.~~**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/in^2) 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 or 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.~~ **10 CFR 71.19.**

~~s.~~**z.** Packaging - Assembly of components necessary to ensure compliance with the packaging requirements of this Part. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

RH-3100. **[§ 71.4].** General Definitions. (con't)

~~t.~~aa. 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~~ 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 10CFR 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.

~~u.~~ab. Specific activity of a radionuclide - The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

ac. **Spent nuclear fuel or Spent fuel -- Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 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.**

~~v.~~ad. State - A State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

RH-3100. **[§ 71.4].** General Definitions. (con't)

~~w.~~ae. Surface Contaminated Object (SCO) - A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two (2) groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:

   A. The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-4} microcurie/cm^2 (4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/cm^2 (0.4 Bq/cm^2) for all other alpha emitters; and

   B. The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 ($4X10^4$ Bq/cm2) for beta and gamma and low toxicity alpha emitters, or 20.1 microcurie/cm^2 ($4X10^3$ Bq/cm) all other alpha emitters; and

   C. The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 (4X104 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 ($4X10^3$Bq/cm^2) all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-1 are exceeded and on which:

   A. The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-2} microcurie/cm^2 (400 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-3} microcurie/cm^2 (40 Bq/cm^2) all other alpha emitters;

B. The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcurie/cm^2 ($8X10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm^2 ($8X10^4$ Bq/cm^2) all other alpha emitters; and

C. The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcurie/cm^2 ($8X10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm^2 ($8X10^4$Bq/cm^2) all other alpha emitters.

~~x.~~af. 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)).

RH-3100. **[§ 71.4].** General Definitions. (con't)

~~y.~~**ag.** Type A quantity - A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Section 3, RH-2700., Table C-1 of this Part or may be determined by procedures described in Appendix C of this Part.

~~z.~~**ah** Type B quantity ~~means~~ -- A quantity of radioactive material greater than a Type A quantity.

ai. **Unirradiated uranium means 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.**

~~aa.~~**aj.** Uranium - natural, depleted, enriched.

1. Natural uranium.
   Uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

2. Depleted uranium.

   Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

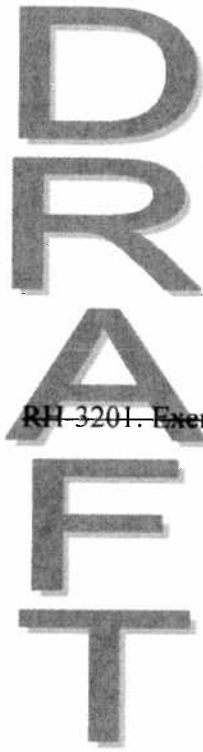
3. Enriched uranium.

   Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

RH-3101.- RH-3199. Reserved.

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

~~RH-3200. 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, no licensee may:~~

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

~~b. Transport licensed material.~~

~~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-3202.~~ ~~Transportation of Radioactive Material.~~

~~a.~~ ~~Each licensee who transports licensed material outside of the confines of the licensee's plant or other place of use, 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 regulations of DOT 49 CFR Parts 170 through 189; and~~

~~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 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 to the same extent as if the shipment was subject to the regulations.~~

~~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:~~

RH-3203.b.3. (Cont'd)

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.

~~RH-3203.b. (Cont'd)~~

~~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-3204.- RH-3299. Reserved.~~

~~PART D. EXEMPTIONS AND ADDITIONAL REQUIREMENTS~~

PART C. EXEMPTIONS

~~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.~~

RH-3300. **[§ 71.12].** 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 part that it determines is authorized by law and will not endanger life or property nor the common defense and security.

RH-3301. [§ 71.13]. Exemption of Physicians

Physicians, as defined in RH-200., licensed by the State of Arkansas to dispense drugs in the practice of medicine is exempt from RH-3005 [§ 71.5] 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 CFR Part 35 Regulations or the equivalent Agreement State Regulations.

RH-3302*. [§ 71.14]. Exemption for Low-Level Radioactive Materials

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

1. 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 RH-2700 Appendix C, 'Determination of A_1 and A_2 ', Table A-2, of this part.

2. Materials for which the activity concentration is not greater than the activity concentration values specified in RH-2700 Appendix C, 'Determination of A_1 and A_2 ', Table A-2 of this part, or for which the consignment activity is not greater than the limit for an exempt consignment found in RH-2700 Appendix C, 'Determination of A_1 and A_2 ', Table A-2, of this part.

RH-3303*. [§ 71.15]. Exemption from Classification as Fissile Material

Fissile material meeting the requirements of at least one of the paragraphs RH-3302.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 part, except as noted.

RH-3303*. [§ 71.15]. Exemption from Classification as Fissile Material (con't)

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:

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

ii. 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 1 percent by weight, and with total plutonium and uranium-233 content of up to 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 5 percent of the uranium mass.

e. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 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 2. The material must be contained in at least a DOT Type A package.

RH-3303*. [§ 71.15]. Exemption from Classification as Fissile Material (con't)

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. 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, 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.~~

~~RH-3302.~~ **RH-3401*** **[§ 71.17].** 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 (NRC).

b. **This general license applies only to a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying Part F 'Quality Assurance'.**

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

1 Has a copy of ~~the specific license,~~ 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 the NRC Regulation § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.**

~~c.~~d. The general license in ~~RH-3302.a.~~ **RH-3401.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.~~

~~RH-3302~~. RH-3401* [§ 71.17]. General License For NRC Approved Packages. (con't)

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 RH-3302.

~~RH-3303. General License For Previously Approved Type B Packages.~~

RH-3402.* [§ 71.19]. General License For Previously Approved Packages.

a. A Type B package previously approved by the NRC, but not designated as B(U), ~~or~~ B(M), B(U)F, or B(M)F in the NRC Certificate of Compliance, (CoC) or Type AF packages approved by the NRC prior to September 6, 1983, may be used under the general license of ~~RH-3302~~. RH-3401* with the following additional ~~limitations~~ conditions:

1. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with NRC regulations; ~~and~~

~~2. The package may not be used for a shipment to a location outside the United States, except approved under special arrangement in accordance with 49 CFR 173.477.~~

2. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging; and

3. RH-3402.a.* expires October 1, 2008.

b. A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC but without the designation "- 85" in the identification number of the NRC CoC, may be used under the general license of RH-3301 with the following additional conditions:

RH-3402.* [§ 71.19]. General License For Previously Approved Packages. (con't)

1. Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with RH-3602.c. [71.85(c)];

2. A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT Regulations at 49 CFR 173.403; and

3. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

c. A Type B(U) package, a Type B(M) package, or a fissile material package previously approved by the NRC with the designation "-85" in the identification number of the NRC CoC, may be used under the general license of RH-3301 with the following additional conditions:

1. Fabrication of the package must be satisfactorily completed by December 31, 2006, as demonstrated by application of its model number in accordance with RH-3602.c. [§ 71.85(c)]; and

2. After December 31, 2003, a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403.

d. NRC will approve modifications to the design and authorized contents of a Type B package, or a fissile material package, previously approved by NRC, provided:

1. The modifications of a Type B package are not significant with respect to the design, operating characteristics, or safe performance of the containment system, when the package is subjected to the tests specified in NRC Regulations §§ 71.71 and 71.73;

RH-3402.* [§ 71.19]. General License For Previously Approved Packages. (con't)

2. The modifications of a fissile material package are not significant, with respect to the prevention of criticality, when the package is subjected to the tests specified in NRC Regulations N§§ 71.71 and 71.73; and

3. The modifications to the package satisfy the requirements of this Part.

e. NRC will revise the package identification number to designate previously approved package designs as B, BF, AF, B(U), B)M)F, B(U)-85, B(U)F-85, B(M)-85, B(M)F-85 or AF-85 as appropriate, and with the identification number suffix "-96" after the receipt of an application demonstrating that the design meets the requirements of this Part.

~~RH-3304.~~ RH-3403* [§ 71.20]. General License For DOT Specification Container.

a. A general license is hereby issued to any licensee to transport or to deliver to a carrier for transport licensed material in a specification container for fissile material or a Type B quantity of radioactive material as specified in the regulations of the U.S. Department of Transportation in 49 CFR Parts 173 and 178.

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-3500. (NOTE: NRC of subpart H of this part).

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

1. Has a copy of the specification;

2. Complies with the terms and conditions of the specification and the applicable requirements of this Section; and

~~3. Has a quality assurance program required by RH-3500.~~

~~c.~~d. This general license in RH-3304.a. is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in the U.S. Department of Transportation's regulation 49 CFR 173.403.

~~RH-3305.~~ **RH-3404*[§ 71.21].**General License For Use of Foreign Approved Package.

a. A general license is hereby issued to any licensee 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*. (NOTE: NRC of subpart H of this part).

~~b.~~**c.** This general license applies only to ~~international~~ shipments **made to and from locations outside the United States.**

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

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;

2 Complies with the terms and conditions of the certificate and revalidation and with applicable requirements of this Section; and

~~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.~~

RH-3405*. [§ 71.22]. 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 transfer, without complying with the package standards of this Section, if the material is shipped in accordance with this Section.~~

RH-3405*. [§ 71.22]. General License: Fissile Material. (con't).

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 this part entitled 'Package Approval Standards' (RH-3500*) and NRC Part 71 Transportation Regulations 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 Part G, 'Quality Assurance'.

~~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.~~

RH-3405*. [§ 71.22]. General License: Fissile Material. (con't).

~~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 plutonium-beryllium sources authorized in RH-3306.c., 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-3405*. [§ 71.22]. General License: Fissile Material. (con't).

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 RH-3405.e. [71.22(e)]

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).

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

RH-3405*. [§ 71.22]. General License: Fissile Material. (con't).

5. Table 71-1 values for X, Y, and Z must be used to determine the CSI if:

i. Uranium-233 is present in the package;

ii. The mass of plutonium exceeds 1 percent of the mass of uranium-235;

iii. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment or

iv. 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-3405.e. [§ 71.22(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-3405.e. [§ 71.22(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
Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X) (grams)
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-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.

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 plutonium-beryllium 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

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	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
Uranium-235 (X)	500	290
Other fissile material (Y)	300	180

~~RH-3307. (Con t'd)~~

~~e. Except for the beryllium contained within the special form plutonium-beryllium 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.~~

~~RH-3308. RH-3399. Reserved.~~

RH-3406* [§ 71.23].General license: Plutonium-beryllium special form material.

a. A general license is issued to any licensee of the Commission 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 subparts E and F of this part; 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 Part G, 'Quality Assurance'.

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.

RH-3406*(Cont'd) [§ 71.23].General license: Plutonium-beryllium special form material.

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).

e. 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10 \left[\frac{\text{grams of } {}^{239}\text{Pu} + \text{grams of } {}^{241}\text{Pu}}{24} \right]$$

2. The calculated CSI must be rounded up to the first decimal place.

PART E PACKAGE APPROVAL STANDARDS

RH- 3500* [71.47] External radiation standards for all packages.

a. Except as provided in RH-3500.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-3500.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):

i. The shipment is made in a closed transport vehicle;

ii. The package is secured within the vehicle so that its position remains fixed during transportation; and

iii. 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

RH- 3500* [71.47] External radiation standards for all packages. (con't)

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

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. [10 CFR 20.1502 (Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.)]

c. For shipments made under the provisions of RH-3500.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.

PART F OPERATING CONTROL AND PROCEDURES

RH-3600* [§ 71.81] 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, 'Quality Assurance' and with the general provisions of Part A of these transportation regulations.

RH-3601* [§ 71.83] 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-3602* [§ 71.85] 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.

~~Part E. Enforcement~~

~~RH-3400. Deleted.~~

~~RH-3401.~~ RH-3603* [§ 71.87] Routine Determination.

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:

~~RH-3401.~~ **RH-3603*** **[§ 71.87]** Routine Determination. **(con't)**

a. The package is proper for the contents to be shipped;

b. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

c. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

d. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

e. Any pressure relief device is operable and set in accordance with written procedures;

f. The package has been loaded and closed in accordance with written procedures;

g. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

~~g.~~ **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 **Regulation §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~~

~~RH-3401.~~ RH-3603* [§ 71.87] Routine Determination. (con't)

~~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-3500 [§ 71.47] at any time during transportation; and**

k. **Accessible package surface temperatures will not exceed the limits specified in U.S. Nuclear Regulatory Commission Regulation § 71.43(g) at any time during transportation.**

~~RH-3402.~~ **RH-3604* [§ 71.88]** 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 **49 CFR Chapter 1, whether for import, export, or domestic shipment**, is not transported by air, or delivered to a carrier for air transport, unless:

~~RH-3402.~~ **RH-3604*** **[§ 71.88]** Air Transport of Plutonium.

~~a.~~ 1. The plutonium is contained in a medical device designed for individual human application; or

~~b.~~ 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 RH-2700, Appendix C, 'Determination of A_1 and A_2', Table A-2, [NRC Appendix A],** and in which the radioactivity is essentially uniformly distributed; or

~~c.~~ 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-3202~~ **RH-3005, [§ 71.5]** 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 49CFR 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-3604.a. [§ 71.88(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 the U.S. Nuclear Regulatory Commission's Regulation § 73.24 'Prohibitions'.**

c. **For a shipment of plutonium by air which is subject to RH-3604.a.4., [§ 71.88(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-3605* [§ 71.89] 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.e. [10 CFR 20.1906(e)].

~~RH-3606*~~ [§ 71.91] ~~RH-3403.~~ Records.

a. Each licensee shall maintain for a period of ~~two (2)~~ three (3) years after shipment a record of each shipment of licensed material not exempt under ~~RH-3201~~. U.S. Nuclear Regulatory Commission Regulation § 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:

   i. Identification by model number and serial number;

   ii. Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

   iii. Any abnormal or unusual condition relevant to radiation safety;

~~6.5.~~ ~~Date of the shipment;~~

7. For fissile packages and for Type B packages, any special controls exercised;

~~6.~~ 8. Name and address of the transferee;

~~7.~~ 9. Address to which the shipment was made; and

~~8.~~ 10. Results of the determinations required by ~~RH-3401~~ RH-3603* [§ 71.87] 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.~~

~~c. The licensee shall report to the Department within thirty (30) days:~~

~~Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and~~
~~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.~~

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.

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 part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

RH-3606* [§ 71.91] ~~RH-3403.~~ Records. (con't)

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-3602* [§ 71.85]; 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-3607* [§ 71.93] Inspection and tests.

a. The licensee, certificate holder, and applicant for a CoC shall permit the U.S. Nuclear Regulatory Commission, 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 U.S. Nuclear Regulatory Commission to perform, any tests the U.S. Nuclear Regulatory Commission deems necessary or appropriate for the administration of the regulations in this Section.

c. The certificate holder and applicant for a CoC shall notify the U.S. Nuclear Regulatory Commission (NRC), in accordance with NRC Regulation §71.1 (Arkansas 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:

i. A decay heat load in excess of 5 kW; or

ii. A maximum normal operating pressure in excess of 103 kPa (15 lbf/in^2) gauge.

RH-3608* [§ § 71.95] Reports.

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.

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 [§ 71.1], 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. [§ 71.1(a)], the licensee shall report to:

Arkansas Department of Health
Radiation Control
4815 West Markham Street Slot #30
Little Rock, Arkansas 72205-3867

AND

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.

2. A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of SECTION 4 and NRC 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.

   i. Status of components or systems that were inoperable at the start of the event and that contributed to the event;

   ii. Dates and approximate times of occurrences;

   iii. The cause of each component or system failure or personnel error, if known;

   iv. The failure mode, mechanism, and effect of each failed component, if known;

   v. A list of systems or secondary functions that were also affected for failures of components with multiple functions;

   vi. The method of discovery of each component or system failure or procedural error;

vii. For each human performance-related root cause, a discussion of the cause(s) and circumstances;

viii. The manufacturer and model number (or other identification) of each component that failed during the event; and

ix. 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.

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-3609*[§ 71.97] ~~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);~~

RH-3609*[§ 71.97] ~~RH-3405. Advance Notification of Transport of Nuclear Waste.2/~~

~~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.~~

RH-3609* [§ 71.97] Advance notification of shipment of irradiated reactor fuel and nuclear waste.

a. As specified in RH-3609.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 the U.S. Nuclear Regulatory Commission's Regulation § 73.37(f). 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 part to be in Type B packaging for transportation;

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

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

i. 3000 times the A_1 value of the radionuclides as specified in RH-2700 Appendix C, 'Determination of A_1 and A_2 ', Table A-1 for special form radioactive material;

ii. 3000 times the A_2 value of the radionuclides as specified in RH-2700 Appendix C, 'Determination of A_1 and A_2 ', Table A-1 for normal form radioactive material; or

iii. 1000 TBq (27,000 Ci).

RH-3609* [§ 71.97] Advance notification of shipment of irradiated reactor fuel and nuclear waste. (Con't)

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 Nuclear Security, 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.

   i. 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).

   ii. The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

   iii. 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.

RH-3609* [§ 71.97] Advance notification of shipment of irradiated reactor fuel and nuclear waste. (con't).

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.

RH-3609* [§ 71.97] Advance notification of shipment of irradiated reactor fuel and nuclear waste. (con't).

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 Nuclear Security, Office of Nuclear Security and Incident Response.

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.

RH-3610* – RH-3699* Reserved

~~PART F.~~ PART G. QUALITY ASSURANCE

~~RH-3500.~~ RH-3700*. [§ 71.101] 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.~~

~~RH-3500~~. RH-3700*. [§ 71.101] Quality Assurance Requirements.

~~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.~~

PART G. QUALITY ASSURANCE

RH-3700*. [§ 71.101] Quality Assurance Requirements.

a. Purpose.

This subpart 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 subpart, "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.

RH-3700*. [§ 71.101] Quality Assurance Requirements. (con't)

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 §§ 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.

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., [71.1(a)] each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this Part G are applicable and how they will be satisfied, by submitting the description to:

Arkansas Department of Health
Radiation Control
4815 West Markham Street Slot #30
Little Rock, Arkansas 72205-3867

AND

U.S. Nuclear Regulatory Commission:
ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

RH-3700*. [§ 71.101] Quality Assurance Requirements. (con't)

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 or in NRC Regulation's Appendix B of part 50 or in NRC Regulation's or subpart G of part 72 and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of RH-3700.b. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the U.S. Nuclear Regulatory Commission in accordance with NRC § 71.1, of its intent to apply its previously approved Arkansas Regulation's Part G or NRC Regulations within above referenced subpart H, Appendix B, or subpart G 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.

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. [NRC § 34.31(b)] or equivalent Agreement State requirement, is deemed to satisfy the requirements of RH-3301.b. and RH-3600.b. [NRC §§ 71.17(b) and 71.101(b).]

~~RH-3501. RH-3999. Reserved.~~

RH-3701*. [§ 71.103] Quality assurance organization.

a. The licensee,[F2] 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-3701*. [§ 71.103] Quality assurance organization. (con't)

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.

NEW FOOTNOTE

[F2] 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.

RH-3702* [§ 71.105] 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 requirements of Part G, 'Quality Assurance' and U.S. Nuclear Regulatory Commission Regulations §§ 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 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-3702* [§ 71.105] Quality assurance program (con't)

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.

RH-3702* [§ 71.105] Quality assurance program (con't)

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 the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

RH-3703*. [§ 71.127] 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-3704*. [§ 71.129] 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-3705*. [§ 71.131] 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-3706*. [§ 71.133] 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-3707*. [§ 71.135] 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 § 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.

RH-3707*. [§ 71.135] Quality Assurance Records (con't)

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-3708*. [§ 71.137] 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. Followup action, including reaudit of deficient areas, must be taken where indicated.

EXISTING FOOTNOTES FOR SECTION 4.

1/ Any notification of incidents referred to in those requirements shall be filed with or made to, the Department.

~~2/ For the purpose of this Section, "nuclear waste" means any large quantity of source, byproduct, or special nuclear material required to be in Type B packaging while transported to, through or across State boundaries to a disposal site, or to a collection point for transport to a disposal site.~~

NOTE: RH-2700 Appendix C – Determination of A_1 and A_2

WILL CHANGED TO REFLECT THE CURRENT NRC PART 71 APPENDIX A (AS AMENDED AND NOTED IN 69FR3800 ON JANUARY 26, 2004)

MEDICAL
PART 35
EQUIVALENT

RATS ID
#2005-2
#2006-1
&
#2007-1

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 - An individual who:~~

~~1. Meets the requirements in RH-8316.; 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~~

~~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.~~

d. Authorized medical physicist means an individual who:

1. Meets the requirements in RH-8616.a. and RH-8319; 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 permittee.

RH-8100. Definitions as used in these Regulations. (Cont'd)

~~e.~~ ~~Authorized nuclear pharmacist - A pharmacist who:~~

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

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

e. Authorized nuclear pharmacist means a pharmacist who:

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

2. Is identified as an authorized nuclear pharmacist on:

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

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

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

RH-8100. Definitions as used in these Regulations. (Cont'd)

e. Authorized nuclear pharmacist (con't)

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

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

F. Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

~~f. Authorized user - A physician, dentist, or podiatrist who:~~

~~1. Meets the requirements in RH-8318. and RH-8510., RH-8540., RH-8560., RH-8516., RH-8621., or RH-8660.; 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~~

~~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.~~

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

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

RH-8100. Definitions as used in these Regulations. (Cont'd)

f. Authorized user means a physician, dentist, or podiatrist who: (con't)

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 permittee that is authorized to permit the medical use of radioactive material.

aa. Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

~~ee~~. ~~Radiation Safety Officer (as used in this Section) – An individual who:~~

~~1.~~ ~~Meets the requirements in RH-8315.; 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~~.

RH-8100. Definitions as used in these Regulations. (Cont'd)

ee. Radiation Safety Officer means an individual who:

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

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.

~~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.~~ ~~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~~.

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. 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.

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~~;

RH-8315.a. Training for Radiation Safety Officer. (con't)

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;

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 authorizes the medical use of radioactive material; or

c. Is an authorized user identified on the licensee's license.

RH-8315. Training for Radiation Safety Officer

Except as provided in RH-3818., 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 bee recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (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 form an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

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 diplomats 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;

RH-8315. Training for Radiation Safety Officer (con't)

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 definition of an authorized user in RH-8100 or who meet the requirements for authorized users in RH-8530. or RH-8550.;

iii. Pass an examination, administered by diplomats 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;

ii. Radiation protection;

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

iv. Radiation biology; and

v. Radiation dosimetry; and

RH-8315. Training for Radiation Safety Officer (con't)

B. One (1) year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

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 this section; 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., a.1.B. or a.2.A. , a.2.B. or b.1. or c.1 or c.2 of this section, 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-8605.e., RH-8640., RH-8641., RH-8642., RH-8643., RH-8644., RH-8645., and RH-8650., as applicable.~~

RH-8316. Training for Authorized Medical Physicist

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

a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs b.2. and c. of this section. (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:

RH-8316. Training for Authorized Medical Physicist (con't)

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 definition of an authorized user in RH-8100 or who meet the requirements for authorized users in RH-8610, or RH-8660; and

3. Pass an examination, administered by diplomats 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

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

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

A. Performing sealed source leak tests and inventories;

B. Performing decay corrections;

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

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

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c. and a.1. and a.2., or b.1. and c. of this section, 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 definition of an authorized medical physicist in RH-8100 or who meets the requirements in RH-8316., 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. Training for Authorized Medical Physicist (con't)

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; and~~

~~B.~~ ~~Supervised experience in a nuclear pharmacy involving the following~~:

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

~~RH-8317. Training for an Authorized Nuclear Pharmacist (con't)~~

~~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~~.

RH-8317 [§ 35.55] Training for an authorized nuclear pharmacist.

Except as provided in RH-8318, [35.57] 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 this section. (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:

RH-8317 [§ 35.55] Training for an authorized nuclear pharmacist. (con't)

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

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

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

A. Radiation physics and instrumentation;

B. Radiation protection;

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

D. Chemistry of byproduct material for medical use; and

E. Radiation biology; and

ii. Supervised practical experience in a nuclear pharmacy involving:

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

B. 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;

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

D. Using administrative controls to avoid medical events in the administration of byproduct material; and

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

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 this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

RH-8318. ~~Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and 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 board scope licensee that authorizes 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 a permit issued by Nuclear Regulatory Commission or Agreement State board 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.~~

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

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

RH-8318. Training for Experienced Radiation Safety Officer, etc. (con't)

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 THE EFFECTIVE DATE OF THESE REVISIONS need not comply with the training requirements of RH-8315., RH-8316., and RH-8317., respectively.

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, [§ 35.50, § 35.51 or § 35.55] when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of Section 9 "Use of Radionuclides in the Healing Arts."

RH-8318. Training for Experienced Radiation Safety Officer, etc. (con't)

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 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.

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 THE EFFECTIVE DATE OF THESE REVISIONS, 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.

RH-8319. [35.59] Recentness of Training

The training and experience specified in Section 9's Part C [General Administrative Requirements], Part ** [Use of Unsealed Radioactive Material of Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required], Part *** [Use of Unsealed Radioactive Material of Uptake, Dilution, or Excretion Studies for which a Written Directive is Required], Part **** [Manual Brachytherapy], Part ***** [Sealed Sources for Diagnosis] and Part ****** [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.

NOTE: THESE DESIGNATION WILL BE ESTABLISHED AT THE TIME THESE PROPOSALS HAVE BE FINALIZED.

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.

RH-8403. Determination of Dosages of Radioactive Material for Medical Use (con't)

d. 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.

e. A licensee shall retain a record of the dosage determination required by Section 9 in accordance with RH-8707.

PART E. ~~Specific Requirements For The Use of Sources For Brachytherapy~~

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 Excretion Studies for which a Written Directive is Not Required.~~

~~A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion 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~~

~~c. Obtained from and prepared by a Department, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by 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-8500. Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required.

A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion 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

RH-8500. (Cont')

b. Prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and who meets the requirements specified in RH-8540., RH-8560. and RH-8540.c.1.B.vii.;

3. An individual under the supervision, as specified in RH-8306., of the authorized nuclear pharmacist in paragraph b.1. of this section or the physician who is an authorized user in paragraph b.2. of this section; or

c. Obtained from and prepared by a Department, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by 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~~

~~RH-8510. Training for Uptake, Dilution, and Excretion Studies (con't)~~

~~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.~~

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:

RH-8510. [35.190] Training for Uptake, Dilution, and Excretion Studies.

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 this section. (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. and c.1.B. of this section; and [RATS 2007-1]

2. Pass an examination, administered by diplomats 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.,[35.390] or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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:

RH-8510. Training for Uptake, Dilution, and Excretion Studies (con't).

i Classroom and laboratory training in the following areas:

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

ii. Work experience, under the supervision of an authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8510., RH-8540., or RH-8560 or equivalent [§§ 35.190, 35.290, 35.390] Agreement State requirements, involving--,

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;

RH-8510. Training for Uptake, Dilution, and Excretion Studies (con't).

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 of radioactive drugs to patients or human research subjects; and

2. Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who requirements in 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 this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500.

~~RH-8530. Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required.~~

~~A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, 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~~

~~RH-8530.~~ ~~Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required.~~

~~c.~~ ~~Obtained from and prepared by the Department, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by 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.~~

~~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~~.

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 [§ 35.40(b)], a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is:

a. Obtained from:

1. A manufacturer or preparer licensed under RH-405.1., U.S. Nuclear Regulatory Commission Regulation § 32.72 or equivalent Agreement State requirements; or

2. A PET radioactive drug producer licensed under RH-403, U.S. Nuclear Regulatory Commission Regulation § 30.32(j), or equivalent Agreement State requirements; or

RH-8530. Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required.

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., [§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G)]; or

3. An individual under the supervision, as specified in RH-8306, [§ 35.27] of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

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.

~~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.~~

~~RH-8540.~~ ~~Training for Imaging and Localization Studies. (con't)~~

~~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, 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;~~

~~RH-8540.~~ ~~Training for Imaging and Localization Studies. (con't)~~

~~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 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~~;

~~RH-8540. Training for Imaging and Localization Studies. (con't)~~

~~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.~~

RH-8540. [35.290] Training for Imaging and Localization Studies.

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

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph c.2. of this section. (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. and c.1.B. of this section; and [RATS 2007-1]

RH-8540. Training for Imaging and Localization Studies (con't)

2. Pass an examination, administered by diplomats 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.cii. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

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

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

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

iv. Chemistry of radioactive material for medical use;

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user, who meets the definition of an authorized user in RH-8100 or who meets the requirements in RH-8540., RH-8540.c.1.B.vii. and RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

RH-8540. Training for Imaging and Localization Studies (con't)

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 safely contain spilled radioactive material and using proper decontamination procedures;

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

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

RH-8540. Training for Imaging and Localization Studies (con't)

2. Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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 this section 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.

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 medical use for which a written directive is required that has been:

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~~

b. Prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and who meets the requirements specified in RH-8540., RH-8560. and RH-8540.c.1.B.vii.; or

RH-8550. Use of Unsealed Radioactive Material for which a Written Directive is Required (con't)

3. An individual under the supervision, as specified in RH-8306., of the authorized nuclear pharmacist in paragraph b.1. of this section or the physician who is an authorized user in paragraph b.2. of this section; or

c. Obtain from and prepared by a Department, Nuclear Regulatory Commission, or Agreement State licensee in accordance with 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 follows:~~

~~RH-8560.~~ ~~Training for Use of Unsealed Radioactive Material for which a Written Directive is Required.~~

~~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 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.~~

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 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 this section. (Specialty boards whose certification processes have been 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 this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats 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 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:

RH-8560. Training for Use of Unsealed Radioactive Material for which a Written Directive is Required. (con't)

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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8560. or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages in the same dosage category or categories (i.e., RH-8560.b.1.B.vii.) as the individual requesting authorized user status. The work experience must involve:

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;

RH-8560. Training for Use of Unsealed Radioactive Material for which a Written Directive is Required. (con't)

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.

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;

(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

RH-8560. Training for Use of Unsealed Radioactive Material for which a Written Directive is Required

(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 this section, 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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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~~:

~~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. (con't)~~

~~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.~~

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

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

a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of this section and whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph c.3. of this section. (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

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 (con't)

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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in RH-8560.b. must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b). The work experience must involve:

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

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 (con't)

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 this section, 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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or equivalent 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 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 user 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.~~

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 certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of this section, and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph c.3. of this section. (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

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. (con't)

2. Has work experience, under the supervision of an authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b). The work experience must involve:

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

   B. Performing quality control procedures in 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

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. (con't)

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of this section, 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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b).

~~RH-8581. RH-8599. Reserved.~~

RH-8581. – RH-8589. Reserved.

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

RH-8590. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive', (con't).

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

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

RH-8590. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive', (con't).

2. Has work experience, under the supervision of an authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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-560.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

RH-8590. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive', (con't).

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

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph b. or c. of this section, 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 written directive. The written attestation must be signed by a preceptor authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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).

RH-8591.- RH-8599. Reserved.

Specific Requirements for 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~~;

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

~~D.~~ ~~Radiation biology; and~~

RH-8610. ~~Training for Use of Manual Brachytherapy Sources. (con't)~~

~~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:~~

RH-8610. ~~Training for Use of Manual Brachytherapy Sources. (con't)~~

~~A. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;~~

~~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 in collaboration with the authorized user.~~

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

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

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph b.3. of this section. (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

RH-8610. Training for Use of Manual Brachytherapy Sources, (con't)

2. Pass an examination, administered by diplomats 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

B. 500 hours of work experience, under the supervision of an authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

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

ii. Checking survey meters for proper operation;

iii. Preparing, implanting, and removing brachytherapy sources;

RH-8610. Training for Use of Manual Brachytherapy Sources. (con't)

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-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 this section; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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 this section 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 authorized user of a strontium-90 source for ophthalmic uses authorized under RH-8600. 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 the 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~~.

RH-8615. [35.491] Training for Ophthalmic Use of Strontium-90.

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

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

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

A. Radiation physics and instrumentation;

B. Radiation protection;

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

D. Radiation biology; and

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

A. Examination of each individual to be treated;

B. Calculation of the dose to be administered;

C. Administration of the dose; and

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

RH-8615. [35.491] Training for Ophthalmic Use of Strontium-90 (con't)

3. Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8610., [35.490] RH-8615., [35.491]or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in RH-8615.b.1. and RH-8615.b.2 of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.
[CR-08-01]

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~~

RH-8621. ~~Training for Use of Sealed Sources for Diagnosis. (con't).~~

~~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 the device for the uses requested.~~

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 by a specialty board whose certification process includes all of the requirements in paragraphs b. and c. of this section 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;

RH-8621. Training for Use of Sealed Sources for Diagnosis (con't)

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.

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 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 use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows:~~

RH-8660. ~~Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (con't).~~

~~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 an 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~~

RH-8660. ~~Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (con't).~~

~~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 after-loader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications~~:

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

RH-8660. ~~Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (con't)~~

~~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~~.

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

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

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs b.3. and c. of this section. (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 diplomats 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

RH-8660. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (con't)

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

B. 500 hours of work experience, under the supervision of an authorized user who meets the definition of an authorized user in RH-8100 for the same uses or who meets the requirements in RH-8660. or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

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

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

iii. Using administrative controls to prevent a medical event 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;

RH-8660. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (con't)

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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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 this section; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs a.1. or b.1. and b.2., and c. of this section, 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 definition of an authorized user in RH-8100 for the same uses or who meets the requirements in 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

RH-8660. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (con't)

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

Specific Requirements for Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

RH-8801. **[35.3047]** Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

a. A licensee shall report any dose to an embryo/fetus that is greater than five (5) millisievert (~~500 mrem~~ **5 rem**) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

b. A licensee shall report any dose to a nursing child that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast-feeding individual that:

1. Is greater than five (5) millisievert (~~500 mrem~~ **5 rem**) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

c. The licensee shall notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in RH-8801.a. or RH-8801.b.

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

1. The written report must include:

   A. The licensee's name;

   B. The name of the prescribing physician;

   C. A brief description of the event;

   D. Why the event occurred;

   E. The effect on the embryo/fetus or the nursing child;

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

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

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

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

e. The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under RH-8801.a. or RH-8801.b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care of the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification.

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

f. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance withRH-8704. A copy of the record required under RH-8704 shall be provided to the referring physician, if other than the licensee, within fifteen (15) days after discovery of the event.

RATS ID #2006-3

RH-1100.** [§20.1003] **ADD DEFINITION OF NATIONALLY TRACKED SOURCE**

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 RH-1513's Appendix XX 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.

RH-1513 [§20.2207] 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.

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;

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;

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.

RH-1513. (Cont'd)

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;

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.

RH-1513. (Cont'd)

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.

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.

RH-1513. (Cont'd)

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

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

2. The name of the individual preparing the report;

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

4. The radioactive material in the sealed source;

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

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

RH-1513 APPENDIX ## [Part 20 APPENDIX E]

NATIONALLY TRACKED SOURCE THRESHOLDS

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

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

RATS ID #2007-1

RH-405.l. **Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under ~~Group Licenses~~. Section 9 "Use of Radionuclides in the Healing Arts". [§ 32.72]**

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals 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. of this Part;

   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;

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

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

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

RH-405.l. (con't)

C. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of radiopharmaceuticals by group 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 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 or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceuticals 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 to be transferred for commercial distribution. The label must include the radiation symbol and the words

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

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

RH-405.l. (con't)

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

A. May prepare radiopharmaceuticals for medical use, as defined in RH-200., provided that the radiopharmaceutical 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, or an individual under the supervision of an authorized nuclear pharmacist as specified in RH-404.b.8.

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-200. and 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-405.2.D. of this section.

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

~~D~~ ~~May designate a pharmacist (as defined in RH-200.) 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.~~

RH-405.l. (con't)

D. May designate a pharmacist (as defined in RH-200) an authorized nuclear pharmacist if:

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

ii. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission (NRC).

~~D.~~ ~~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.l.2.B.i. and RH-405.l.2.B.iii. of this Section, the individual to work as an authorized nuclear pharmacist.~~

E. Shall provide to the Department:

i. (a) 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. [§ 35.55(a)] with the written attestation signed by a preceptor as required by RH-8317.b.2. [§ 35.55(b)(2)] or

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

iii. **The permit issued by a licensee of broad scope; and**

iv. **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, 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.**

3. A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. 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 radiopharmaceuticals 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 Section relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs.

RH-405.n. **Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. [§ 32.74]**

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. will be approved if:

1. The applicant satisfies the general requirements in RH-404. of this Part;

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

   A. The radioactive material contained, its chemical and physical form and amount,

   B. Details of design and construction of the source or device,

   C. Procedures for and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

   D. For devices containing radioactive material the radiation profile of a prototype device,

   E. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

   F. Procedures and standards for calibrating sources and devices,

   G. Legend and methods for labeling sources and devices as to their radioactive content, and

   H. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

3. The label affixed to the source or device or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay and a statement that the Department has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in RH-8404., RH-8600., RH-8620., and RH-8630. as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six (6) months, he shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

5. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

   A. Primary containment ~~or~~ (source capsule);

   B. Protection of primary containment;

   C. Method of sealing containment;

   D. Containment construction material;

   E. Form of contained radioactive material;

   F. Maximum temperature withstood during prototype tests;

   G. Maximum pressure withstood during prototype tests;

   H. Maximum quantity of contained radioactive material;

RH-405.n. (con't)

I. Radiotoxicity of contained radioactive material;

J. Operation experience with identical sources or devices or similarly designed and constructed sources or devices.

RH-8420. **[35.75]** Release of Individuals Containing Radioactive Drugs or Implants.

a. A licensee may authorized the release from its control of any individual who has been administered Iodine 131 as Sodium Iodide if:

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). **Footnote** **

Footnote ** 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.

RH-405.n. (con't)

d. Release of the patient must be approved by an individual listed as an authorized user on a Department license, and who is approved for 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.

f. The licensee shall maintain a record of instructions provided to breastfeeding women in accordance with RH-8710.

g. Notwithstanding RH-8420.a., the licensee may be held financially responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

h. The licensee shall immediately notify the Department in accordance with RH-8803. if a patient departs prior to an authorized release.

i. The licensee shall notify the Department in accordance with RH-8804:

1. When they are aware that a patient containing radioactive material and who has been released in accordance with RH-8420. dies; and

2. If it is possible that any individual could receive exposures in excess of five (5) millisievert (500 mrem) as a result of the deceased's body.

RH-8410. [§ 35.92] Decay-in-Storage.

a. A licensee may hold radioactive material with a physical half-life of less than ~~65 days~~ **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

3. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b For radioactive material disposed in accordance with RH-8410.a. of this Section, the licensee shall retain a record of each disposal in accordance with RH-8712.

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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**. [§20.2205]

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-2804. **Notifications and Reports to Individuals** [§19.13]

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;

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 as shown in records maintained by the licensee or registrant pursuant to RH-1301. 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.~~

b. Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee under the provisions of RH-1500.f. [10 CFR 20.2106] The licensee shall provide an annual report to each individual monitored under RH-1302 [10 CFR 20.1502] of the dose received in that monitoring year if:

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

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

RH-2804. **Notifications and Reports to Individuals (con't)** [§19.13]

c. At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall:

1. Be furnished within thirty (30) days from the time the request is made or within thirty (30) days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

2. Cover, within the period of time specified in the request, each calendar year in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the Department; and

3. Include the dates and locations of work under the license or registration in which the worker participated during this period.

d Each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material upon termination of employment. Such report shall be furnished within thirty (30) days from the time of termination of employment or within thirty (30) days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar year in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.

e. At the request of a worker who is terminating employment with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar year or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

RH-2804. **Notifications and Reports to Individuals (con't)** [§19.13]

f. When a licensee or registrant is required pursuant to 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/her~~ **his or her** exposure data included ~~therein~~ **in the report to the Department.** ~~Such reports~~ **The report** ~~shall~~ **must** be transmitted ~~at a time~~ not later than the transmittal to the Department.

RH-1100. Definitions

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

di. Total Effective Dose Equivalent (TEDE) - The sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

RH-1200. Occupational Dose Limits for Adults.

~~c. 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.~~

RH-1200. Occupational Dose Limits for Adults. (Con't)

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.

RH-1303 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~~ ~~RADIOACTIVE MATERIAL~~ ~~or~~ ~~DANGER~~ ~~RADIOACTIVE MATERIAL~~

~~It shall also provide sufficient information 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;~~

RH-1303 h. **Containers.(con't).**

~~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 Transportation4/;~~

~~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.~~

~~i. Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.~~

~~j. All devices and equipment capable of producing radiation when operated shall be appropriately labeled so as to caution individuals that such devices or equipment produce radiation when operated.~~

~~k. Each radiation machine, except radiographic and fluoroscopic x-ray machines used solely in the healing arts, which is capable of producing, in any area accessible to individuals, a dose rate in excess of ten (10) millirems per hour shall be provided with a warning signal or light. Such a signal or light shall be so connected as to be activated automatically when the machine is "on" in order to provide adequate warning against entering the area.~~

RH-1309 Labeling containers. [§ 20.1904]

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, RADIOACTIVE MATERIAL"
or
"DANGER, 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. [§ 20.1905]

A licensee is not required to label:

a. Containers holding licensed material in quantities less than the quantities listed in RH-2793, Appendix H entitled "Quantities of Licensed Materials Requiring Labeling"; or

b. Containers holding licensed material in concentrations less than those specified in Table 3 of RH-2792. 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 part; or

RH-1310 Exemptions to labeling requirements. (con't) [§ 20.1905]

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

Footnote: (**) = Labeling of packages containing radioactive materials is required by the Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49CFR 173.403(m) and (w) and 173.421-424.

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 [§ 20.1902] 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 at RH-1309 [§ 20.1904] before being removed from the posted area.

HOUSE KEEPING

Housekeeping

MODIFICATION

RH-1100. Definitions.

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

RESTORATION

- Add Back Appendix F "List of Elements" (RH-2791)
- Add Back Appendix G "ALI's and DAC's of Radionuclides for Occupational Exposure, Effluent Concentrations, Concentrations for Release to Sewage **(RH-2792)**
- Add Back Appendix H "Quantities of Licensed Material Requiring Labeling'**(RH-2793)**