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Rules of the Department of Natural Resources, Chapter 391-3-17, Radioactive Materials, are hereby amended, added to, repealed in part, revised, as hereinafter explicitly set forth in the attached amendments, additions, partial repeals, and revisions for specific rules, or such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(11), "Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material," is being 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 μSv) 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 applicable U.S. Nuclear Regulatory Commission or Agreement 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 the U.S. Nuclear Regulatory Commission or another Agreement 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 or an Agreement 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 the following statement, 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)

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 or an Agreement 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 or Agreement 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 or the Agreement 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 or the Agreement 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. The following statement, as appropriate, or a substantially similar statement which contains the information called for in the following statement, 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)

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 207.17(a)~~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 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 not withstanding 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 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. Nothing in this subparagraph~~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 or an Agreement 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 10 CFR 32.210 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-.03(12), "Precautionary Procedures," is being amended to read as follows:

(12) **Precautionary Procedures**

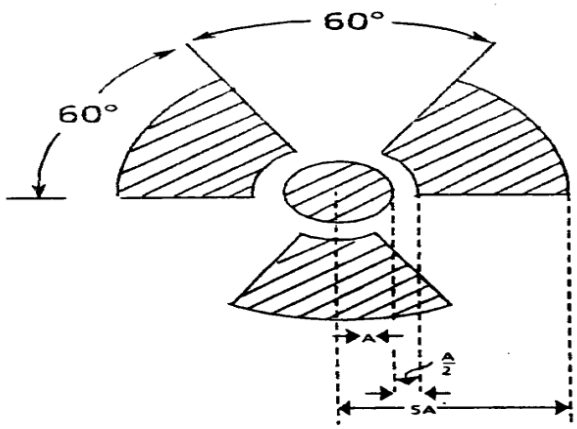
(a) Caution Signs.

1. Standard Radiation Symbol. Unless otherwise authorized by the Division, the symbol prescribed by (12)(a) of this Rule uses the colors magenta (or purple or black) on yellow background. The symbol prescribed is the three-bladed design as follows:

(i) Cross-hatched area is to be magenta, purple, or black; and

(ii) The background is to be yellow.

2. Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of (12)(a)1. of this Rule, licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures with conspicuously etched or stamped radiation caution symbols without a color requirement.



3. In addition to the contents of signs and labels prescribed in this Rule, the licensee shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(b) Posting Requirements.

1. Posting of Radiation Areas. The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

2. Posting of High Radiation Areas. The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH

RADIATION AREA" or "DANGER, HIGH RADIATION AREA." The licensee may satisfy this requirement by posting the sign at the boundary of the high radiation area.

3. Posting of Very High Radiation Areas. The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

4. Posting of Airborne Radioactivity Areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

5. Posting of Areas or Rooms in which Licensed Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C of 10 CFR Part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

(c) Exceptions to Posting Requirements.

1. A licensee is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if all of the following conditions are met:

(i) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Rule; and

(ii) The area or room is subject to the licensee's control.

2. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to (12)(b) of this Rule provided that the patient could be released from licensee control pursuant to Rule 391-3-17-.05.

3. A room or area is not required to be posted with a caution sign pursuant to (12)(b) of this Rule because of the presence of a sealed source provided that the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

(d) Labeling Containers and Radiation Machines.

1. The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment,

to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

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

(e) Exemptions to Labeling Requirements. A licensee is not required to label:

1. Containers holding licensed material in quantities less than the quantities listed in Appendix C of 10 CFR 20;

2. Containers holding licensed material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20;

3. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Rule;

4. Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[4];

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

6. Installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.

(f) Procedures for Receiving and Opening Packages.

1. Each licensee who is authorized to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in Rule 391-3-17-.06(3), shall make arrangements to receive:

(i) The package when the carrier offers it for delivery; or

(ii) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

2. Each licensee shall:

[4] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation (DOT) regulations, 49 CFR 172.403-172.440.

(i) Monitor the external surfaces of a labeled[5] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in "special form" as defined in Rule 391-3-17-.01(2);

(ii) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in Rule 391-3-17-.06(3), and the radioactive material is in the form of a gas or in special form as defined in Rule 391-3-17-.01(2); and

(iii) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if the package has evidence of potential contamination, such as packages that are crushed, wet, or damaged.

3. The licensee shall perform the monitoring required by (12)(f)2. of this Rule as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

4. The licensee shall immediately notify the final delivery carrier~~, the NRC Headquarters Operations Center~~ and the Division by telephone, telegram, mailgram, or facsimile, when:

(i) Removable radioactive surface contamination exceeds the limits of Rule 391-3-17-.06(16)(i); or

(ii) External radiation levels exceed the limits of Rule 391-3-17-.06(14).

5. Each licensee shall:

(i) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(ii) Ensure that the procedures are followed and that special instructions for the type of package being opened are followed.

6. Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of (12)(f)2. of this Rule, but are not exempt from the monitoring requirement in (12)(f)2. of this Rule for measuring radiation levels to ensure that the source is still properly lodged in its shield.

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

Rule 391-3-17-.03(15), "Reports," is being amended to read as follows:

(15) **Reports**

(a) Reports of Stolen, Lost, or Missing Licensed Sources of Radiation.

1. Telephone. Each licensee shall report to the Division ~~and the NRC Headquarters Operation Center~~ by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR 20, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

(ii) Within 30 days after its occurrence becomes known to the licensee, lost, stolen or missing licensed radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C of 10 CFR 20 that is still missing.

2. Written. Each licensee who is required to make a report pursuant to (15)(a)1. of this Rule shall, within 30 days after making the telephone report, make a written report to the Division ~~and the NRC Headquarters Operation Center~~ setting forth the following information:

(i) A description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form;

(ii) A description of the circumstances under which the loss or theft occurred;

(iii) A statement of disposition, or probable disposition, of the licensed material or source of radiation involved;

(iv) Exposures of individuals to radiation, the circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(v) Actions that have been taken, or will be taken, to recover the source of radiation; and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed sources of radiation.

3. Subsequent to filing the written report, the licensee shall also report additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

4. The licensee shall prepare any report filed with the Division ~~and the NRC Headquarters Operation Center~~ pursuant to (15)(a) of this Rule so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(b) Notification of Incidents.

1. Immediate notification. Each licensee shall:

(i) Notify the Division ~~and the NRC Headquarters Operation Center~~ as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(ii) Notwithstanding any other requirements for notification, immediately report, to the Division, any event involving radioactive material or sources of radiation possessed by the licensee that may have caused or threatens to cause any of the following conditions:

(I) An individual to receive:

I. A total effective dose equivalent of 25 rem (0.25 Sv) or more; or

II. A lens dose equivalent of 75 rem (0.75 Sv) or more; or

III. A shallow-dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more; or

(II) The release of radioactive material, inside or outside a restricted area, so that had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot cells or process enclosures).

2. Twenty-four hour report. Each licensee shall notify the Division ~~and the NRC Headquarters Operation Center~~ within 24 hours after the discovery of any of the following events involving licensed material:

(i) An unplanned contamination event that:

(I) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(II) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; and

(III) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(ii) An event in which equipment is disabled or fails to function as designed when:

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

(II) The equipment is required to be available and operable when it is disabled or fails to function; and

(III) No redundant equipment is available and operable to perform the required safety function.

(iii) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;

(iv) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(I) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; and

(II) The damage affects the integrity of the licensed material or its container.

(v) Notwithstanding any other requirements for notification, within 24 hours report, to the Division ~~and the NRC Headquarters Operation Center~~ any event involving radioactive material or sources of radiation possessed by the licensee that may have caused or threatens to cause any of the following conditions:

(I) An individual to receive, in a period of 24 hours:

I. A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

II. A lens dose equivalent exceeding 15 rems (0.15 Sv); or

III. A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

(II) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

3. Preparation and submission of reports. Reports made by licensees in response to the requirements of this paragraph must be made as follows:

(i) Licensees shall make reports required by (15)(b)1. and 2. by telephone to the Division ~~and the NRC Headquarters Operation Center~~. To the extent that the information is available at the time of notification, the information provided in these must include:

(I) The caller's name, position title, and call back telephone number;

(II) Date, time, and the exact location of the event;

(III) Description of the event, including:

I. Radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released;

II. Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

III. The sequence of occurrences leading to the event, including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

IV. Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their function;

(IV) External conditions affecting the event;

(V) Additional actions taken by the licensee in response to the event;

(VI) Status of the event (e.g., whether the event is on-going or was terminated);

(VII) Current and planned site status, including any declared emergency class;

(VIII) Notifications, related to the event, that were made or are planned to any local, State, or other Federal agencies;

(IX) Status of any press releases, related to the event, that were made or are planned.

(ii) Written report. Each licensee who makes a report required by (15)(b)1. and 2. shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Radioactive Materials Program, 4244 International Parkway, Suite 120, Atlanta, Georgia 30354 or current mailing address ~~and USNRC, Region II, 245 Peachtree Center Avenue, NE., Suite 1200, Atlanta, GA 30303–1257~~. The written report must include the following:

(I) Complete applicable information required by (b)3.(i);

(II) A description of the event, including the probable cause, all factors that contributed to the event, and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned; and

(III) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments.

4. The licensee shall prepare each report filed with the Division ~~and the NRC Headquarters Operation Center~~ pursuant to (15)(b) of this Rule so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

5. Licensees shall make the required by (15)(b)1. and 2. of this Rule by telephone to the Division, and shall confirm the initial contact by telegram, mailgram, or facsimile to the Division.

6. The provisions of (15)(b) of this Rule do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to (15)(d) of this Rule.

(c) Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

1. Reportable Events. In addition to the notification required by (15)(b) of this Rule, each licensee shall submit a written report to the Division within 30 days after learning of any of the following occurrences:

(i) Incidents for which notification is required by (15)(b) of this Rule;

(ii) Doses in excess of any of the following:

(I) The occupational dose limits for adults in (5)(a) of this Rule;

(II) The occupational dose limits for a minor in (5)(g) of this Rule;

(III) The limits for an embryo/fetus of a declared pregnant woman in (5)(h) of this Rule;

(IV) The limits for an individual member of the public in (5)(i) of this Rule;

(V) Any applicable limit in the license; or

(VI) The ALARA constraints for air emissions established under .03(4)(d).

(iii) Levels of radiation or concentrations of radioactive material in:

(I) A restricted area in excess of applicable limits in the license; or

(II) An unrestricted area in excess of ten times the applicable limit set forth in this Rule or in the license, whether or not the exposure of any individual in excess of the limits in (5)(i) of this Rule is involved; or

(iv) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards[7].

2. Contents of Reports.

(i) Each report required by (15)(c)1. of this Rule shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(I) Estimates of each individual's dose;

(II) The levels of radiation and concentrations of radioactive material involved;

(III) The cause of the elevated exposures, dose rates, or concentrations; and

(IV) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(ii) Each report filed pursuant to (14)(c)1. of this Rule shall include for each occupationally exposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in (5)(h) of this Rule, the identification should be that of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

3. All licensees who make pursuant to (15)(c)1. of this Rule shall submit the report in writing to the Division.

(d) Reports of Planned Special Exposures. The licensee shall submit a written report to the Division within 30 days following any planned special exposure conducted in accordance with (5)(f) of this Rule, informing the Division that a planned special exposure was conducted and indicating the date that the planned special exposure occurred and the information required by (14)(g) of this Rule.

(e) Reports to Individuals of Exceeding Dose Limits. When a licensee is required, pursuant to the provisions of (15)(c), (15)(d), or (15)(f), to report to the Division any exposure of an identified occupationally exposed individual, or an identified member of the public to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Division to the individual. This report must be transmitted at a time no later than the transmittal to the Division.

(f) Notifications and Reports to Individuals.

[7] For purposes of these Regulations, the U.S. Environmental Protection Agency Standards apply only to source material mills and nuclear power plants.

1. Requirements for notification and to individuals of exposure to radiation or radioactive material are specified in Rule 391-3-17-.07(4).

2. When a licensee is required pursuant to (15)(c) of this Rule to report to the Division any exposure of an identified occupationally exposed individual or identified member of the public 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. This report shall be transmitted at a time not later than the transmittal to the Division, and shall comply with the provisions of Rule 391-3-17-.07(4)(a).

(g) Reports of Leaking or Contaminated Sealed Sources. If the test for leakage or contamination required pursuant to Rule .03(6) indicates that the sealed source is leaking or contaminated, a report of the test shall be filed within five days with the Division describing the equipment involved, the test results, and the corrective action taken.

(h) [Reserve]

(i) Serialization of Nationally Tracked Sources.

1. Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

(j) Reports of Transactions Involving Nationally Tracked Sources.

1. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally-tracked source shall complete and submit a National Source Tracking Transaction Report as specified below for each type of transaction.

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

(i) The name, address, and license number of the reporting licensee;

(ii) The name of the individual preparing the report;

(iii) The manufacturer, model, and serial number of the source;

(iv) The radioactive material in the source;

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

(vi) The manufacture date of the source.

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

(i) The name, address, and license number of the reporting licensee;

(ii) The name of the individual preparing the report;

(iii) The name and license number of the recipient facility and shipping address;

(iv) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(v) The radioactive material in the source;

(vi) The initial or current source strength in becquerels (curies);

(vii) The date for which the source strength is reported;

(viii) The shipping date;

(ix) The estimated arrival date; and

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

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

(i) The name, address, and license number of the reporting licensee;

(ii) The name of the individual preparing the report;

(iii) The name, address and license number of the person that provided the source;

(iv) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(v) The radioactive material in the source;

(vi) The initial or current source strength in becquerels (curies);

(vii) The date for which the source strength is reported;

(viii) The date of receipt; and

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

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

(i) The name, address, and license number of the reporting licensee;

(ii) The name of the individual preparing the report;

(iii) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(iv) The radioactive material in the source;

(v) The initial or current source strength in becquerels (curies);

(vi) The date for which the source strength is reported; and

(vii) The disassemble date of the source.

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

(i) The name, address, and license number of the reporting licensee;

(ii) The name of the individual preparing the report;

(iii) The waste manifest number;

(iv) The container identification with the nationally tracked source;

(v) The date of disposal; and

(vi) The method of disposal.

7. The reports discussed in (15)(j)2.-6. above must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(i) The on-line National Source Tracking System;

(ii) Electronically using a computer-readable format;

(iii) By facsimile;

(iv) By mail to the address on the National Sources Tracking Transaction Report Form (NRC Form 748); or

(v) By telephone with follow-up by facsimile or mail.

8. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified in (15)(j)2.-6. of this paragraph. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

Table 3: Nationally Tracked Source Thresholds

Radioactive Material	**Category 1 (TBq)**	**Category 1 (Ci)**	**Category 2 (TBq)**	**Category 2 (Ci)**
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Beryllium	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-238/Beryllium	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

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

Authority: O.C.G.A. Section 31-13-1 et seq., as amended.