

PROPOSED AMENDMENTS TO THE RULES OF THE
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION
RADIOACTIVE MATERIALS, CHAPTER 391-3-17

The Rules of the Department of Natural Resources, Chapter 391-3-17, Radioactive Materials, are hereby amended, added to, repealed in part, revised, as hereinafter explicitly set forth in the attached amendments, additions, partial repeals, and revisions for specific rules, or such subdivisions thereof as may be indicated.

[Note: Underlined text is proposed to be added. Lined-through text is proposed for deletion.]

Rule 391-3-17-.02(5), “General Licenses - Source Material,” is amended to read as follows:

(5) General Licenses - Source Material.

(a) A general license is hereby issued authorizing persons to hold bare title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

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

1. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this subparagraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Nuclear Regulatory Commission takes final action on a pending application submitted on or August 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Nuclear Regulatory Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

2. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this subparagraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this subparagraph unless it is accounted for under the limits of subparagraph (b)(1) of this section; or

3. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this subparagraph; or

4. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this subparagraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(c) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in subparagraph (b) of this section.

1. Is prohibited from administering source material, or the radiation there from, either externally or internally, to human beings except as may be authorized by the NRC in a specific license.

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

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this subparagraph (c) is exempt from the requirements to obtain a license under paragraph (5) to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under 391-3-17-.02(7) through 391-3-17-.02(13); or

(ii) In accordance with 391-3-17-.03(13) of this Chapter.

3. Is subject to the provisions of 391-3-17-.03(13) of this Chapter.

4. Is subject to the provisions in 391-3-17-.01(4), (5), (6) and (8), 391-3-17-.02(13), (18) and (19), and 391-3-17-.03(14) and (15).

5. Shall not export such source material except in accordance with 10 CFR Part 110.

(d) Depleted Uranium in Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of (5)(d)2., 3., 4., and 5., depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in (5)(d)1. applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the

products or devices in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by (5)(d)1. shall:

(i) File Division form "Registration Certificate - Use of Depleted Uranium Under General License" with the Division. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on the form the following information and such other information as may be required by that form:

(I) Name and address of the registrant;

(II) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in (5)(d)1. and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(III) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in (5)(d)3.(i)(II); and

(ii) Report in writing to the Division any changes in information furnished by him in Division form "Registration Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by (5)(d)1:

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) Shall not abandon such depleted uranium;

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of (19). In the case where the transferee receives the depleted uranium pursuant to the general license established by (5)(d)1., the transferor shall furnish the transferee a copy of this Regulation and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License". In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to (5)(d)1., the transferor shall furnish the transferee a copy of this Regulation and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is

regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this Regulation;

(iv) Shall report in writing to the Division the name and address of the person receiving the depleted uranium pursuant to such transfer within 30 days of any transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by (5)(d)1. is exempt from the requirements of Rule .03 and Rule .07 of this Chapter with respect to the depleted uranium covered by that general license.

(e) Any person who receives, possesses, uses, or transfers source material in accordance with subparagraph (b) of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Division about such contamination and may consult with the Division as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 10 CFR 20.1402.

(f) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in subparagraph (b)(e) and (e) of this section is exempt from the provisions of ~~10 CFR parts 19, 20, and 21~~ 391-3-17-.03 and 391-3-17-.07 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of ~~this Chapter~~ 391-3-17-.03(7)(b) and 391-3-17-.03(13)(a) to the extent necessary to meet the provisions of subparagraphs (c)(2) and (e) of this section. However, this exemption does not apply to any person who also holds a specific license issued under ~~this Chapter~~ 391-3-17-.02(7) through 391-3-17-.02(13).

(g) No person may initially transfer or distribute source material to persons generally licensed under subparagraph (b) of this section, or equivalent regulations of an Agreement State or NRC, unless authorized by a specific license issued in accordance with ~~this Chapter~~ 391-3-17-.02(5)(h), 10 CFR 40.54, or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

(h) An application for a specific license to initially transfer source material for use under 391-3-17-.02 will be approved if:

1. The applicant satisfies the general requirements specified in this Chapter; and
2. The applicant submits adequate information on, and the Division approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(i) Each person licensed under 391-3-17-.02 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(j) Each person licensed under 391-3-17-.02 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(k) Each person licensed under 391-3-17-.02 shall report transfers as follows:

1. File a report with the Division. The report shall include the following information:

(i) The name, address, and license number of the person who transferred the source material;

(ii) For each general licensee under 391-3-17-.02, 10 CFR 40.22 and equivalent Agreement State regulations or provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

2. File a report with each responsible Agreement State agency or NRC that identifies all persons, operating under provisions equivalent to this Chapter, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State or NRC being reported to:

(i) The name, address, and license number of the person who transferred the source material; and

(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or NRC.

3. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 10 CFR Part 40.22 or equivalent Agreement State or NRC provisions during the current period, a report shall be submitted indicating so. If no transfers have been made to general licensees in a particular Agreement State or falling under the jurisdiction of the NRC, during the reporting period, this information shall be reported to the NRC or responsible Agreement State agency upon request of the ~~Division~~ agency or NRC.

(l) Each person licensed under 391-3-17-.02 shall maintain all information that supports the reports required by this subparagraph concerning each transfer to a general licensee for a period

of 1 year after the event is included in a report to the Division, Commission or to an Agreement State agency.

(m) Each person licensed under 391-3-17-.02(5)(h) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under 391-3-17-.02(5)(b). This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

1. A copy of 391-3-17-.02(5)(b) and .02(19) or relevant equivalent regulations of the NRC or an Agreement State.

2. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

Rule 391-3-17-.02(11), “Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material,” is amended to read as follows:

(11) Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.

(a) [Reserved]

(b) Licensing the Distribution of Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) in Exempt Quantities.

Nota Bene: See Note, in (3)(c)1.

1. An application for a specific license to distribute NARM to persons exempted from this Chapter pursuant to (3)(b) will be approved if:

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) The radioactive material is in the form of processed chemical elements, compounds, mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) The applicant submits copies of prototype labels and brochures and the Division approves such labels and brochures.

2. The license issued under (11)(b)1. is subject to the following conditions:

(i) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to (3)(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 μ Sv) per hour.

(iii) The immediate container of each quantity or separately- packaged fractional quantity of radioactive material shall bear a durable and legible label which:

(I) Identifies the radionuclide and the quantity of radioactivity, and

(II) Bears the words "Radioactive Material".

(iv) In addition to the labeling information required by (11)(b)2.(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(I) State that the contents are exempt from Licensing State requirements,

(II) Bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined", and

(III) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3. Each person licensed under (11)(b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under (3)(b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Division. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to (11)(b) during the reporting period, the report shall so indicate.

(c) [Reserved]

(d) Licensing the Manufacture and Initial Transfer of Devices to Persons Generally Licensed Under (6)(c).

1. An application for a specific license to initially transfer devices containing radioactive material to persons generally licensed under (6)(c) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

- (i) The applicant satisfies the general requirements of (8);
- (ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - (I) The device can be safely operated by persons not having training in radiological protection,
 - (II) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of ten percent of the annual limits specified in Rule .03(5)(a)1. of this Chapter, and
 - (III) Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:
 - I. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye
15 rem (150 mSv);
 - II. Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter
200 rem (2 Sv);
 - III. Other Organs
50 rem (500 mSv); and
- (iii) Each device bears a durable, legible, and clearly visible label or labels approved by the Division, which contain in a clearly identified and separate statement:
 - (I) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);
 - (II) The requirement, or lack of requirement, for leak testing, or for testing any on/off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
 - (III) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:
 - I. The receipt, possession, use, and transfer of this device, Model ____, Serial No.____, are subject to a general license or the equivalent and to the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has

entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

II. The receipt, possession, use, and transfer of this device, Model ____, Serial No. ____, are subject to a general license or the equivalent, and to the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

Note: The model, serial number, and name of the manufacturer or distributor may be omitted from the appropriate label provided the information is elsewhere specified in labeling affixed to the device. Devices distributed pursuant to Regulations equivalent to (11)(d) prior to January 1, 1981, may bear labels authorized by the Regulations in effect on January 1, 1980. Devices distributed on or after January 1, 1981, including devices redistributed upon radioactive sources exchange, shall bear labels authorized in (11)(d).

(iv) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in Rule .03(12), and the name of the manufacturer or initial distributor.

(v) Each device meeting the criteria of (6)(c)3.(xii), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practical, the radiation symbol described in Rule .03(12).

(vi) The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be tested at intervals longer than six months, either for proper operation of the on/off mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the

on/off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Division will consider information that includes, but is not limited to:

- (i) Primary containment (source capsule);
- (ii) Protection of primary containment;
- (iii) Method of sealing containment;
- (iv) Containment construction materials;
- (v) Form of contained radioactive material;
- (vi) Maximum temperature withstood during prototype tests;
- (vii) Maximum pressure withstood during prototype tests;
- (viii) Maximum quantity of contained radioactive material;
- (ix) Radiotoxicity of contained radioactive material; and
- (x) Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under (6)(c), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on/off mechanism and indicator, or remove the device from installation, the applicant shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the basis for such estimates. The submitted information shall demonstrate that the performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in Rule .03(5)(a)1. of this Chapter.

4. Each person licensed under (11)(d) shall provide the information specified in (11)(d)4.(i) to each generally licensed recipient to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person.

(i) The required information includes:

(I) A copy of the general license contained in (6)(c); if (6)(c)3.(ii) through (iv) or (6)(c)3.(xii) do not apply to the particular device, these rules may be omitted.

(II) A copy of Rule .01(4), (5), (6), (7), (8), (9) and (10), Rule .02(13), (18), and (19), Rule .03(15)(a) and (b) and Rule .06;

(III) A list of the services that can only be performed by a specific licensee;

(IV) Information on acceptable disposal options including estimated costs of disposal; and

(V) An indication that improper disposal can result in high civil penalties.

(ii) If a device containing radioactive material is to be transferred for use under a general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to (6)(c), the licensee shall provide the information specified in (11)(d)4.(ii) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(I) A copy of this equivalent regulation or, alternatively, furnish a copy of the general license contained in (6)(c) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State, or the Licensing State. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. If a copy of the general license in (6)(c) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State under requirements substantially the same as those in (6)(c); if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(II) A list of the services that can only be performed by a specific licensee;

(III) Information on acceptable disposal options including estimated costs of disposal;

(IV) An indication that improper disposal can result in high civil penalties; and

(V) The name or title, address, and telephone number of the contact at the appropriate NRC Regional Office or Agreement State from which additional information may be obtained.

(iii) An alternative approach to informing customers may be proposed by the licensee for approval by the Division.

5. Each device that is transferred after January 1, 2003, must meet the labeling requirements of (11)(d)1.(iii) through (v).

6. If a notification of bankruptcy has been made under (13)(e) or the license is to be terminated, each person licensed under (11)(d) shall provide, upon request, to the Division and as appropriate to any Agreement State or the NRC, records of final disposition required under (11)(d)4.(viii).

7. The licensee shall report to the Division all transfers of such devices to persons for use under the general license in (6)(c) and report all receipts of such devices from persons licensed under (6)(c).

(i) Such report shall identify each general licensee by the following:

(I) The name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

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

(III) The date of the transfer;

(IV) The type, model number, and serial number of the device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) For devices received from a (6)(c) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a (6)(c) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(v) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(vi) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(vii) If no transfers have been made to or from persons generally licensed under (6)(c) during the reporting period, the report shall so indicate.

8. The licensee shall furnish reports to other agencies as follows:

- (i) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR, Part 31 and all receipts of devices from U.S. Nuclear Regulatory Commission Section 31.5 general licensees;
- (ii) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to (11)(d) for use under a general license in that state's regulations equivalent to (6)(c) and all receipts of devices from general licensees in the state agency's jurisdiction;
- (iii) The reports identified in 8.(i) and 8.(ii) shall identify each general licensee by the following:
 - (I) The name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.
 - (II) The name, title and telephone number the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
 - (III) The date of the transfer;
 - (IV) The type, model, and serial number of the device transferred; and
 - (V) The quantity and type of radioactive material contained in the device.
- (iv) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
- (v) For devices received from a (6)(c) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
- (vi) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
- (vii) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
- (viii) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(ix) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, report this information to the U.S. Nuclear Regulatory Commission; and

(x) If no transfers have been made to general licensees within a particular state during the reporting period, report this information to the responsible state agency upon request of that agency.

9. Each person licensed under (11)(d) to distribute devices to generally licensed persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by (11)(d)4. These records shall be maintained for a period of three years following the date of the recorded event.

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, and for distribution to persons generally licensed under (6)(d), will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in (8), and
2. The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 CFR, Part 32, or their equivalent.

(f) Special Requirements for License to Manufacture or Initially Transfer Calibration Sources Containing Americium-241, Plutonium, or Radium-226 for Distribution to Persons Generally Licensed Under (6)(f). An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium, or radium-226 to persons generally licensed under (6)(f) will be approved subject to the following conditions:

1. The applicant satisfies the general requirement of (8), and
2. The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 CFR, Part 32, and Section 70.39 of 10 CFR, Part 70, or their equivalent.

(g) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of (6)(g) will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in (8);
2. The radioactive material is to be prepared for distribution in prepackaged units of:
 - (i) Iodine-125 in units not exceeding ten microcuries (370 kBq) each,
 - (ii) Iodine-131 in units not exceeding ten microcuries (370 kBq) each,

- (iii) Carbon-14 in units not exceeding ten microcuries (370 kBq) each,
- (iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each,
- (v) Iron-59 in units not exceeding 20 microcuries (740 kBq) each,
- (vi) Cobalt-57 in units not exceeding ten microcuries (370 kBq) each,
- (vii) Selenium-75 in units not exceeding ten microcuries (370 kBq) each,
- (viii) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each;

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

- (i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 Mbq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and
- (ii) Displaying the radiation caution symbol described in Rule 391-3-17-.03, of this Chapter, and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals";

4. One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- (i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations of and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

(NAME OF MANUFACTURER)

- (ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition,

possession, use, and transfer are subject to the regulations of and a general license of a Licensing State.

(NAME OF MANUFACTURER);

and

5. The label affixed to the unit, or the leaflet or brochure, which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule .03(13) of this Chapter.

(h) Licensing the Manufacture and Distribution of Ice-Detection Devices. An application for a specific license to manufacture and initially transfer ice-detection devices to persons generally licensed under (6)(e) will be approved subject to the following conditions:

1. The applicant satisfies the general requirements of (8), and
2. The criteria of Sections 32.61 and 32.62 of 10 CFR, Part 32, are met.

(i) Manufacture, Preparation, or Transfer, for Commercial Distribution of Pharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture, prepare, or transfer for commercial distribution pharmaceuticals containing radioactive material for use by persons licensed pursuant to (9) for the uses listed in (41), (44), and (48) of Rule .05 of this Chapter will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in (8);
2. 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 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 the Georgia State Board of Pharmacy;
 - (iv) Operating as a nuclear pharmacy within a Federal medical institution; or
 - (v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

3. 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 shielding provided by the packaging to show it is appropriate for safe handling and storage of radiopharmaceuticals by licensees; and

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

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical to be transferred for commercial distribution. The label must include the radiation symbol and words "Caution, Radioactive Material" or "Danger Radioactive Material"; the name of the radiopharmaceutical or its abbreviation, and quantity of radioactivity at a specified date and time. For radiopharmaceuticals with a half-life greater than 100 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 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, leaflet, or brochure.

5. A licensee described by (11)(i)2.(iii) or (iv):

(i) May prepare radiopharmaceuticals for medical use, as defined in Rule .05(2)(s) provided that the radiopharmaceutical is prepared by either an authorized nuclear pharmacist, as specified in (ii) and (iv) or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .05(18)(b).

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if this individual:

(I) Qualifies as an authorized nuclear pharmacist as defined in .05(2)(e),

(II) Meets the requirements specified in Rule .05 (24)(b) and .05(27) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or has notified the Division in accordance with Rule .05(11), or

(III) Is designated as an authorized nuclear pharmacist in accordance with (iv).

(iii) The actions authorized in (i) and (ii) are permitted notwithstanding more restrictive language in license conditions.

(iv) May designate a nuclear pharmacist in accordance with Rule .05(26) as an authorized nuclear pharmacist if the individual is identified as of December 31, 1996, as an "authorized user" on a license issued by the Director, the NRC, or an Agreement State, under this rule or equivalent requirements, or if the individual was a nuclear pharmacist preparing only radiopharmaceuticals containing accelerator produced radioactive material and the individual

practiced 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 NRC.

(v) Shall provide to the Division a copy of each individual's certification by ~~the Board of Pharmaceutical Specialties~~ a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in 391-3-17-.05(24), or a Division, NRC, or Agreement State issued license, or permit issued by a licensee of broad scope, or 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 NRC, and a copy of the individual's license to practice pharmacy in the State of Georgia issued by the Secretary of State's office, no later than 30 days after the date that the licensee allows pursuant to (ii) and (iii), the individual to work as an authorized nuclear pharmacist.

6. A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall measure, by direct measurements 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:

- (i) Perform test 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
- (ii) Check each instrument for constancy and proper operation at the beginning of each day of use.

7. A licensee shall satisfy the labeling requirements in subparagraph (11)(i)4.

8.7. Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, or other State requirements governing radiopharmaceuticals.

(j) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Rule .05 of this chapter for use as a calibration, transmission, or reference source or for medical uses regulated by Rule .05(55), (65), or (67) of this Chapter will be approved subject to the following conditions:

- 1. The applicant satisfies the general requirements of (8);
- 2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (i) The radioactive material contained, its chemical and physical form, and amount,
 - (ii) Details of design and construction of the source or device,

- (iii) 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,
 - (iv) For devices containing radioactive material, the radiation profile of a prototype device,
 - (v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
 - (vi) Procedures and standards for calibrating sources and devices,
 - (vii) Legend and methods for labeling sources and devices as to their radioactive content, and
 - (viii) 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. Instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure that 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 source or device is licensed by the Director for distribution to persons licensed pursuant to (9) and to Rule .05(55), (65), or (67) of this Chapter or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State;
4. The source or device has been registered in the Sealed Source and Device Registry;
5. 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 months, he shall include in his 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;
6. In determining the acceptable interval for test of leakage of radioactive material, the Division will consider information that includes, but is not limited to, that which is listed in (11)(d)2.
- (k) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.
1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to (5)(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved subject to the following conditions:
- (i) The applicant satisfies the general requirements specified in (8);

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 year a radiation dose in excess of ten percent of the annual limits specified in Rule .03(5)(a)1. of this Chapter; and

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the Director will approve an application for a specific license under (11)(k) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The Director may deny any application for a specific license under (11)(k) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to (11)(k)1. shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(I) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(II) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and to the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(iii) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv) Furnish a copy of the general license contained in:

(I) (5)(d) and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License" to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in (5)(d), or

(II) The U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to (5)(d) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or, alternatively, furnish a copy of the general license contained in (5)(d) and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License" to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in (5)(d);

(v) Report to the Division all transfers of industrial products or devices to persons for use under the general license in (5)(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Division and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under (5)(d) during the reporting period, the report shall so indicate;

(vi) Report to other agencies as follows:

(I) To the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Regulatory Commission general license in Section 40.25 of 10 CFR, Part 40;

(II) To the responsible state agency all transfers of devices manufactured and distributed pursuant to 10CFR32.210 for use under a general license in that state's regulations equivalent to (5)(d);

(III) Have such reports identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

(IV) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, report this information to the U.S. Nuclear Regulatory Commission; and

(V) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, report this information to the responsible Agreement State agency upon the request of that agency; and

(vii) Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in (5)(d) or equivalent regulations of the U.S. Nuclear Regulatory

Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of (11).

(l) [Reserved]

Rule 391-3-17-.02(13), “Specific Terms and Conditions of Licenses,” is amended to read as follows:

(13) Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this Rule shall be subject to all the provisions of the Act, and to all Rules of the Division and Orders of the Director.

(b) No license issued or granted under this Rule and no right to possess or utilize radioactive material granted by any license issued pursuant to this Rule shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Division, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

1. An application for transfer of license must include:

(i) The identity, technical and financial qualification of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by .02(8)(g).

(c) Each person licensed by the Director pursuant to this Rule shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Division in writing immediately and request termination of his license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request for termination must include the information specified in (18)(d).

(e) Each general licensee required to register by (6)(c)3.(xi) and each specific licensee shall notify the Division in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;

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

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

(f) The notification specified in (13)(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(g) Security requirements for portable gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(h) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule .05(45)(a)(b) and (c). The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 391-3-17-.05(45) at the time of generator elution, in accordance with 391-3-17-.05(120).

(i) Authorization under .02(7)(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

1. Each licensee authorized under .02(7)(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in .02(11)(i)4. of this Rule for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in .02(11)(i)6. of this Rule.

2. A licensee that is a pharmacy authorized under .02(7)(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in .02(11)(i)5. of this Rule, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .05(18).

3. A pharmacy, authorized under .02(7)(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of .02(11)(i)5.(v) of this Rule.

Rule 391-3-17-.05, "Use of Radionuclides in the Healing Arts," is amended to read as follows:

391-3-17-.05 Use of Radionuclides in the Healing Arts

(1) **Purpose and Scope.** This Rule, 391-3-17-.05, establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this Rule are in addition to, and not in substitution for, others in these regulations unless specifically exempted. All numbered and lettered references within this Rule refer to parts of this Rule, unless stated otherwise.

(2) **Definitions.**

(a) "Accredited institution," means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

(b) "Address of use," means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

(c) "Area of use," means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

(d) "Authorized medical physicist," means an individual who:

1. Meets the requirements in Rules .05(23)(a) and .05(27); or
2. Is identified as an authorized medical physicist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State; or
3. Is identified as an authorized medical physicist on a permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State specific license 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 Rules .05(24)(a) and .05(27); or
2. Is identified as an authorized nuclear pharmacist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State; or
3. Is identified as an authorized nuclear pharmacist on a permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(f) "Authorized user," means a physician, dentist, or podiatrist who:

1. Meets the requirements in Rule .05(27) and .05(43)(a), .05(47)(a), .05(52)(a), .05(53)(a), .05(54)(a), .05(63)(a), .05(66)(a), or .05(84)(a); or
2. Is identified as an authorized user on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State; or
3. Is identified as an authorized user on a permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(g) "Brachytherapy," means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

(h) "Brachytherapy source," means a radioactive source or a manufacturer- assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(i) "Client's address," means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with Rule .05(38).

(j) "Dedicated check source," means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(k) "Dentist," means an individual licensed to engage in the practice dentistry under the Authority of O.C.G.A. 43-11-40.

(l) "Diagnostic clinical procedures manual," means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

(m) "High dose-rate remote afterloader," (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rad) per hour at the treatment site.

(n) "Low dose-rate remote afterloader," (LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rad) per hour at the treatment site.

(o) "Management," means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

(p) "Manual brachytherapy," means a type of therapy in which brachytherapy sources are manually applied or inserted.

- (q) "Medical institution," means an organization in which several medical disciplines are practiced.
- (r) "Medical use," means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.
- (s) "Medium dose-rate remote afterloader," (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rad), but less than, or equal to, 12 gray (1200 rad) per hour at the treatment site.
- (t) "Misadministration," means an event that meets the criteria in Rule .05(115)(a).
- (u) "Mobile medical service," means the transportation of radioactive material or its medical use at the client's address.
- (v) "Nuclear medicine technologist," means an individual who meets the requirements of Rule .05(25)(a) and, is under the supervision of an authorized user, to prepare or administers radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.
- (w) "Nuclear medicine technology," means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.
- (x) "Output," means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.
- (y) "Patient intervention," means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.
- (z) "Pharmacist," means any individual who is licensed to practice Pharmacy in this State by the Georgia State Board of Pharmacy.
- (aa) "Physician," means any person who is licensed to engage in the practice of medicine under the Authority of O.C.G.A. 43-34-20 or the limited practice of medicine under O.C.G.A. 43-35-1.
- (bb) "Podiatrist," means an individual licensed by the appropriate authority to practice podiatry in the state of Georgia.
- (cc) "Positron Emission Tomography (PET) radionuclide production facility" is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(dd) "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, an Associate Radiation Safety Officer or a Radiation Safety Officer.

(ee) "Prescribed dosage," means the specified activity or range of activity of radioactive drug as documented:

1. In a written directive; or
2. In accordance with the directions of the authorized user for procedures performed pursuant to Rule .05(41), (44) and (48).

(ff) "Prescribed dose," means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive;
3. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(gg) "Pulsed dose-rate remote afterloader," (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(hh) "Radiation Safety Officer," means an individual who:

1. Meets the requirements in Rule .05(22)(a) or .05(22)(c)1. And .05(27); 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 Division for similar types and uses of radioactive material.

(ii) "Radiation therapist," means an individual who meets the requirements of Rule .05(25)(b) and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

(jj) "Radiation therapy technology," means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

(kk) "Radioactive drug," means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

(ll) "Sealed source," means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(mm) "Sealed Source and Device Registry," means the national registry that contains the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(nn) "Stereotactic radiosurgery," means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a treatment site.

(oo) "Structured educational program," means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(pp) "Teletherapy," as used in this Rule, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(qq) "Temporary jobsite," as used in this Rule, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

(rr) "Therapeutic dosage," means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(ss) "Therapeutic dose," means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(tt) "Treatment site," means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(uu) "Type of use," means use of radioactive material as specified under Rule .05(41), (44), (48), (55), (65), (67) or (85).

(vv) "Unit dosage," means a dosage that:

1. Is obtained or prepared in accordance with the regulations for uses described in Rule .05(41), (44), (48); and

2. Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(ww) "Written directive," means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Rule .05(19).

(xx) "Associate Radiation Safety Officer," means an individual who:

1. Meets the requirements in 391-3-17-.05(22) and .05(27); and

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

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

(yy) "Ophthalmic physicist," means an individual who:

1. Meets the requirements in 391-3-17-.05(27) and 391-3-17-.05(64)(c)2.; and

2. Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the Commission or an Agreement State;

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

(3) **Maintenance of Records.** Each record required by Rule .05 must be legible throughout the retention period specified by each Division Rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and 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.

(4) **Provisions for Research Involving Human Subjects.** A licensee may conduct research involving human subjects using radioactive material provided:

(a) That the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Division license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(b) The research involving human subjects authorized in .05(4)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in Rule .05(4) relieves licensees from complying with the other requirements in Rule.05.

(5) **U.S. Food and Drug Administration, Federal, and State Requirements.** Nothing in Rule .05 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

(6) Implementation.

(a) A licensee shall implement the provisions in Rule .05 on July 1, 2003.

(b) When a requirement in Rule .05 differs from the requirement in an existing license condition, the requirement in Rule .05 shall govern.

(c) Any existing license condition that is not affected by a requirement in Rule .05 remains in effect until there is a license amendment or license renewal.

(d) If a license condition exempted a licensee from a provision of Rule .05 on July 1, 2003, it will continue to exempt a licensee from the corresponding provision in Rule .05.

(e) If a license condition cites provisions in Rule .05 that will be deleted on July 1, 2003, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(f) Licensees shall continue to comply with any license condition that requires it to implement procedures required by Rule .05(70), (76), (77) and (78) until there is a license amendment or renewal that modifies the license condition.

(7) License Required.

(a) A person may manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Director, the Nuclear Regulatory Commission or an Agreement State, or as allowed in Rule .05(7)(b) or (7)(c).

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Rule .05 under the supervision of an authorized user as provided in Rule .05(18), unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in Rule .05 under the supervision of an authorized nuclear pharmacist or authorized user as provided in Rule .05(18), unless prohibited by license condition.

(8) Application for License, Amendment, or Renewal.

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

(b) An application for a license for medical use of radioactive material as described in Rule .05(41), (44), (48), (55), (65), (67) or (85) must be made by:

1. Filing an original Application for Radioactive Materials License, and
2. Submitting procedures required by sections Rule .05(70), (76), (77), and (78), as applicable.

(c) A request for a license amendment or renewal must be made by:

1. Submitting an original in letter format.
2. Submitting procedures required by sections Rule .05(70), (76), (77) and (78), as applicable.

(d) In addition to the requirements in (8)(b) and (8)(c), an application for a license or amendment for medical use of radioactive material as described in (85) of Rule .05 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Rule .05(1) through Rule .05(40), as well as any specific information on:

1. Radiation safety precautions and instructions;
2. Training and experience of proposed users;
3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

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

(f) An applicant that satisfies the requirements specified in Rule .02(10)(b) may apply for a Type A specific license of broad scope.

(9) Mobile Medical Service Administrative Requirements.

(a) The Director shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the clinic's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

(c) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(d) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with Rule .05(97).

(f) A mobile medical service licensee shall maintain on each mobile unit:

1. The current operating and emergency procedures;
2. A copy of the license;
3. Copies of the letter required by .05(9)(b);
4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

(g) A mobile medical service licensee shall maintain records required by Rules .03 and .05 of this Chapter at a location within the Division's jurisdiction that is:

1. A single address of use:

(i) Identified as the records retention location; and

(ii) Staffed at all reasonable hours by individual(s) authorized to provide the Division with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Division.

(10) **License Amendments.** A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses radioactive material for a type of use that is permitted under Rule .05, but that is not authorized on the licensee's current license issued pursuant to Rule .05;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

1. For an authorized user, an individual who meets the requirements in Rule .05(27) and (43)(a), Rule .05(47)(a), (52)(a), (53)(a), (54)(a), (63)(a), (64)(a), (66)(a), or (84)(a) or;

2. For an authorized nuclear pharmacist, an individual who meets the requirements in Rule .05(24)(a) and (27);

3. For an authorized medical physicist, an individual who meets the requirements in Rule .05(23)(a) and (27);

4. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or Licensing State license or other equivalent permit or license recognized by the Division that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

5. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Nuclear Regulatory Commission or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers, except as provided in (15)(c);

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

(e) Before it adds to or changes the areas of use identified in the application or on the license, except as specified in (11)(b)4.;

- (f) Before it changes the address(es) of use identified in the application or on the license;
- (g) Before it changes statements, representations, and procedures which are incorporated into the license; and
- (h) Before it releases licensed facilities for unrestricted use.

(11) Notifications.

(a) A licensee shall provide to the Division a copy of the board certification, the Nuclear Regulatory Commission, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist, pursuant to (10)(b).

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

1. A Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
2. The licensee's mailing address changes;
3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Rule .02 (13)(b) of these regulations; or
4. The licensee has added to or changed the areas where radioactive material is used in accordance with Rule .05(41) and (44).

(12) Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

- (a) The provisions of (8)(d) of these regulations, regarding the need to file an amendment to the license for medical uses of radioactive material, as described in .05(85);
- (b) The provisions of (10)(b) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;
- (c) The provisions of (10)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;
- (d) The provisions of .05(11)(a) regarding notification to the Division for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and
- (e) The provisions of .05(21)(a) regarding suppliers for sealed sources.

(13) License Issuance.

(a) The Director shall issue a license for the medical use of radioactive material if:

1. The applicant has filed Application for Radioactive Materials License in accordance with the instructions in .05(8);
2. The applicant has paid any applicable fee;
3. The applicant meets the requirements of Rule .02 of this Chapter; and
4. The Director finds the applicant equipped and committed to observe the safety standards established by the Division in these Rules for the protection of the public health and safety.

(b) The Director shall issue a license for mobile services if the applicant:

1. Meets the requirements in .05(13)(a); and
2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with .05(37).

(14) Specific Exemptions. The Director may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Rule .05 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

General Administrative Requirements**(15) Authority and Responsibilities for the Radiation Protection Program.**

(a) In addition to the radiation protection program requirements of Rule .03(4), a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Division;
2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist, and
3. Radiation protection program changes that do not require a license amendment and are permitted under .05(16);

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

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

(c) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in .05(15)(e), provided the licensee takes the actions required in .05(15)(b),(d),(e) and (h). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

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

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

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and,
4. Verify implementation of corrective actions.

(f) Licensees that are authorized for two or more different types of radioactive material use under Rule .05(48), (55), (67), and (85), or two or more types of units under Rule .05(67) shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(g) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each required meeting in accordance with Rule .05(86)(c).

(h) A licensee shall retain a record of actions taken pursuant to Rule .05(15)(a), (15)(b) and (15)(d) in accordance with Rule .05(86)(a) and (b).

(16) Radiation Protection Program Changes.

(a) A licensee may revise its radiation protection program without Division approval if:

1. The revision does not require an amendment under Rule .05(10);
2. The revision is in compliance with the regulations and the license;
3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
4. The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with Rule .05(87).

(17) Duties of Authorized User and Authorized Medical Physicist.

(a) A licensee shall assure that only authorized users for the type of radioactive material use:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;
2. Direct, as specified in Rule .05(18) and (19), or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and
3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with Rule .05(7)(b) and (7)(c) and (18).

(b) A licensee shall assure that only authorized medical physicists perform, as applicable:

1. Full calibration measurements as described in Rule .05(73), (74), and (75);
2. Periodic spot checks as described in Rule .05(76), (77), and (78);and
3. Radiation surveys as described in Rule 5(80).

(18) Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by Rule .05(7)(b) shall:

1. In addition to the requirements in Rule .07(3) of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Rule .05(7)(c), shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Rule .05, and license conditions.

(c) Unless physical presence is required in other sections of Rule .05, a licensee who permits supervised activities under Rule .05(18)(a) and (18)(b) shall require an authorized user to be immediately available to communicate with the supervised individual, and when a written directive is required, be able to be physically present within one hour of notification; and

(d) A licensee that permits supervised activities under Rule .05(18)(a) and (18)(b) is responsible for the acts and omissions of the supervised individual.

(19) Written Directives.

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

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

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

3. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as

possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

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

1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;
2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
4. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

5. For all other brachytherapy including LDR, MDR, and PDR:

(i) Prior to implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose); or;

6. For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date.

(c) The licensee shall retain the written directive in accordance with Rule.05 (88).

(20) Procedures for Administrations Requiring a Written Directive.

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

1. The patient's or human research subject's identity is verified before each administration; and
2. Each administration is in accordance with the written directive.

(b) The procedures required by Rule .05(20)(a) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

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

2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
3. Checking both manual and computer-generated dose calculations;~~and~~
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Rule .05(67);₁
5. Determining if a medical event, as defined in Rule .05(115), has occurred; and
6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(c) A licensee shall retain a copy of the procedures required under subparagraph (a) in accordance with 391-3-17-.05(20) and (88).

(21) 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 Rule .02 of this Chapter or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; or
- (b) Sealed sources or devices non-commercially transferred from Rule .05 licensee or a Nuclear Regulatory Commission, an Agreement State or a Licensing State medical use licensee.

(22) Training for Radiation Safety Officer. Except as provided in Rule .05(26), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in Rule .05(15) to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rule .05(22)(d) and (e), and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that 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. (i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

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

2. (i) 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;

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

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

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(47) or .05(52); and

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

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

(i) 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

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

safety experience must involveing the following;

- (I) Shipping, receiving, and performing related radiation surveys;
- (II) Using and performing checks for proper operation of dose calibrators, 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. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in subparagraphs (b)1. and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(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 Rule .05(23)(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or Associate Radiation Safety Officer and who meets the requirements in .05(22)(d) ~~and .05(22)(e)~~; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State on the licensee's license, a permit issued by a Commission master material license, a permit issued by a Commission or an Agreement State license broad scope permittee, and has experience with the radiation safety aspects of similar types of use of radioactive byproduct material for which the licensee seeks the approval of the individual as the individual has Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in subparagraph .05(22)(d); ~~or responsibilities; and~~

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

Commission master material license. The individual must also meet the requirements in subparagraph .05(22)(d).

~~(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph .05(22)(e) and .05(22)(a)1.(i) and .05(22)(a)1.(ii) or .05(22)(a)2.(i) and .05(22)(a)2.(ii) or .05(22)(b)1. or .05(22)(c)1. or .05(22)(c)2., and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

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

(23) Training for Authorized Medical Physicist. Except as provided in Rule .05(26) the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in ~~.05(23)(b)2. and~~ .05(23)(c) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
2. Have 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 radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(63) or .05(84); and
3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or
- (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

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 1 million electron volts) and brachytherapy services and must include:

- (i) Performing sealed source leak tests and inventories;
- (ii) Performing decay corrections;
- (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (iv) 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 .05(23)(c) ~~and .05(23)(a)1. and 2., or .05(23)(b)1. and .05(23)(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 requirements in Rule .05(23) and .05(26), 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

(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.

(24) Training for an Authorized Nuclear Pharmacist. Except as provided in Rule .05(26), 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 Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in .05(24)(b)2.~~ (The names of board certifications that 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. 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 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 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
 - (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
 - (ii) Supervised practical experience in a nuclear pharmacy involving:
 - (I) Shipping, receiving, and performing related radiation surveys;
 - (II) Using and performing checks for proper operation of 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 misadministrations in the administration of radioactive material; and
 - (V) 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 Rule ~~.05(24)(a)1., .05(24)(a)2. and .05(24)(a)3. or .05(24)(b)1.~~ and has achieved a level of competency sufficient to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist and operate a nuclear

pharmacy, and

(c) Licensed as a Nuclear Pharmacist by the Georgia Board of Pharmacy.

(25) Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.

(a) The licensee shall require a nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in:

(i) Nuclear Medicine by the Nuclear Medicine Technology Certification Board;

(ii) Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,

2. Is board eligible to take the CNMT or ARRT(N) examinations; or,

3. Has successfully completed a training program in nuclear medicine which has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,

4. Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or,

5. Has completed 80 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:

(i) 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

(ii) Work experience, under the supervision of an authorized user involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Quality Control checking of 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 misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) Administering dosages to patients or human research subjects; and

(iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a nuclear medicine technologist.

(b) The licensee shall require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or

2. Is board eligible to take the ARRT(T) examination; or,

3. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology¹; or,

4. Has performed as a full-time radiation therapist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or

5. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

¹ "Essentials and guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

- (III) Mathematics pertaining to the use and measurement of radioactivity; and
- (IV) Radiation biology; and
- (ii) Work experience, under the supervision of an authorized user involving:
 - (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (II) Assisting the authorized user in simulating the patient for treatment;
 - (III) Preparing the patient for treatment;
 - (IV) Implementing treatment plans as prescribed by the authorized user;
 - (V) Providing written documentation of treatment setup and patient treatments;
 - (VI) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
 - (VII) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
 - (VIII) Delivering doses to patients or human research subjects under the supervision of the authorized user;
 - (IX) Preparing, implanting, and removing sealed sources;
 - (X) Delivering dose to patients or human research subjects;
 - (XI) Maintaining running inventories of material on hand;
 - (XII) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,
 - (XIII) Properly implementing emergency procedures and
- (iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a radiation therapist.
- (c) Individuals working as nuclear medicine technologists or radiation therapists prior to July 1, 2003 for a facility holding a Division license need not comply with the training requirements of this section.

(d) The licensee shall maintain records of the above training as specified in Rule .05(100).

(26) Provisions 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 Division, Nuclear Regulatory Commission or Agreement State license or on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before ~~July 1, 2003~~ the effective date of this rule, need not comply with the training requirements of Rules .05(22), .05(23), or .05(24), respectively except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in Rule .05(22) or .05(23), as appropriate, for any material or uses for which they were not authorized prior to this date.

2. ~~An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Division, Nuclear Regulatory Commission or Agreement State license or a permit issued by the Director, 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 July 1, 2003 and July 1, 2008 need not comply with the training requirements of Rules .05(22), .05(23), or .05(24), respectively.~~ Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Rule .05(22) to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Rule .05(23), for those materials and uses that these individuals performed on or before October 24, 2005.

43. 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 Rules .05(22), .05(23) or .05(24), respectively, when performing the same uses. A nuclear pharmacist,

who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b) 1. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Director, Nuclear Regulatory Commission or Agreement State, a permit issued by a Director, Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before ~~July 1, 2003~~ the effective date of this rule who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Director, Nuclear Regulatory Commission or Agreement State, a permit issued by a Director, Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized ~~between July 1, 2003 and July 1, 2008~~ on or before October 24, 2005, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84) ~~respectively~~, as follows:

(i) For uses authorized under Rules .05(41) or .05(44), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under Rule .05(48), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under Rules .05(55) or .05(67), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under Rules .05(65), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84) respectively, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

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

(27) **Recentness of Training.** The training and experience specified in Rule .05 must have been obtained within the 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.

GENERAL TECHNICAL REQUIREMENTS

(28) **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures that have been approved by the Division. The licensee shall conduct quality control procedures in accordance with written procedures.

(29) **Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.**

(a) For direct measurements performed in accordance with Rule .05(31), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(b) A licensee shall test the instrumentation required in Rule .05(29)(a) in accordance with nationally recognized standards or the manufacturer's instructions.

(c) The tests required in Rule .05(29)(b) shall include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

(d) A licensee shall retain a record of each instrument test required by Rule .05(29) in accordance with Rule .05(91).

(30) Calibration of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with Rule .05 and Rule .03 of this Chapter, have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of Rule .05(30)(a), the licensee shall:

1. Calibrate all required scale readings up to 10 millisievert (1,000 mrem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisievert (2 and 1,000 mrem) per hour; and

(iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

3. Conspicuously note on the instrument the date of calibration.

(c) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

(d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each survey instrument calibration in accordance with Rule .05(92).

(31) 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.

(b) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory

Commission, Agreement State or Licensing State.

(c) For other than unit dosages, 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 Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.

(d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by Rule .05(31)(a) through (31)(c) in accordance with Rule .05(93).

(32) Authorization for Calibration, Transmission and Reference Sources. Any person authorized by Rule .05(7) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerel (30 mCi) each;

(b) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerel (15 mCi);

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

1. 7.4 megabecquerel (200 μ Ci); or

2. 1,000 times the quantities in Schedule B of Rule .02(21)(b) of this Chapter; and

(d) Technetium-99m in amounts as needed.

(33) Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Division.

(b) A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Rule .03 of this Chapter.

2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved

by the Division, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) If the leak test reveals the presence of 185 becquerel (0.005 μ Ci) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Rules .02 and .03 of this Chapter; and
2. File a report with the Division within 5 days of receiving the leak test results in accordance with Rule .05(117).

(d) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with Rule .05(94).

(34) **Labels.** Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(35) **Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

(36) Surveys for Ambient Radiation Dose Rate and Contamination.

(a) Except as provided in Rule .05(36)(h), a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by Rule .05(36)(a) and (b) so as to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by Rule .05(36)(a) and (36)(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by Rule .05(36)(e) so as to be able to detect contamination on each wipe sample of 33.3 becquerel (2,000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by Rule .05(36)(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by Rule .05(36)(a) in area(s) where patients or human research subjects are confined when they cannot be released pursuant to Rule .05(37).

(i) A licensee shall retain a record of each survey in accordance with Rule .05(95)

(37) Release of Individuals Containing Radioactive Drugs or Implants.

(a) A licensee may authorize the release of any individual who has been administered radioactive drugs 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 5 mSv (0.5 rem).

(b) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including 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.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with Rule .05(96).

(d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with Rule .05(96).

(e) Notwithstanding Rule .05(37)(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(f) The licensee shall immediately notify the Division in accordance with Rule .05(118) if a patient departs prior to an authorized release.

(g) The licensee shall notify the Division in accordance with Rule .05(119):

1. When they are aware that a patient containing radioactive material and who has been released in accordance with Rule .05(37) dies; and,

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

(38) Mobile Medical Service Technical Requirements. A licensee providing mobile medical service shall:

- (a) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;
- (b) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- (c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;
- (d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;
- (e) Check survey instruments for consistent response with a dedicated check source before use at each client's address;
- (f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Rule .03 of this Chapter;
- (g) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Division for compliance with airborne release standards; and,
- (h) Retain a record of each survey required by Rule .05(38)(f) in accordance with Rule .05(97)(b).

(39) Storage and Control of Volatiles and Gases.

- (a) A licensee shall store volatile radioactive materials and radioactive gases in the shippers' radiation shield and container.
- (b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- (c) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Rule .03 of this Chapter.
- (d) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- (e) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

(40) Decay-in-Storage.

(a) A licensee may hold radioactive material with a physical half-life of less than 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 (40)(a) of this section, the licensee shall retain a record of each disposal in accordance with Rule .05(98).

**SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL
WRITTEN DIRECTIVE NOT REQUIRED**

(41) 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 Rule .02 of this Chapter or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- (b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or
- (c) Obtained from and prepared by a Division, Nuclear Regulatory Commission, Agreement State or Licensing 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.

(42) **Possession of Survey Instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with Rule .05(30).

(43) **Training for Uptake, Dilution, and Excretion Studies.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a unsealed radioactive material for the uses authorized under Rule .05(41) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in Rule .05(43)(c)(2).~~ (The names of board certifications that have been recognized by the 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 Rule .05(43)(c)1.(i) through .05(43)(c)1.(ii)(VI); and

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

(b) Is an authorized user under Rule .05(47) or .05(52) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 60 hours of training and experience, including a minimum of 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 that includes:

(i) 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

(ii) Work experience, under the supervision of an authorized user who meets the requirements

in Rules .05(26), (43), (47) or (52) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, involving:

- (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (VI) Administering dosages to patients or human research subjects; and

2. ~~Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rule .05(43)(a)1. or (c)1. and is able to independently fulfill the radiation safety-related duties as has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under Rule .05(41). The signed attestation must be obtained from either:~~

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(43)(c)1.

(44) 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 (except aerosol or gaseous forms) prepared for medical use, in quantities that do not require a written directive as described in Rule .05(19) that is:

- (a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- (b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or
- (c) Obtained from and prepared by the Division, Nuclear Regulatory Commission, Agreement State or Licensing 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, or
- (e) Provided the conditions of Rule .05(39) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Division.

(45) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

- (a) A licensee shall not administer to humans a radioactive drug containing:
 1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μ Ci of Mo-99 per mCi of Tc-99m); or
 2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μ Ci of Sr-82 per mCi of Rb-82 chloride); or
 3. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μ Ci of Sr-85 per mCi of Rb-82);
- (b) To demonstrate compliance with Rule .05(45)(a), the licensee preparing radioactive drugs from radionuclide generators shall:
 1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator; molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subparagraph .05(45)(a);
 2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems. Before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with subparagraph .05(45)(a).
- (c) A licensee who must measure radionuclide contaminant concentration shall retain a record

of each measurement in accordance with Rule .05(99).

(d) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in Rule .05(45)(a).

(46) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(47) **Training for Imaging and Localization Studies.** Except as provided in Rule .05(26), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Rule .05(44) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State, ~~and who meets the requirements in Rule .05(47)(c)2.~~ (The names of board certifications that 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 (c)1.(i) through (c)1.(ii)(VII) of this rule; and

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

(b) Is listed as an authorized user under Rule .05(52) and meets the requirements in .05(47)(c)1.(ii)(VII) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission 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 that includes, at a minimum:

(i) 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

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Rule .05(26), .05(47) or .05(47)(c)1.(ii)(VII) and Rule .05(52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; An authorized nuclear pharmacist who meets the requirements in 391-3-17-.05(24) or 391-3-17-.05(26) may provide the supervised work experience for subparagraph .05(47)(c)1.(ii)(VII). Work experience must involveing:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) Administering dosages 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 radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. ~~Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rules .05(26), .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; that the individual has satisfactorily completed the requirements in Rule .05(47)(a)1. or .05(47)(c)1. and is able to independently fulfill the radiation safety-related duties~~has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under Rules .05(41) and .05(44).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(47)(c)1.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL WRITTEN DIRECTIVE REQUIRED

(48) Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee may use any unsealed radioactive material identified in subparagraph (52)(b)1.(ii)(VII) prepared for diagnostic or therapeutic medical use for which a written directive is required that has been:

- (a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- (b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or (52), or an individual under the supervision of either as specified in Rule .05(26); or
- (c) Obtained from and prepared by the Division, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or
- (d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

(49) Safety Instruction. In addition to the requirements of Rule .07(3) of this Chapter:

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with Rule .05(37). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;
2. Visitor control to include the following:

- (i) Routine visitation to hospitalized individuals in accordance with Rule .03 of this Chapter;
- (ii) Contamination control;
- (iii) Waste control; and
- (iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101).

(50) Safety Precautions.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with Rule .05(37), a licensee shall:

1. Quarter the patient or the human research subject either in:

- (i) A private room with a private sanitary facility; or
- (ii) A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who cannot be released in accordance with Rule .05(37); and,

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

3. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) The Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule .05(119) if it is possible that any individual could receive exposures in excess of the limits in Rule .03(5)(i) of this Chapter as a result of the deceased's body.

(51) Possession of Survey Instruments. A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in

accordance with Rule .05(30).

(52) Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required. Except as provided in Rule .05(26), the licensee shall require an authorized user of radioactive material for the uses authorized under Rule .05(48) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State, and who meets the requirements of Rules .05(52)(b)1(ii)(VII). ~~and .05(52)(b)2.~~ (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 Rule .05(52)(b)1.(i) through .05(52)(b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

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

(i) 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

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(52) or equivalent Agreement State, or Nuclear Regulatory Commission requirements. ~~A supervising authorized user, who meets the requirements of Rule .05(52)(b) must have experience in administering dosages in the same dosage category or categories listed in Rule .05(52)(b)1.(ii)(VII) as the individual requesting authorized user status.~~ The work

experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

(VI) Reserved.

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by Rule .05(52)(b)1.(ii):

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

(ii) Oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131²;

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

(iv) 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 Rules .05(52)(a)1. ~~And .05(52)(b)1.(ii)(VII) or .05(52)(b)1., and is able to independently fulfill the radiation safety-related duties~~has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Rule .05(48). ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule .05(26), .05(52) or equivalent Agreement State, or Nuclear Regulatory Commission requirements. The preceptor authorized user, who meets the requirements in Rule .05(52)(b), must have experience in administering dosages in the same dosage category or~~

2 Experience with at least 3 cases in category (VII)(ii) also satisfies the requirement in category (VII)(i).

~~categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status.~~

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(52)(b)1.

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

Except as provided in Rule .05(26), 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 gigabecquerel (33 millicurie), 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 .05(53)(c)1. and .05(53)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission ~~and who meets the requirements in .05(53)(c)3.~~ (The names of board certifications that 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 Rule (52) for uses listed in (52)(b)1.(ii)(VII)(i) or (ii), or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully 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:

(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

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), (53) or (54), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b) must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(i) or (ii); 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 for survey meters;

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

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

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

(vi) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(53)(c)1. and (53)(c)2. and is able to independently fulfill the radiation safety-related duties~~has achieved a level of competency sufficient to independently function as~~ an authorized user for medical uses authorized under .05(48).~~The written attestation must be signed by a preceptor authorized user, who meets the requirements in Rules .05(52), .05(26), .05(53) or .05(54), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. The preceptor authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(i) or (52)(b)1.(ii)(VII)(ii).~~

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(53)(c)1. and 2.

(54) Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerel (33 millicurie) for which a Written Directive is Required. Except as provided in Rule .05(26), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerel (33 millicurie), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in Rules .05(54)(c)1. and .05(54)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission ~~and who meets the requirements in Rule .05(54)(c)3.~~ (The names of board certifications that 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 Rule .05(52) for uses listed in Rule.05(52)(b)1.(ii)(VII)(ii), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully 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:

(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

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), or (54), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in

Rule .05(52)(b)1.(ii)(VII)(ii); 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 for survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;
- (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(54)(c)1. and .05(54)(c)2. and is able to independently fulfill the duties~~has achieved a level of competency sufficient to independently function~~ as an authorized user for medical uses authorized under Rule .05(48). The written attestation must be signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(52), or .05(54), or equivalent Agreement State Licensing State or Nuclear Regulatory Commission requirements. The preceptor authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii).

(54.1) Except as provided in Rule .05(26) 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 Rule .05(52) for uses listed in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- (b) Is an authorized user under Rules .05(63), .05(84), or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in .05(54.1)(d); or
- (c) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State under Rules .05(63) or .05(84), and who meets the requirements in paragraph .05(54.1)(d).
- (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:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of byproduct material for medical use; and
- (v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), .05(52), .05(54.1) or equivalent Agreement State or Nuclear Regulatory Commission 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 Rule .05(52) or .05(54.1) must have experience in administering dosages as specified in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv). The work experience must involve:

- (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
- (vi) 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 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 .05(54.1)(b)(d)1. and (d)2. or .05(54.1)(c), and has achieved a level of competency sufficient to function independently and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed

radioactive material requiring a written directive. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in Rules .05(26), .05(52), .05(54.1), or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in .05(52), must have experience in administering dosages as specified in .05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv).~~

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (52), (54.1) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (52) or (54.1), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(54.1)(d)1. and 2.

Manual Brachytherapy

(55) Use of Sealed Sources for Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

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

(b) In research ~~in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA~~ to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(56) Surveys After Source Implant and Removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human

research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

(57) Brachytherapy Sources Inventory.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with Rule .05(103).

(58) Safety Instruction. In addition to the requirements of Rule .07(3) of this Chapter:

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with Rule .05(37). Instruction must be commensurate with the duties of the personnel and shall include the following:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions;

3. Patient or human research subject control;

4. Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with Rule .03(5)(i)1.(i) of this Chapter; and

(ii) Visitation authorized in accordance with Rule .03(5)(i)2. of this Chapter; and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule .05(119) if it is possible for any individual to receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101).

(59) Safety Precautions for Patients or Human Research Subjects Receiving

Brachytherapy.

(a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with Rule .05(37), a licensee shall:

1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

1. Dislodged from the patient; or
2. Lodged within the patient following removal of the source applicators.

(c) Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

(60) Calibration Measurements of Brachytherapy Sealed Sources.

(a) Prior to the first medical use of a brachytherapy sealed source on or after July 1, 2003, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of Rule .05(72)(a);
2. Determine source positioning accuracy within applicators; and
3. Use published protocols accepted by nationally recognized bodies to meet the requirements of Rule .05(60)(a)1. and .05(60)(a)2.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with Rule .05(60)(a).

(c) A licensee shall mathematically correct the outputs or activities determined in Rule .05(60)(a) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to Rule .05(60)(a), (60)(b), or (60)(c).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with Rule .05(60)(a), (60)(b), and (60)(c).

(f) A licensee shall retain a record of each calibration in accordance with Rule .05(104).

(g) A licensee shall retain a record of decay calculations required by Rule .05(60)(e) in accordance with Rule .05(105).

(61) Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- (a) The source-specific input parameters required by the dose calculation algorithm;
- (b) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (c) The accuracy of isodose plots and graphic displays; and
- (d) The accuracy of the software used to determine radioactive source positions from radiographic images.

(62) Possession of Survey Instruments. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(63) Training for Use of Manual Brachytherapy Sources. Except as provided in Rule .05(26), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Rule .05(55) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission, ~~and who meets the requirements in .05(63)(b)3.~~ (The names of board certifications that 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 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

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

(i) 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

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in .05(26), (63) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution authorized to use byproduct material under Rule .05(55), involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of material on hand;

(V) Using administrative controls to prevent a misadministration involving the use of radioactive material; and

(VI) Using emergency procedures to control radioactive material; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(63) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission 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 Rule .05(63)(b).1.(ii); and

3. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(63) or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rules ~~.05(63)(a)1. or .05(63)(b)1. and (63)(b)2. and is able to independently fulfill the radiation safety-related duties~~ has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under in Rule .05(55).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

(64) Training for Ophthalmic Use of Strontium-90. Except as provided in Rule .05(26), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under Rule .05(55) to be a physician who:

(a) Is an authorized user under Rule .05(63) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission 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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) 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, and that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

- (i) Examination of each individual to be treated;
- (ii) Calculation of the dose to be administered;
- (iii) Administration of the dose; and
- (iv) Follow-up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(63) or .05(64) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rule .05(64)(b)1. and 2., and is able to independently fulfill the radiation safety-related duties~~has achieved a level of competency sufficient to independently function~~ as an authorized user of strontium-90 for ophthalmic use.

(c) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subparagraph .05(64)(d) are performed by either:

1. An authorized medical physicist; or

2. An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

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

(iv) Has documented training in:

(I) The creation, modification, and completion of written directives;

(II) Procedures for administrations requiring a written directive; and

(III) Performing the calibration measurements of brachytherapy sources as detailed in Rule (.05)(60).

(d) The individuals who are identified in subparagraph .05(64)(c) must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule (.05)(60); and
2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subparagraph .05(64)(c) will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(e) Licensees must retain a record of the activity of each strontium-90 source in accordance with Rule (.05)(105).

Sealed Sources For Diagnosis

(65) Use of Sealed Sources and Medical Devices for Diagnosis. ~~A licensee shall use only sealed sources for diagnostic medical uses:~~

- ~~(a) Approved in the Sealed Source and Device Registry; and~~ A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.
- ~~(b) Handled in accordance with the manufacturer's radiation safety instructions.~~ A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.
- (c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(20)(a) are met.

(66) Training for Use of Sealed Sources for Diagnosis and Medical Devices for Diagnosis. Except as provided in Rule .05(26), the licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under Rule .05(65) to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rules .05(66)(~~bc~~) and .05(66)(~~ed~~) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that 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 for uses listed in Rule .05(44) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

~~(bc)~~ Has had 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; and
4. Radiation biology; and

~~(ed)~~ Has completed training in the use of the device for the uses requested.

Photon-Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(67) Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. ~~A licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:~~

~~(a) As approved in the Sealed Source and Device Registry; or~~ A licensee must only use sealed sources:

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

2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly

provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

~~(b)~~2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Rule .05(21)(a) are met.

(68) Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(b) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

(69) Installation, Maintenance, Adjustment, and Repair.

(a) Only a person specifically licensed by the Director, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Director, an Agreement State, Licensing State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Director, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with Rule .05(106).

(70) Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall:

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

when unattended;

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

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

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

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

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

(b) A copy of the procedures required by Rule .05(70)(a)4. must be physically located at the unit console.

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

1. The location of the procedures required by Rule .05(70)(a)4.; and

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

~~(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:~~

~~1. The procedures identified in Rule .05(70)(a)4.; and~~

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

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

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

(i) The procedures identified in Rule .05(70)(a)4.; and

(ii) The operating procedures for the unit.

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

(f) A licensee shall retain a record of individuals receiving instruction required by Rule .05(70)(d), in accordance with Rule .05(101).

(g) A licensee shall retain a copy of the procedures required by subparagraphs .05(70)(a)4. and (d)2.(ii).

(71) Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

2. Cause the source(s) to be shielded promptly when an entrance door is opened; and

3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in Rule .05(71)(a) through (71)(e), a licensee shall:

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

- (i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
- (ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader unit, require:

- (i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
- (ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(g) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

- 1. Remains in the unshielded position; or
- 2. Lodges within the patient following completion of the treatment.

(72) Dosimetry Equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

- 1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of

Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

2. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been inter-compared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the inter-comparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with Rule .05(72)(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in Rule .05(72)(a).

(c) The licensee shall retain a record of each calibration, inter-comparison, and comparison in accordance with Rule .05(107).

(73) Full Calibration Measurements on Teletherapy Units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding 1 year.

(b) To satisfy the requirement of Rule .05(73)(a), full calibration measurements must include determination of:

1. The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy and linearity over the range of use;
5. On-off error; and
6. The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(73)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(73)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(73)(b)1. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by Rule .05(73)(a) and physical decay corrections required by Rule .05(73)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(74) Full Calibration Measurements on Remote Afterloader Units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:
 - (i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - (ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of Rule .05(74)(a), full calibration measurements must include, as applicable, determination of:

1. The output within ± 5 percent;

2. Source positioning accuracy to within ± 1 millimeter;

3. Source retraction with backup battery upon power failure; and

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Rule .05(74)(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output.

(e) A licensee shall make full calibration measurements required by Rule .05(74)(a) in accordance with published protocols accepted by nationally recognized bodies.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Rule .05(74)(a) through (74)(e).

(g) A licensee shall mathematically correct the outputs determined in Rule .05(74)(b)1. of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by Rule .05(74)(a) and physical decay corrections required by Rule .05(74)(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(75) Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:
 - (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
 - (iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of Rule .05(75)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule

.05(75)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(75)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(75)(b)1. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by Rule .05(75)(a) and physical decay corrections required by Rule .05(75)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(76) Periodic Spot-Checks for Teletherapy Units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b); and
6. The difference between the measurement made in Rule .05(76)(a)5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by Rule .05(76)(a) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
 2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
 3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
 4. Viewing and intercom systems;
 5. Treatment room doors from inside and outside the treatment room; and
 6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- (e) If the results of the checks required in Rule .05(76)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (f) A licensee shall retain a record of each spot-check required by Rule.05(76)(a) and (76)(d), in accordance with Rule .05(109).

(77) Periodic Spot-Checks for Remote Afterloader Units.

- (a) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
1. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
 2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and
 3. After each source installation.
- (b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in Rule .05(77)(a). The authorized medical physicist need not actually perform the spot-check measurements.
- (c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.
- (d) To satisfy the requirements of Rule .05(77)(a), spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in Rule .05(77)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by Rule .05(77)(d) in accordance with Rule .05(110).

(78) Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. At the beginning of each day of use; and
3. After each source installation.

(b) The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in Rule .05(78)(a); and
2. Review the results of each spot-check required by Rule .05(78)(a)1. within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of Rule .05(78)(a)1., spot-checks must, at a minimum:

1. Assure proper operation of:

- (i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
- (ii) Helmet microswitches;
- (iii) Emergency timing circuits; and
- (iv) Stereotactic frames and localizing devices (trunnions).

2. Determine:

- (i) The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b);
 - (ii) The difference between the measurement made in Rule .05(78)(c)2.(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
 - (iii) Source output against computer calculation;
 - (iv) Timer accuracy and linearity over the range of use;
 - (v) On-off error; and
 - (vi) Trunnion centricity.
- (d) To satisfy the requirements of Rule .05(78)(a)2. and (78)(a)3., spot- checks must assure proper operation of:
- 1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 - 2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 - 3. Viewing and intercom systems;
 - 4. Timer termination;
 - 5. Radiation monitors used to indicate room exposures; and
 - 6. Emergency off buttons.
- (e) A licensee shall arrange for prompt repair of any system identified in Rule .05(78)(c) that is

not operating properly.

(f) If the results of the checks required in Rule .05(78)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by Rule .05(78)(c) and (78)(d) in accordance with Rule .05(111).

(79) Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

2. Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by Rule .05(77), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in Rule .05(79)(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in Rule .05(79)(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by Rule .05(79)(b) in accordance with Rule .05(112).

(80) Radiation Surveys.

(a) In addition to the survey requirements in Rule .03(8) of this Chapter, a person licensed pursuant to Rule .05 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by Rule .05(80)(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by Rule .05(80)(a) of this section in accordance with Rule .05(113).

(81) Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism and other safety components.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Director, an Agreement State, a Licensing State or the Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with Rule .05(114).

(82) Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- (a) The source-specific input parameters required by the dose calculation algorithm;
- (b) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (c) The accuracy of isodose plots and graphic displays;
- (d) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(83) **Possession of Survey Instruments.** A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(84) **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a sealed source for a use authorized under Rule .05(67) to be a physician who:

(a) Is certified by a medical specialty board whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in .05(84)(b)3. and (c). (The names of board certifications that 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 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

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

- (i) 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

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution that is authorized to use radioactive materials in Rule .05(67), 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 mis-administration involving the use of radioactive material;
- (IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- (V) Checking and using survey meters; and
- (VI) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State or Nuclear Regulatory Commission 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 Rule .05(84)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule ~~.05(84)(a)1. or .05(84)(b)1.~~ and .05(84)(b)2., and .05(84)(c), and is able to independently fulfill the radiation safety-related duties~~has achieved a level of competency sufficient to function independently~~ as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and~~

The signed attestation must be obtained from either:

- (i) A preceptor authorized user, who meets the requirements in Rules .05(26), (84), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or
- (ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (84), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency

program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

(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.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

(85) Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Rule .05 if:

- (a) The applicant or licensee has submitted the information required by Rule .05(8)(b), (8)(c) and (8)(d); and
- (b) The applicant or licensee has received written approval from the NRC, an Agreement State, or Licensing State in a license and uses the material in accordance with the regulations and specific conditions the NRC, Agreement State, or Licensing State considers necessary for the medical use of the material.

Records

(86) Records of Authority and Responsibilities for Radiation Protection Programs.

- (a) A licensee shall retain a record of actions taken by the licensee's management in accordance with Rule .05(15)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.
- (b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by Rule .05(15)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by Rule .05(15)(b). The record must include the signature of the Radiation Safety Officer and licensee management.
- (c) The minutes of each Radiation Safety Committee meeting held in accordance with Rule .05(15)(g) shall include:
 - 1. The date of the meeting;

2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

(87) **Records of Radiation Protection Program Safety Changes.** A licensee shall retain a record of each radiation protection program change made in accordance with Rule .05(16)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(88) **Records of Written Directives.** A licensee shall retain a copy of each written directive as required by Rule .05(19) for 3 years.

(89) **Records of Misadministrations.** A licensee shall retain a record of misadministrations reported in accordance with Rule .05(115) for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(90) **Record of a Dose to an Embryo/Fetus or a Nursing Child.** A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with Rule .05(116) for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(91) **Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.** A licensee shall maintain a record of instrument calibrations required by Rule .05(29) for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(92) **Records of Survey Instrument Calibrations.** A licensee shall maintain a record of instrument calibrations required by Rule .05(30) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(93) **Records of Dosages of Unsealed Radioactive Material for Medical Use.** A licensee shall maintain a record of dosage determinations required by Rule .05(31) for 3 years. The

record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.11 MBq (30 μ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(94) **Records of Possession of Sealed Sources and Brachytherapy Sources.** A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Rule .05(33)(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(95) **Records of Surveys for Ambient Radiation Exposure Rate.** A licensee shall retain a record of each survey required by Rule .05(36) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(96) **Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.**

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release,

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by Rule .05(37)(b) were provided to a breast-feeding woman.

(97) **Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.**

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by Rule .05(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by Rule .05(38)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(98) **Records of Decay-in-Storage.** A licensee shall maintain records of the disposal of licensed materials, as required by Rule .05(40), for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(99) **Records of Radionuclide Purity.** A licensee shall maintain a record of the radionuclide contaminant concentration tests required by Rule .05(45) for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the

measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcurie/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(100) **Records of Training.** A licensee shall maintain records of training required by Rule .05(25) for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

(101) **Records of Safety Instruction and Training.** A licensee shall maintain a record of safety instructions and training required by Rules .05(49), (58) and (70) for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(102) **Records of Radiation Surveys of Patients and Human Research Subjects.** A licensee shall maintain a record of the surveys required by Rule .05(56) and (68) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(103) **Records of Brachytherapy Source Inventory.**

(a) A licensee shall maintain a record of brachytherapy source accountability required by Rule .05(57) for 3 years.

(b) For temporary implants, the record must include:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use;
2. The number and activity of unused sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of temporarily implanted sources removed from the patient or human research subject, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of sources permanently implanted in the patient or human research

subject.

(104) **Records of Calibration Measurements on Brachytherapy Sources.** A licensee shall maintain a record of the calibrations on brachytherapy sources required by Rule .05(60) for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(105) **Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.** The licensee shall maintain a record of the activity of a strontium 90 source required by Rule .05(60) for the life of the source. The record must include the date and initial activity of the source as determined under Rule .05(60), and for each decay calculation, the date, and the source activity and the signature of the authorized medical physicist.

(106) **Records of Installation, Maintenance, Adjustment, and Repair.** A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by Rule .05(69) for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(107) **Records of Dosimetry Equipment.**

(a) A licensee shall retain a record of the calibration, inter-comparison, and comparisons of its dosimetry equipment done in accordance with Rule .05(72) for the duration of the license.

(b) For each calibration, inter-comparison, or comparison, the record must include:

1. The date;
2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by Rule .05(72)(a) and (72)(b);
3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and
4. The names of the individuals who performed the calibration, inter- comparison, or comparison.

(108) **Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.**

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by Rule .05(73), (74) and (75) for 3 years.

(b) The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
3. The results and assessments of the full calibrations;
4. The results of the autoradiograph required for low dose-rate remote afterloader units; and
5. The signature of the authorized medical physicist who performed the full calibration.

(109) Records of Periodic Spot-Checks for Teletherapy Units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Rule .05(76) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(110) Records of Periodic Spot-Checks for Remote Afterloader Units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by

Rule .05(77) for 3 years.

(b) The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(111) Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Rule .05(78) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot-check and the signature of the

authorized medical physicist who reviewed the record of the spot-check.

(112) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by Rule .05(79) for 3 years.

(b) The record must include:

1. The date of the check;
2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
3. Notations accounting for all sources before the licensee departs from a facility;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
5. The signature of the individual who performed the check.

(113) Records of Surveys of Therapeutic Treatment Units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Rule .05(80) for the duration of use of the unit.

(b) The record must include:

1. The date of the measurements;
2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
4. The signature of the individual who performed the test.

(114) Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

(a) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Rule .05(81) for the duration of use of the unit.

(b) The record must contain:

1. The inspector's radioactive materials license number;
2. The date of inspection;
3. The manufacturer's name and model number and serial number of both the treatment unit and source;
4. A list of components inspected and serviced, and the type of service; and
5. The signature of the inspector.

Reports

(115) Reports and Notifications of Misadministrations.

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

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

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

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

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

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

(i) An administration of a wrong radioactive drug or the wrong radionuclide for brachytherapy procedures;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5Sv (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site). A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

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

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

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

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

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

(iii) An administration that includes any of the following:

(I) The wrong radionuclide;

(II) The wrong individual or human research subject;

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

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

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

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

(d) The licensee shall submit a written report to the Division within 15 days after discovery of

the misadministration.

1. The written report must include:

- (i) The licensee's name;
- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect, if any, on the individual(s) who received the administration;
- (vi) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- (vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

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

(e) The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

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

(g) A licensee shall retain a record of a misadministration in accordance with Rule .05(89). A copy of the record required under Rule .05(89) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

(116) 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 5 mSv (500 mrem) 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 5 mSv (500 mrem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the Division no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

(d) The licensee shall submit a written report to the Division within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

1. The written report must include:

- (i) The licensee's name;
- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect on the embryo/fetus or the nursing child;
- (vi) What actions, if any, have been taken, or are planned, to prevent recurrence; and
- (vii) 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.

(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 of discovery of an event that would require reporting under Rule .05(116)(a) or (116)(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 for 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 with Rule .05(90). A copy of the record required under Rule .05(90) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(117) **Reports of Leaking Sources.** A licensee shall file a report with the Division within 5 days if a leakage test required by Rule .05(33) reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(118) **Reports of Patient Departure Prior to Authorized Release.**

(a) A licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under Rule .05(37)(a).

(b) The licensee shall submit a written report to the Division within 30 days after discovery of the unauthorized departure. The written report must include:

1. The licensee's name;
2. The date and time of the unauthorized departure;
3. The projected date and time when release would have occurred;
4. The address of the patient's or human research subject's home or anticipated destination following departure;
5. The radionuclide, chemical and physical form and calculated activity at time of release;
6. The apparent reason(s) for the departure prior to authorized release; and
7. A description of any changes in the licensee's patient release criteria or patient instructions

that are designed to avoid a recurrence of such an event.

(119) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(a) The licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of limits specified in Rule .03(5)(i) of this Chapter as a result of the deceased's body.

(b) The licensee shall submit a written report to the Division within 30 days after discovery that the patient or human research subject referenced in (119)(a) has died. The written report must include:

1. The licensee's name;
2. The date of death;
3. The radionuclide, chemical and physical form and calculated activity at time of death; and,
4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisievert (500 mrem).

(120) Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

(a) The licensee shall notify by telephone the Georgia Department of Natural Resources, Environmental Protection Division and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 391-3-17-.05(45)(a) at the time of generator elution. The telephone report to the Georgia EPD must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(b) By an appropriate method listed in 391-3-17-.01(13), the licensee shall submit a written report to Georgia Department of Natural Resources, Environmental Protection Division within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subparagraph .05(120)(a).

Rule 391-3-17-.07, “Notices, Instructions, and Reports To Workers; Inspections,” is amended to read as follows:

391-3-17-.07 Notices, Instructions, and Reports To Workers; ~~Inspections~~: Inspection and Investigations

(1) **Purpose and Scope.** This Rule, 391-3-17-.07, establishes requirements for notices, instructions, and reports by licensees to individuals engaged in activities under a license and options available to such individuals in connection with Division inspections of licensees to ascertain compliance with the provisions of the Act and Regulations, Orders, and licenses issued thereunder regarding radiological working conditions. The Regulations in this Rule apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed by the Director pursuant to Rules 391-3-17-.02, .04, .05, .08, and .09.

(2) **Posting of Notices to Workers.**

(a) Each licensee shall post current copies of the following documents:

1. This Rule and Rule 391-3-17-.03 of this Chapter;
2. The license, license conditions and documents incorporated into the license by reference and amendments thereto;
3. The operating procedures applicable to activities under the license; and
4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or Order issued pursuant to this Chapter, and any response from the licensee.

(b) If posting of a document specified in (2)(a)1., 2., or 3. of this Rule is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

(c) Division's form "Notice to Employees" shall be posted by each licensee.

(d) Division documents posted pursuant to (2)(a)4. of this Rule shall be posted within 5 working days after receipt of the documents from the Division; the licensee's response, if any, shall be posted within five working days after dispatch from the licensee. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices, or forms posted pursuant to (2) of this Rule shall appear in a sufficient number of places to permit individuals engaged in work under the license to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous and shall be replaced if defaced or altered.

(3) **Instructions to Workers.**

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be:

1. Kept informed of the storage, transfer, or use of sources of radiation in the licensee's facility;
2. Instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
3. Instructed in, and instructed and required to observe, to the extent within the workers' control, the applicable provisions of this Chapter and the license for the protection of personnel from exposures to radiation or radioactive material;
4. Instructed of their responsibility to report promptly to the licensee any condition which may constitute, lead to, or cause a violation of the Act, this Chapter, and the license or unnecessary exposure to radiation or radioactive material;
5. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
6. Advised as to the radiation exposure reports which workers shall be furnished pursuant to (4) of this Rule.

(b) In determining those individuals subject to the requirements of (3)(a) above, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of the facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

(4) Notifications and Reports to Individuals.

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, when required by Rule 391-3-17-.03(8)(b) of this Chapter, shall be reported to the individual as specified in (4) of this Rule. The information reported shall include data and results obtained pursuant to this Chapter, Orders, or license conditions, as shown in records maintained by the licensee pursuant to this Chapter. Each notification and report shall:

1. Be in writing;
2. Include appropriate identifying data such as the name of the licensee, the name of the individual, and the individual's identification number, preferably 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 Rule 391-3-17-.07. You should preserve this report for further reference."

(b) Each licensee shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee pursuant to Rule 391-3-17-.03(14)(g) of this Chapter. The licensee shall provide an annual report to each individual monitored under .03(8)(b) 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.

(c) Each licensee shall furnish a written report of a worker's exposure to sources of radiation at the request of the worker formerly engaged in activities controlled by the licensee. The report shall include the dose record for each year the worker was required to be monitored pursuant to Rule 391-3-17-.03(8)(b). Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license in which the worker participated during this period.

(d) When a licensee is required pursuant to Rule 391-3-17-.03(15)(b), (c), and (d) of this Chapter to report to the Division any exposure of an individual to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Division. Such reports shall be transmitted at a time not later than the transmittal to the Division.

(e) At the request of a worker who is terminating employment with the licensee in work involving exposure to radiation or radioactive material, during the current year, each licensee shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

(5) Presence of Representatives of Licensees and Workers During Inspection.

(a) Each licensee shall afford to the Division at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to this Chapter.

(b) During an inspection, Division inspectors may consult privately with workers as specified in (6) of this Rule. The licensee may accompany Division inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Division inspections, the licensee shall notify the inspectors of such authorization

and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee and shall have received instructions as specified in (3) of this Rule.

(e) Different representatives of the licensee and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee and the workers' representative, an individual who is not routinely engaged in work under control of the licensee, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Division inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of (5) of this Rule, Division inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

(6) Consultation with Workers During Inspections.

(a) Division inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of this Chapter and the license to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, this Chapter, or license conditions, or any unnecessary exposure of an individual to sources of radiation under the licensee's control. Any such notice in writing shall comply with the requirements of (7)(a) of this Rule.

(c) The provisions of (6)(b) of this Rule shall not be interpreted as authorization to disregard instructions pursuant to (3) of this Rule.

(7) Requests by Workers for Inspections

(a) Any worker or representative of workers believing that a violation of the Act, this Chapter, or license conditions exists or has occurred in work under a license with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Division's Radioactive Materials Program. Any such notice shall

be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee by the Division no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Division, except for good cause shown.

(b) If, upon receipt of such notice, the Division determines that the complaint meets the requirements set forth in (7)(a) of this Rule, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to (7) of this Rule need not be limited to matters referred to in the complaint.

(c) No licensee or contractor or subcontractor of a licensee shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this Chapter or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this Rule.

(8) Inspections Not Warranted; Informal Review

(a) If the Division's Radioactive Materials Program determines, with respect to a complaint under (7) of this Rule, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Radioactive Materials Program shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of (7)(a) of this Rule. The complainant may obtain review of such determination by submitting a written statement of position with the Director of the Environmental Protection Division. The Division will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position to the Director of the Environmental Protection Division who will provide the complainant with a copy of such statement by certified mail.

(b) Upon the request of the complainant, the Director of the Environmental Protection Division may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Director of the Environmental Protection Division shall affirm, modify, or reverse the determination of the Manager of Radioactive Materials Program, and furnish the complainant and the licensee a written notification of the decision and the reason for it.

Rule 391-3-17-.10, “Administration,” is amended to read as follows:

391-3-17-.10 Administration

(1) Scope. The provisions of this Rule, 391-3-17-.10, shall apply to the administrative procedures required by this Chapter.

(2) Administration.

(a) Administrative Examination of Applications. Applications for the issuance of a license, amendment of a license at the request of the holder, and renewal of a license will be given a docket or other identifying number for administrative examination. The applicant may be required to submit additional information and may be requested to confer informally regarding the application. The Division will give to others such notice of the filing of applications as is required under the applicable provisions of this Chapter and such additional notices as it deems appropriate.

(b) Effect of Timely Renewal Application. In the case of an application for renewal, if the licensee has made application for the renewal of an existing license at least 30 days prior to its expiration date, the license shall not be deemed to have expired until such application shall have been determined.

(c) Filing of Papers. Unless otherwise specified, papers required to be filed with the Division shall be filed with the Environmental Protection Division, Radioactive Materials Program, 4244 International Parkway, Suite 120 Atlanta, Georgia 30354. Papers required to be filed with the Division shall be deemed filed upon actual receipt with the Division at the location specified. Unless otherwise specified, the filing, when by mail, shall upon actual receipt be deemed complete as of the date of deposit in the mail. Papers may be filed at the Division’s offices in Atlanta, Georgia.

(d) Payment of Fees. All licensees shall remit annual fees; in accordance with Table 1, the Radioactive Materials License Fee Schedule. Annual fee payments for general and specific licenses are due before the end of the calendar year for the following calendar year. New ~~L~~icensees shall be invoiced for annual fees at a prorated rate. Such fees shall be due and payable thirty (30) days after the invoice date. Fees for applications for specific licenses, and annual fees for reciprocity applicants, shall accompany the request. An application fee must accompany renewal applications that are submitted after a license has expired. Licensees with fees which are delinquent shall not have any request for amendment or renewal of their licenses, except in the interest of public health and safety, honored by the Division until such fees are paid in full or a payment plan has been accepted by the Division.

Table 1
Radioactive Materials License Fee Schedule

License Category	Fee Category	New License Application Fee	Annual Fee, Nominal	Annual Fee, Small Entity [See subparagraph (e)]	Annual Fee, Lower Tier [See subparagraph (f)]
Medical Teletherapy	A.1.a	\$3,256.00	\$6,623.00	\$2,026.50	\$1,212.75
Stereotactic Radiosurgery (i.e., Gamma Knife)	A.1.b	\$3,256.00	\$6,623.00	\$2,026.50	\$1,212.75
Broad Medical	A.10	\$3,145.00	\$17,057.00	\$4,550.00	\$3,736.25
Eye Applicators	A.11	\$999.00	\$3,182.00	\$1,982.75	\$1,169.00
Source Material	A.12	\$1,998.00	\$4,588.00	\$435.75	\$435.75
Depleted Uranium	A.12	\$222.00	\$666.00	\$266.00	\$266.00
Institutional Medical-Mult. Use (Including HDR)	A.2.a	\$999.00	\$3,182.00	\$3,150.00	\$2,336.25
Institutional Medical-Mult. Use	A.2.b	\$999.00	\$3,182.00	\$1,982.75	\$1,169.00
Institutional Medical-Mult. Use (diagnostic only)	A.2.c	\$999.00	\$3,182.00	\$1,750.00	\$936.25
Institutional Medical-Single Use (therapy only)	A.3	\$999.00	\$3,182.00	\$1,982.75	\$1,169.00
Private Practice (Therapy-HDR)	A.4.a	\$999.00	\$3,182.00	\$3,150.00	\$2,336.25
Private Practice (Limited Therapy)	A.4.b	\$999.00	\$3,182.00	\$1,982.75	\$1,169.00
Private Practice (Diagnostic Only)	A.4.c	\$999.00	\$3,182.00	\$1,837.50	\$1,023.75
Private Practice (Veterinary)	A.4.d	\$555.00	\$1,813.00	\$1,750.00	\$936.25
In-Vitro Specific Licenses	A.5	\$555.00	\$1,813.00	\$1,470.00	\$831.25
In-Vitro General Licenses	A.6	\$0.00	\$100.00	\$100.00	\$100.00
Bone Mineral Analyzers	A.7	\$999.00	\$3,182.00	\$1,750.00	\$936.25
Nuclear Pharmacy	A.8.a.1	\$2,405.00	\$6,253.00	\$3,990.00	\$3,176.25
Medical Manufacturer for Distribution	A.8.a.2	\$2,405.00	\$6,253.00	\$2,357.25	\$1,543.50
Medical Distribution or Redistribution Only (sealed)	A.8.b.1	\$1,885.72	\$3,717.19	\$1,692.25	\$878.50
Medical Distribution or Redistribution Only (GL)	A.8.b.2	\$407.00	\$1,184.00	\$1,184.00	\$691.25
Mobile Nuclear Medicine	A.9.a	\$999.00	\$3,182.00	\$2,275.00	\$1,461.25
Mobile HDR	A.9.b	\$999.00	\$3,182.00	\$2,275.00	\$1,461.25
Special Nuclear Material (sealed sources in devices)	B.1.a	\$481.00	\$1,332.00	\$1,036.00	\$572.25

License Category	Fee Category	New License Application Fee	Annual Fee, Nominal	Annual Fee, Small Entity [See subparagraph (e)]	Annual Fee, Lower Tier [See subparagraph (f)]
Special Nuclear Material (power sources in devices)	B.1.b	\$925.00	\$2,701.00	\$990.50	\$526.75
Special Nuclear Material (other)	B.2	\$925.00	\$2,701.00	\$1,895.25	\$1,081.50
Pacemaker, Byproduct or SNM -- Medical Inst	B.3	\$999.00	\$3,182.00	\$1,895.25	\$1,081.50
Industrial Mfg. for Distribution	C.1	\$1,628.00	\$4,588.00	\$2,437.75	\$1,624.00
Installed Gauges	C.10.a	\$555.00	\$1,813.00	\$1,470.00	\$831.25
Gas Chromatograph, etc.	C.10.b	\$555.00	\$1,813.00	\$1,400.00	\$761.25
Portable Moisture Density Gauges, Pb analyzers, etc.	C.11	\$555.00	\$1,813.00	\$1,750.00	\$1,111.25
Calibration Sources	C.12.a	\$555.00	\$1,813.00	\$1,750.00	\$1,111.25
Calibration Sources (Radium)	C.12.b	\$555.00	\$1,813.00	\$1,349.25	\$710.50
Decontamination Services	C.13.a	\$2,368.00	\$5,513.00	\$2,100.00	\$1,461.25
Industrial (other) (NORM)(Gauge Service)	C.13.b	\$2,368.00	\$5,513.00	\$1,750.00	\$1,111.25
Contaminated Equipment	C.14	\$555.00	\$1,813.00	\$1,349.25	\$710.50
In-house Industrial Radiography	C.2	\$1,480.00	\$9,583.00	\$3,780.00	\$2,966.25
Multiple Job-Site Industrial Radiography	C.3	\$1,480.00	\$9,583.00	\$3,780.00	\$2,966.25
Gamma Irradiators (Self-Shielded)	C.4.a	\$1,184.00	\$3,367.00	\$1,135.75	\$672.00
Gamma Irradiators (<10K Ci)	C.4.b.1	\$2,368.00	\$5,735.00	\$1,750.00	\$936.25
Gamma Irradiators (>10K<100K Ci)	C.4.b.2	\$22,644.00	\$52,133.00	\$4,462.50	\$3,648.75
Gamma Irradiators (>100K<1M Ci)	C.4.b.3	\$22,644.00	\$52,133.00	\$8,050.00	\$7,236.25
Gamma Irradiators (>1M Ci)	C.4.b.4	\$22,644.00	\$52,133.00	\$17,675.00	\$16,861.25
Broad Scope Distribution, Specific (Type A)	C.5.a.1	\$4,736.00	\$16,095.00	\$5,215.00	\$4,401.25
Broad Scope Distribution, Specific (Type B)	C.5.a.2	\$4,736.00	\$16,095.00	\$2,765.00	\$1,951.25
Broad Scope Distribution, Specific (Type C)	C.5.a.3	\$4,736.00	\$16,095.00	\$2,275.00	\$1,461.25
GL Distribution (source and / or device evaluation)	C.5.b	\$740.00	\$1,776.00	\$1,655.50	\$841.75
GL Distribution (no source and /or device evaluation)	C.5.c	\$407.00	\$1,184.00	\$1,184.00	\$967.75
Possession Incident to NRC Exempt Distribution	C.6.c	\$555.00	\$1,813.00	\$1,739.50	\$925.75
Well Logging /Tracers	C.7.a	\$1,221.00	\$3,774.00	\$2,217.25	\$1,403.50
Field Flooding Studies	C.7.b	\$857.15	\$2,933.85	\$1,750.00	\$1,111.25
Nuclear Laundries	C.8	\$8,066.00	\$17,057.00	\$2,590.00	\$1,776.25
Industrial Research & Development	C.9	\$1,295.00	\$3,219.00	\$1,902.25	\$1,088.50
Broad Scope (Academic) (Type A & B)	D.1.a	\$1,998.00	\$5,439.00	\$2,563.75	\$1,750.00
Broad Scope (Academic) (Type C)	D.1.b	\$1,998.00	\$5,439.00	\$2,075.50	\$1,261.75
Broad Scope (Industrial R&D) (Type A)	D.2.a	\$1,998.00	\$5,439.00	\$2,563.75	\$1,750.00
Broad Scope (Industrial R&D) (Type B)	D.2.b	\$1,998.00	\$5,439.00	\$2,292.50	\$1,478.75
Broad Scope (Industrial R&D) (Type C)	D.2.c	\$1,998.00	\$5,439.00	\$2,075.50	\$1,261.75
Broad Scope (Medical Manufacturer for Distribution) (R&D)	D.3	\$2,405.00	\$5,735.00	\$2,765.00	\$1,951.25

Civil Defense (Emergency Management)	E.1	\$925.00	\$3,330.00	\$1,256.50	\$617.75
Civil Defense (Emergency Response)	E.2	\$925.00	\$3,330.00	\$1,188.25	\$549.50
Teletherapy Service Co.	F	\$2,368.00	\$5,513.00	\$1,902.25	\$1,088.50
Consultants(Leak Testing Service)	G	\$555.00	\$1,813.00	\$1,349.25	\$411.25
G L Devices (except tritium safety signs)	GL	\$0.00	\$100.00	\$100.00	\$100.00
Academic (Non-Broad)	I	\$1,295.00	\$3,219.00	\$1,400.00	\$761.25
Device Evaluation	J.1	\$4,595.40	\$5,350.20	\$1,050.00	\$236.25
Source Evaluation	J.2	\$1,709.40	\$2,319.90	\$875.00	\$236.25
Radioactive Waste Disposal-Burial	L.1	\$154,286.53	\$155,200.77	\$39,550.00	\$38,736.25
Radioactive Waste Disposal-Incineration	L.2	\$154,286.53	\$155,200.77	\$39,550.00	\$38,736.25
Radioactive Waste, Processing & Repackaging	L.3.a	\$3,108.00	\$11,840.00	\$5,390.00	\$4,576.25
Radioactive Waste, Prepackaged	L.3.b	\$1,813.00	\$5,513.00	\$3,552.50	\$2,738.75
Reciprocity	K.	appropriate nominal annual fee <u>(eligible for Small Entity/Lower Tier)</u>			

(e) **Small Entity**

The size standards for Georgia small entities are as follows:

1. A small business is a business with annual receipts of \$3.5 million or less except private practice physicians for which the standard is annual receipts of \$1 million or less.
2. A small organization is a not-for-profit organization which is independently owned and operated and has annual receipts of \$3.5 million or less.
3. Small governmental jurisdictions are governments of cities, counties, towns, school districts, or special districts with a population of less than 50,000.
4. A small educational institution is one that is (1) supported by a qualifying small governmental jurisdiction, or (2) one that is not state or publicly supported and has 500 employees or less.

(f) **Small Entity Lower Tier**

Small businesses and not-for-profit organizations with annual receipts of less than \$250,000 and small governmental jurisdictions with populations of less than 20,000 qualify for the lower tier small entity fee.

(3) **Penalties.**

(a) Any person who engages in any of the following conduct shall be guilty of a misdemeanor as found in O.C.G.A. Section 31-13-13: 1. Hindering, obstructing, or otherwise interfering with any representative of the Department in the discharge of his official duties in making inspections or impounding radioactive materials as provided in Code Section 31-13-5 and 31-13-11 respectively; or 2. Violating the provisions of Code Section 31-13-7 (permits for disposal of

radioactive waste; bonding of permittees), or any Rule or Regulation promulgated thereunder; or
3. Violating the provisions of Code Section 31-13-12 (Prohibited Uses of Sources of Radiation).

(b) Any person who submits any false statements or writings, concealment of facts, and fraudulent documents in matters within the jurisdiction of the Division shall be guilty of a felony as found in O.C.G.A. Section 16-10-20:

1. A person who knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; makes a false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document, knowing the same to contain any false, fictitious, or fraudulent statement or entry, in any matter within the jurisdiction of the Division shall, upon conviction thereof, be punished by a fine of not more than \$1,000.00 or by imprisonment for not less than one nor more than five years, or both.

(c) Any person who:

1. Violates any licensing provision of this 31-13-1, et. seq., or any Rule, Regulation, or Order issued under 31-13-1, et. seq., or any term, condition, or limitation of any license issued under this Chapter; or

2. Commits any violation for which a license may be revoked under rules or regulations issued pursuant to this 31-13-1, et. seq., may be subject to a civil penalty, to be imposed by the Division, not to exceed \$10,000.00. If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty.

3. If a violation is found to exist during an inspection or visit and is then found to exist on a subsequent inspection or visit, there shall arise a rebuttable presumption that the violation continued throughout the period of time between the initial inspection or visit and the subsequent inspection or visit.

(d) Whenever the Division proposes to subject a person to the imposition of a civil penalty, it shall notify such person in writing:

1. Setting forth the date, facts, and nature of each act or omission with which the person is charged.

2. Specifically identifying the particular provision or provisions of the Code section, Rule, Order, or license condition involved in the violation; and

3. Advising of each penalty which the Division proposes to impose and its amount.

(e) Such written notice shall be sent by registered or certified mail by the Division to the last known address of such person. The person so notified shall be granted an opportunity to show in writing, within ten days from receipt of such notice, why such penalty should not be imposed. The notice shall also advise such person that upon failure to pay the civil penalty subsequently determined by the Division, if any, the penalty may be collected by civil action.

(f) Upon receipt of a written response from the person so notified, alleging that a penalty should not be imposed, the Director shall consider the response and make a final decision on the appropriateness and amount of the penalty. The Division may, at its discretion, conduct an onsite inspection in order to make a final decision. In making this decision, the Director may, as deemed appropriate by the Director, consider such factors as: errors concerning the amount or nature of the penalty, corrective action taken by the licensee, and approved disposal of radioactive material by the licensee.

(g) The Division shall inform the licensee of its final decision by registered or certified mail to the last known address of the licensee. Within 10 days of receipt of the Division's final determination concerning the civil penalty, the licensee may request an administrative hearing pursuant to the Georgia Administrative Procedure Act, O.C.G.A. 50-13-1, et. seq.

Authority: O.C.G.A. Section 31-13-1 et seq., as amended.