PART II

LICENSING OF RADIOACTIVE MATERIALS

RHA 2.1 PURPOSE AND SCOPE

2.1.1 No person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to these regulations, or as otherwise provided in these regulations.

NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, by-product, or special nuclear material, intended for use by the general public may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

2.1.2 Deliberate misconduct

2.1.2.1 Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

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

2.1.2.1.2 Deliberately submit to the Department, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

2.1.2.2 A person who violates RHA 2.1.2.1.1 or 2.1.2.1.2 of this section may be subject to enforcement action in accordance with the procedures in RHA 1.12.

2.1.2.3 For the purposes of RHA 2.1.2.1.1, deliberate misconduct by a person means an intentional act or omission that the person knows that:

2.1.2.3.1 Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or

2.1.2.3.2 Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

RHA 2.2 TYPES OF LICENSES

Licenses for radioactive materials are of two types; general and specific.

The Department issues a specific license to a named person who has filed an application for the license under the provisions of this regulation (61-63). A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the

filing of an application with the Department or the issuance of a licensing document to a particular person. However, registration with the Department may be required by the particular general license.

RHA 2.3 GENERAL LICENSES –SOURCE MATERIAL

2.3.1 A general license is hereby issued authorizing possession, use and transfer of not more than fifteen (15) pounds of source material at any one time by persons in the following categories:

Commercial and industrial firms and research, educational and medical institutions, and State and Local governmental agencies for research, development, educational, commercial or operational purposes; and provided, that no person shall pursuant to this general license, receive more than a total of 150 pounds of source material in any one calendar year.

2.3.2 Persons who receive, possess, use, or transfer source material pursuant to the general license issued in Paragraph 2.3.1 are exempt from provisions of Part III and Part VI of these regulation to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this Part.

2.3.3 A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

2.3.4 Depleted Uranium in Industrial Products and Devices

2.3.4.1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of sub-paragraphs 2.3.4.2, 2.3.4.3, 2.3.4.4, and 2.3.4.5, 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.

2.3.4.2 The general license in subparagraph 2.3.4.1 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 pursuant to RHA 2.27 or 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.

2.3.4.3 Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by subparagraph 2.3.4.1 shall file Department Form RHA 100-2 "Registration Certificate Use of Depleted Uranium Under General License," with the Department. The form shall be submitted within 30 days after the first receipt of acquisition of such depleted Uranium. The registrant shall furnish on Department Form RHA 100-2 the following information and such other information as may be required by that form:

2.3.4.3.1 Name and address of the registrant.

2.3.4.3.2 A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subparagraph 2.3.4.1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive depleted uranium; and

2.3.4.3.3 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 2.3.4.3.2. The registrant possessing or using depleted uranium under the general license established by subparagraph 2.3.4.1 shall report in writing to the Department any changes in information furnished by him in Department Form RHA 100-2 "Registration Certificate – Use of Depleted Uranium." The report shall be submitted within 30 days after the effective date of such change.

2.3.4.4 A person who receives, acquires, possesses, or uses uranium pursuant to the general license established by subparagraph 2.3.4.1:

2.3.4.4.1 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.

2.3.4.4.2 Shall not abandon such depleted uranium.

2.3.4.4.3 Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of RHA 2.18. In the case where the transferee receives the depleted uranium pursuant to the general license established by subparagraph 2.3.4.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Department Form RHA 100-2. In the case where the transferee receives the depleted uranium pursuant to a general license obtained in the USNRC or Agreement State's regulation equivalent to subparagraph 2.3.4.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Department Form RHA 100-2 accompanied by a note explaining that use of the product or device is regulated by the USNRC or Agreement State under requirements substantially the same as those in this regulation.

2.3.4.4.4 Within 30 days of any transfer, shall report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer.

2.3.4.4.5 Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

2.3.4.5 Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by subparagraph 2.3.4.1 is exempt from the requirements of Parts III and VI of these regulations with respect to the depleted uranium covered by that general license.

RHA 2.4 GENERAL LICENSES – RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

2.4.1 Purpose and Scope

This part establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. Specific provisions of Part II are applicable to general licenses established by this section. These provisions are specified herein or in the particular general license. The general licenses provided in this part are subject to the general provisions of Part II and RHA 1.5, 1.6, 1.7, 1.8, 1.11, 1.12, 2.9, 2.17, 2.18, 2.20.2.1.2, Part III and Part VI of these regulations unless indicated otherwise in the specific provision of the general license[1].

[1]Attention is directed particularly to the provisions of Part III of this regulation concerning labeling of containers.

2.4.2 Certain Detecting, Measuring, Gauging or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere

2.4.2.1 A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of RHA 2.4.2.2, 2.4.2.3, and 2.4.2.4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative chemical composition, or for producing light or an ionized atmosphere.

2.4.2.2 The general license in RHA 2.4.2.1 of this section applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued under RHA 2.7 of this part or an equivalent specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

The devices must have been received from one of the specific licensees described in the above paragraph or through a transfer made under RHA 2.4.2.3.8 of this part.

2.4.2.2.1 A specific license issued under Part 2 of this Regulation; or

2.4.2.2.2 An equivalent specific license issued by an Agreement State; or

2.4.2.2.3 An equivalent specific license issued by a State with provisions comparable to Part 2 of this Regulation.

2.4.2.3 Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in RHA 2.4.2.1:

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

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

2.4.2.3.2.1 Devices containing only krypton need not be tested for leakage of radioactive material, and

2.4.2.3.2.2 Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and materials held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

2.4.2.3.3 Shall assure that the tests required by RHA 2.4.2.3.2 and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

2.4.2.3.3.1 In accordance with the instructions provided by the labels; or

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

2.4.2.3.4 Shall maintain records showing compliance with the requirements of RHA 2.4.2.3.2 and 2.4.2.3.3. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of the persons performing, testing installation services, and removal from installation concerning the radioactive material, its shielding or containment;

The licensee shall retain these records as follows:

2.4.2.3.4.1 Each record of a test for leakage of radioactive material required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.2 Each record of a test of the on-off mechanism and indicator required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.3 Each record that is required by paragraph RHA 2.4.2.3.3 of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

2.4.2.3.5 Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 bequerel) or more of removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by the Department or by the U.S. Nuclear Regulatory Commission or an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department within 30 days. Under these circumstances, the criteria set out in RHA 3.57.2 “Radiological criteria for unrestricted use,” may be applicable, as determined by the Department on a case-by-case basis;

2.4.2.3.6 Shall not abandon the device containing radioactive material;

2.4.2.3.7 Shall transfer or dispose of the device containing radioactive material only by export as provided by RHA 2.4.2.3.14 of this section, by transfer to another general licensee as authorized in RHA 2.4.2.3.8 or to a person authorized to receive the device by a specific license issued by this Department or by the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved under RHA 2.4.2.3.7.2. In complying with this section, the licensee:

2.4.2.3.7.1 Shall furnish a report to the Department within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device by manufacturer’s (or initial transferor’s) name, model number, and serial number; the name, address, and license number of the person receiving the device (license number not applicable if exported); and the date of the transfer.

2.4.2.3.7.2 Shall obtain written Departmental approval before transferring the device to any other specific licensee not specifically identified in RHA 2.4.2.3.7; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

2.4.2.3.7.2.1 verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

2.4.2.3.7.2.2 Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RHA 2.4.2.3.1) so that the device is labeled in compliance with RHA 3.24; however the manufacturer, model number, and serial number must be retained;

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

2.4.2.3.7.2.4 Reports the transfer under RHA 2.4.2.3.7.1.

2.4.2.3.8 shall transfer the device to another general licensee only:

2.4.2.3.8.1 Where the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this regulation, a copy of RHA 2.4.1, 2.18, 3.44, and 3.45 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Department the manufacturer's (or initial transferor's) name; the model number and the serial number of the device transferred; the transferee's name and mailing address for the location of use; and the name, title, and phone number of the responsible individual identified by the transferee in accordance with RHA 2.4.2.3.10 to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements or:

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

2.4.2.3.9 Shall comply with the provisions of RHA 3.44 and 3.45 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts III and VI.

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

2.4.2.3.11 Shall register generally licensed devices:

2.4.2.3.11.1 When the device contains at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, or 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph RHA 2.4.2.3.11.3 (iv), represents a separate general licensee and requires a separate registration and fee.

2.4.2.3.11.2 Annually, if in possession of a device meeting the criteria of RHA 2.4.2.3.11.1. Registration shall be made with the Department and the fee required by Department Regulation 61-30

shall be paid. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of RHA 2.4.2.3.11.1 is subject to the bankruptcy notification requirement in RHA 2.10.6.

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

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

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

(iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under RHA 2.4.2.3.10.

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

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

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

2.4.2.3.11.4 Persons generally licensed by the U.S. Nuclear Regulatory Commission with respect to devices meeting the criteria in RHA 2.4.2.3.11.1 are not subject to registration requirements if the devices are used in areas subject to Departmental jurisdiction for a period less than 180 days in any calendar year. The Department will not request registration information from such licensees.

2.4.2.3.12 Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Department within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

2.4.2.3.13 May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by RHA 2.4.2.3.2 need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

2.4.2.3.14 Shall not export the device containing radioactive material except in accordance with 10CFR part 110, Code of Federal Regulations;

2.4.2.3.15 Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall,

within that same time period, request a longer period to supply the information by providing the Chief of the Bureau of Radiological Health, SC Department of Health and Environmental Control, by an appropriate method listed in RHA 1.13 of this regulation, a written justification for the request.

2.4.2.4 The general license in RHA 2.4.2.1 does not authorize the manufacture of devices B containing radioactive material.

2.4.2.5 The general license provided in RHA 2.4.2.1 is subject to the provisions of RHA 1.5 through 1.8, RHA 1.11, RHA 1.12, RHA 2.10, RHA 2.18, RHA 2.19, and RHA 2.22.

2.4.3 General License for In Vitro Clinical or Laboratory Testing

2.4.3.1 A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of subparagraphs 2.4.3.2, 2.4.3.3, 2.4.3.4, 2.4.3.5, and 2.4.3.6 of this paragraph:

2.4.3.1.1 Iodine-125, in units not exceeding 10 microcuries each for use in in vitro or laboratory tests not involving internal or external administration or radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.2 Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.3 Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.4 Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.5 Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.6 Cobalt-57, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.7 Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.1.8 Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each for use in in vitro clinical or laboratory administration of radioactive material, or the radiation therefrom, to human beings or animals.

2.4.3.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subparagraph 2.4.3.1 of this paragraph until he has filed Form RHA-100-1,

"Certificate –In Vitro Testing with Radioactive Material Under General License," with the Department and received from the Department a validated copy of Form RHA-100-1 with a certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Form RHA-100-1 the following information and such other information as may be required by that form:

2.4.3.2.1 Name and address of the physician, veterinarian, clinical laboratory, or hospital;

2.4.3.2.2 The location of use; and

2.4.3.2.3 A statement that the physician, veterinarian, laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under the general license in subparagraph 2.4.3.1 of this paragraph and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

2.4.3.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subparagraph 2.4.3.1 of this paragraph shall comply with the following:

2.4.3.3.1 The general licensee shall not possess at any one time, pursuant to the general license in subparagraph 2.4.3.1 of this paragraph, at any one location of storage or use a total amount of Iodine-125, Iodine-131, Selenium-75, Iron-59 and/or Cobalt-57 in excess of 200 microcuries.

2.4.3.3.2 The general licensee shall store the radioactive material, until used, in the original shipping container of in a container providing equivalent radiation protection.

2.4.3.3.3 The general licensee shall use the radioactive material only for the uses authorized by subparagraph 2.4.3.1 of this paragraph.

2.4.3.3.4 The general licensee shall only transfer radioactive material to a person who is authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

2.4.3.3.5 The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in subparagraph 2.4.3.1.8 as required by RHA 3.27.

2.4.3.4 The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subparagraph 2.4.3.1 of this paragraph:

2.4.3.4.1 Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under Paragraph 2.7.5 of this Part or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State which authorizes the manufacture of Iodine-125, Iodine-131 or Cobalt-57 for distribution to persons generally licensed under Paragraph 2.4.3 or its equivalent.

2.4.3.4.2 Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each pre-packaged unit or appears in a leaflet or brochure which accompanies the package: This radioactive material may be received, acquired, possessed, and used only by physicians, 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 and a general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

_____
Name of Manufacturer

2.4.3.5 The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive materials under the general license of subparagraph 2.4.3.1 of this paragraph shall report in writing to the Department, any changes in the information furnished by him in the "Certification – In Vitro Testing with Radioactive Material Under General License," Form RHA-100-1. The report shall be furnished within 30 days after the effective date of such change.

2.4.3.6 Any person using radioactive material pursuant to the general license of subparagraph 2.4.3.1 of this paragraph is exempt from the requirements of Part III and Part VI of these regulations with respect to radioactive materials covered by that general license, except that such persons using Mock Iodine-125 described in subparagraphs 2.4.3.1.8 shall comply with the provisions RHA 3.26, RHA 3.44, and RHA 3.45.

2.4.4 Luminous Safety Devices for Aircraft

2.4.4.1 A general license is hereby issued to own, receive, acquire, possess and use Tritium or Promethium-147 contained in luminous safety devices for use in aircraft provided:

2.4.4.1.1 Each device contains not more than 10 curies of tritium or 300 millicuries of Promethium-147; and

2.4.4.1.2 Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department, any Agreement State or a Licensing State, to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

2.4.4.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 2.4.4.1 are exempt from the requirements of Part III and Part VI, except that they shall comply with the provisions of RHA 3.44 and RHA 3.45.

2.4.4.3 This general license does not authorize the manufacture, assembly, or repair or luminous safety devices containing tritium or Promethium-147.

2.4.4.4 This general license does not authorize the ownership, receipt, acquisition, possession, or use of Promethium-147 contained in instrument dials.

2.4.4.5 The general license provided in RHA 2.4.4 is subject to the provisions of RHA 1.5 through RHA 1.8, RHA 1.12, RHA 1.13, RHA 2.18, RHA 2.19, and RHA 2.22.

2.4.5 Calibration and Reference Sources

2.4.5.1 A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of 2.4.5.3, and 2.4.5.4, Americium-241 in the form of calibration or reference sources;

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

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

2.4.5.2 A general license is hereby issued to receive, possess, use and transfer, Plutonium and Radium-226 in the form of calibration or reference sources in accordance with the provisions of 2.4.5.3 and 2.4.5.4, to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material.

2.4.5.3 The general licenses in paragraphs 2.4.5.1 and 2.4.5.2 of this subsection apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR, Part 32, Section 70.39 of 10 CFR, Part 70 or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the Department, any Agreement State, or a Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR, Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

2.4.5.4 The general licenses in paragraphs 2.4.5.1 and 2.4.5.2 of this subsection are subject to the provisions of Section RHA 1.5 through RHA 1.8, RHA 1.12, RHA 1.13, RHA 2.10, RHA 2.18, RHA 2.19, RHA 2.22, Part III and Part VI of these regulations. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to these general licenses;

2.4.5.4.1 Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of Americium-241, or 5 microcuries of Plutonium or 5 microcuries of radium-226 in such sources;

2.4.5.4.2 Shall not receive, possess, use or transfer such source unless the source or the storage container bears a label which includes the following statement or a substantially similar statement which contains the following information called for in the following statement:

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. Do not remove this label. **CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM). *DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.**

_____
(Name of Manufacturer or Importer)
*Showing only the name of the appropriate material.

2.4.5.4.3 Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive the source;

2.4.5.4.4 Shall store such source, except when the source is being used, in a closed container, adequately designed and constructed to contain Americium-241, Plutonium or Radium-226 which might otherwise escape during storage; and,

2.4.5.4.5 Shall not use such source for any purpose other than the calibration radiation detectors or the standardization of other sources.

2.4.5.5 These general licenses do not authorize the manufacture of calibration of reference sources containing Americium-241, Plutonium or Radium-226.

2.4.6 Medical Diagnostic Uses

2.4.6.1 A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of 2.4.6.2, 2.4.6.3, and 2.4.6.4, the following radioactive materials in capsules, disposable syringes, or other forms of prepackaged individual doses*, and the radioactive material has been manufactured in accordance with the specific license issued pursuant to RHA 2.7.3 by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State authorizing distribution under the general license granted in this paragraph or its equivalent:

2.4.6.1.1 Iodine-131 as Sodium Iodide (NaI-131) for measurement of thyroid uptake;

2.4.6.1.2 Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

2.4.6.1.3 Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

2.4.6.1.4 Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

2.4.6.1.5 Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

2.4.6.1.6 Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

2.4.6.1.7 Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

2.4.6.2 No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by 2.4.6.1 until he has filed Form RHA-100, "Certificate – Medical Use of Radioactive Materiel Under General License" with the Department and received from the Department a validated copy of the Form RHA-100. The generally licensed physician shall furnish on Form RHA-100 the following information and such other information as may be required by that form;

2.4.6.2.1 Name and address of the generally licensed physician;

[2]*Note: RHA 2.73 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

2.4.6.2.2 A statement that the generally licensed physician is a duly licensed physician authorized to dispense drugs in the practice of medicine in the State of South Carolina and specifying the license number; and,

2.4.6.2.3 A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposed to use radioactive material under the general license of 2.4.6 and that he is competent in the use of such instruments.

2.4.6.3 A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by 2.4.6.1 shall comply with the following:

2.4.6.3.1 He shall not possess at any one time pursuant to the general license in 2.4.6.1 more than;

2.4.6.3.1.1 200 microcuries of Iodine-131,

2.4.6.3.1.2 200 microcuries of Iodine-125,

2.4.6.3.1.3 5 microcuries of Cobalt-57,

2.4.6.3.1.4 5 microcuries of Cobalt-60,

2.4.6.3.1.5 5 microcuries of Cobalt-58, and

2.4.6.3.1.6 200 microcuries of Chromium-51;

2.4.6.3.2 He shall store the pharmaceutical, until administered, in the original shipping container or a container providing the equivalent radiation protection;

2.4.6.3.3 He shall use the pharmaceutical only for the uses authorized in 2.4.6.1;

2.4.6.3.4 He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to persons under 18 years of age;

2.4.6.3.5 He shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

2.4.6.4 The generally licensed physician possessing or using radioactive material under the general license of 2.4.6.1 shall report in duplicate to the Department, any changes in the information furnished by him in the "Certificate-Medical Use of Radioactive Material Under General License," Form RHA-100. The report shall be submitted within 30 days after the effective date of changes.

2.4.6.5 Any person using radioactive material pursuant to the general license of 2.4.6.1 is exempt from the requirements of Part III and Part VI of these regulations with respect to the radioactive materials covered by the general license.

2.4.7 Ice Detection Devices

2.4.7.1 A general license is hereby issued to own, receive, acquire, possess, use, and transfer Strontium-90 contained in ice detection devices, provided each device contains not more than fifty

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

2.4.7.2 Persons who own, receive, acquire, possess, use or transfer Strontium-90 contained in ice detection devices pursuant to the general license in paragraph 2.4.7.1:

2.4.7.2.1 Shall, upon occurrence of visually observable damage, such as a bend or crack discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license or equivalent licensing document from the U.S. Nuclear Regulatory Commission or Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of this regulation;

2.4.7.2.2 Shall assure that all labels affixed tot he device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintain thereon; and

2.4.7.2.3 Are exempt from the requirements of Part III and Part VI except that such persons shall comply with the provisions of Sections RHA 3.27, RHA 3.44, and RHA 3.45 of these regulations.

2.4.7.3 This general license does not authorize the manufacture, assembly, disassembly, or repair of Strontium-90 in ice detection devices.

2.4.7.4 This general license provided in this paragraph is subject to the provisions of Sections RHA 1.5, through RHA 1.8, RHA 1.11, RHA 1.12, RHA 2.10, RHA 2.18, RHA 2.19, and RHA 2.22.

2.4.8 Self-Luminous Products Containing Ra-226

2.4.8.1 A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs 2.4.8.2, 2.4.8.3, and 2.4.8.4 of this section, Radium-226 contained in the following products manufactured prior to November 30, 2007.

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

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

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

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

2.4.8.1.5 Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of Radium-226. For the purposes of this paragraph, ‘‘small radium sources’’ means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in

educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

2.4.8.2 Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in 2.4.8.1 of this section are exempt from the provisions of Parts 3 and 6 of this Regulation, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

2.4.8.3 Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 2.4.8.1 of this section:

2.4.8.3.1 Shall notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Division of Waste Management, South Carolina Department of Health & Environmental Control, 2600 Bull Street, Columbia SC, 29201 within 30 days.

2.4.8.3.2 Shall not abandon products containing Radium-226. The product, and any radioactive material from the product, may only be disposed of according to Part 3 of this Regulation or by transfer to a person authorized by a specific license to receive the Radium- 226 in the product or as otherwise approved by the Department.

2.4.8.3.3 Shall not export products containing Radium-226 except in accordance with this Regulation.

2.4.8.3.4 Shall dispose of products containing Radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive Radium-226 by a specific license issued under this Regulation, or equivalent regulations of an Agreement State, or as otherwise approved by the Department.

2.4.8.3.5 Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Division of Waste Management, South Carolina Department of Health & Environmental Control, 2600 Bull Street, Columbia SC, 29201, a written justification for the request.

2.4.8.4 The general license in paragraph 2.4.8.1 of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing Radium-226, except that timepieces may be disassembled and repaired.

RHA 2.5 FILING OF APPLICATION FOR SPECIFIC LICENSES

2.5.1 Applications for specific licenses shall be filed on a form prescribed by the Department. The applicant shall set forth all applicable information called for by the form.

2.5.2 The Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

Pre-licensing visits may be made to the applicant's facility for the purpose of verifying information furnished in the original application.

2.5.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

2.5.4 An application for a license may include a request for a license authorizing one or more activities.

2.5.5 In his application, the applicant may not incorporate by reference information contained in previous applications, statements, or reports filed with the Department. All items and subitems must be completed entirely without reference to previously submitted documents.

2.5.6 Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold, upon request, any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

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

2.5.7.1 Identify the source or device by manufacturer and model number as registered with the Department pursuant to RHA 2.29, the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State; or registered with the NRC under the provisions of 10 CFR 32.210, with an Agreement State, or for a source or a device containing Radium-226 or accelerator-produced radioactive material with a State under provisions comparable to the NRC; or

2.5.7.2 Contain the information identified by the NRC in 10 CFR 32.210(c); or

2.5.7.3 For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under the provisions of 10 CFR 32.310 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified by the NRC, the applicant must provide:

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

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

2.5.8 An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part 4 of this Regulation shall include:

2.5.8.1 A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part 2 of this Regulation for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2.5.8.2 Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Part 2 of this Regulation.

2.5.8.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Part 2 of this Regulation.

2.5.8.4 Information identified in Part 2 of this Regulation on the PET drugs to be noncommercially transferred to members of its consortium.

RHA 2.6 GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES

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

2.6.1 The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations and in such a manner as to protect health and minimize danger to life and property; and

2.6.2 The applicant's proposed equipment, facilities, and procedures are adequate to protect health and minimize danger to life and property; and

2.6.3 The issuance of the license will not be inimical to the health and safety of the public; and

2.6.4 The applicant satisfies any applicable special requirements in RHA 2.7 and RHA 2.8 of this Part and Parts IV, V, VII and VIII of these regulations.

RHA 2.7 SPECIAL REQUIREMENTS FOR ISSUANCE OF CERTAIN SPECIFIC LICENSES FOR RADIOACTIVE MATERIALS

2.7.1 Licensing the Manufacture and the Distribution of Devices to Persons Generally Licensed Under RHA 2.4.2

2.7.1.1 An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under RHA 2.4.2 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

2.7.1.1.1 The applicant satisfies the general requirements of RHA 2.6;

2.7.1.1.2 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:

2.7.1.1.2.1 The device can be safely operated by persons not having training in radiological protection;

2.7.1.1.2.2 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 calendar quarter a dose in excess of 10% of the limits specified in RHA 3.5.1; and

2.7.1.1.2.3 Under accident conditions (such as fire and explosion) associated with handling, storage, and the 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:

Whole body: head and trunk; active bloodforming organs;
gonads; or lens of eye.....15 rems
Hands and forearms: feet and ankles; localized areas of
skin averaged over areas no larger than 1 square centimeter.....200 rems
Other organs.....50 rems

2.7.1.1.3 Each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:

2.7.1.1.3.1 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);

2.7.1.1.3.2 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

2.7.1.1.3.3 The information called for in the following statement in the same or substantially similar form:

Receipt, possession, use, and transfer of this device Model[3]*, Serial No [3]*, containing (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or 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, assembler, or initial transferor)[3*]

2.7.1.1.4 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 RHA 3.21, and the name of the manufacturer or initial distributor.

2.7.1.1.5 Each device meeting the criteria of RHA 2.4.2.3.11.1 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 practicable the radiation symbol described in RHA 3.21.

2.7.1.2 In the event the applicant desires that the device be required to 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, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar

[3]The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

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 Department will consider information which includes, but is not limited to:

2.7.1.2.1 Primary containment (source capsule);

2.7.1.2.2 Protection of primary containment;

2.7.1.2.3 Method of sealing containment;

2.7.1.2.4 Containment construction materials;

2.7.1.2.5 Form of contained radioactive material;

2.7.1.2.6 Maximum temperature withstood during prototype test;

2.7.1.2.7 Maximum pressure withstood during prototype tests;

2.7.1.2.8 Maximum quantity of contained radioactive material;

2.7.1.2.9 Radiotoxicity of contained radioactive material;

2.7.1.2.10 Operating experience with identical devices or similarly designed and constructed devices.

2.7.1.3 In the event the applicant desires that the general licensee under RHA 2.4.2, or under the 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, he 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 bases for such estimates. The submitted information shall demonstrate that 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 calendar quarter dose in excess of 10% of the limits specified in RHA 3.5.1.

2.7.1.4 If a device containing radioactive material is to be transferred for use under the general license contained in RHA 2.4.2 of this part, each person that is licensed under RHA 2.7.1 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes—

2.7.1.4.1 A copy of the general license contained in RHA 2.4.2; if RHA 2.4.2.3.2 through 2.4.2.3.4 or RHA 2.4.2.3.11 do not apply to the particular device, those paragraphs may be omitted.

2.7.1.4.2 A copy of RHA 2.4.1, 2.18, 3.44, and 3.45 of this part;

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

2.7.1.4.4 Information on acceptable disposal options including estimated costs of disposal; and

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

2.7.1.5 If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or another Agreement State, each person that is licensed under RHA 2.7.1 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

2.7.1.5.1 A copy of the NRC or Agreement State or regulations equivalent to RHA 2.4.1, 2.4.2, 2.18, 3.44 and 3.45 of this part or a copy of these Agreement State regulations. If a copy of the Department's regulations is provided to a prospective general licensee in lieu of the NRC regulations**,** it shall be accompanied by a note explaining that use of the device is regulated by the NRC or other Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

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

2.7.1.5.3 Information on acceptable disposal options including estimated costs of disposal; and

2.7.1.5.4 The name or title, address, and phone number of the contact at the appropriate regulatory agency, NRC or Agreement State, having jurisdiction at the devices new location, from which additional information may be obtained.

2.7.1.6 An alternative approach to informing customers may be proposed by the licensee for approval by the Department.

2.7.1.7 Each device that is transferred after February 2004 must meet the labeling requirements in RHA 2.7.1.4.3 through 2.7.1.4.5.

2.7.1.8 If a notification of bankruptcy has been made under RHA 2.10.6 or the license is to be terminated, each person licensed under RHA 2.7.1 shall provide, upon request, to the Department and to the appropriate regulatory agency, NRC or Agreement State, having jurisdiction at the devices new location, records of final disposition required under RHA 2.7.1.9.2.

2.7.1.9 Each person licensed under RHA 2.7.1 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

2.7.1.9.1 The person shall report all transfers of devices to persons for use under the general license in RHA 2.4.2 of these regulations and for use under equivalent NRC regulations (10CFR31.5) or other Agreement State's regulations and all receipts of devices from persons licensed under RHA 2.4.2 to the Department or to the appropriate NRC office or other Agreement State office. The report must be submitted on a quarterly basis on NRC Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form. (NRC Form 653 may be obtained from the Department or found in NUREG-1556, Vol. 16.)

2.7.1.9.1.1 The required information for transfers to general licensees includes--

(i) The identity of each general licensee by 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 phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of 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.

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

2.7.1.9.1.3 For devices received from a 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.

2.7.1.9.1.4 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.

2.7.1.9.1.5 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.

2.7.1.9.1.6 The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

2.7.1.9.1.7 If no transfers have been made to or from persons generally licensed under RHA 2.4.2 during the reporting period, the report must so indicate. If no transfers have been made to or from an NRC or other Agreement State during the reporting period, this information should be made available to the responsible agency upon their request.

2.7.1.9.2 The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

2.7.2 Licensing the Introduction of Radioactive Material Into Products in Exempt Concentration

In addition to the requirements set forth in RHA 2.6, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of a licensee or another to be transferred to persons exempt under 2.20.2.1.1 will be issued only if:

2.7.2.1 The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the

product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the radioactive material in the product or material at the time of transfer; and

2.7.2.2 The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in RHA 2.25 Schedule C, that reconcentration of the radioactive material in concentrations exceeding those in RHA 2.25 Schedule C is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being. Each person licensed under this section 2.7.2 shall file an annual report with the Department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material into which radioactive material has been introduced at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

If no transfers of radioactive material have been made pursuant to this section 2.7.2 during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

2.7.3 Manufacture and Distribution of Radioactive Materials for Medical Use Under General License

In addition to the requirements set forth in RHA 2.6 above, a specific license authorizing the distribution of radioactive material for use by physicians under the general license of 2.4.6 will be issued only if:

2.7.3.1 The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of the Food and Drug Administration has approved, or in accordance with a license for biologic product issued by the Secretary, Department of Health, Education, and Welfare; and,

2.7.3.2 The following statement, or a substantially similar statement which contains information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package: "This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license (or the equivalent) of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State."

_____
(Name of Manufacturer)

2.7.4 Manufacture and Distribution of Radioactive Materials 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 2.4.3 of this part will be applied if:

2.7.4.1 The applicant satisfies the general requirements specified in RHA 2.6.

2.7.4.2 The radioactive material is to be prepared for distribution in prepackaged units of:

2.7.4.2.1 Iodine-125 in units not exceeding 10 microcuries each.

2.7.4.2.2 Iodine-131 in units not exceeding 10 microcuries each.

2.7.4.2.3 Carbon-14 in units not exceeding 10 microcuries each.

2.7.4.2.4 Hydogen-3 (tritium) in units not exceeding 50 microcuries each.

2.7.4.2.5 Iron-59 in units not exceeding 20 microcuries each.

2.7.4.2.6 Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq) each.

2.7.4.2.7 Selenium-75 in units not exceeding 10 microcuries each.

2.7.4.2.8 Mock Iodine-125 in units not exceeding 0.05 microcuries of Iodine 129 and 0.005 microcuries of Americium-241 each.

2.7.4.3 Each prepackaged unit bears a durable, clearly visible label:

2.7.4.3.1 Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (0.37 MBq) of Iodine-125, Iodine-131, Selenium-75, or Carbon-14; 50 microcuries (1.85 MBq) of Hydrogen-3 (tritium); or 20 microcuries (0.74 MBq) of Iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of Iodine-129 and 0.005 microcurie (0.185 kBq) of Americium-241 each; or Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq); and

2.7.4.3.2 Displaying the radiation caution symbol described in RHA 3.21 (3.21.1) of Part III and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

2.7.4.4 The following statement, or 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.

"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 and a general license of the United States Nuclear Regulatory Commission, an Agreement State, or a Licensing State."

_____

Name of Manufacturer

2.7.4.5 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 RHA 3.27.

2.7.5 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Part IV.

2.7.5.1 An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons licensed pursuant to Part IV of these regulations will be approved if:

2.7.5.1.1 The applicant satisfies the general requirements specified in RHA 2.6;

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

2.7.5.1.2.1 Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

2.7.5.1.2.2 Registered or licensed with a state agency as a drug manufacturer:

2.7.5.1.2.3 Licensed as a pharmacy by a State Board of Pharmacy;

2.7.5.1.2.4 Operating as a nuclear pharmacy within a Federal medical institution; or

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

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

2.7.5.1.4 The applicant satisfies the following labeling requirements:

2.7.5.1.4.1 A label is affixed to each transport radiation shield, whether it is constructed of lead glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

2.7.5.1.4.2 A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2.7.5.2 A licensee described by paragraph 2.7.5.1.2.3 or 2.7.5.1.2.4 of this section:

2.7.5.2.1 May prepare radioactive drugs for medical use, as defined in RHA 4.2 provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 2.7.5.2.2 and 2.7.5.2.4 of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in RHA 4.22 (or for a period of two years following the effective date of these regulations, RHA 4.86).

2.7.5.2.2 May allow a pharmacist to work as an authorized nuclear pharmacist if:

2.7.5.2.2.1 This individual qualifies as an authorized nuclear pharmacist as defined in RHA 4.2.

2.7.5.2.2.2 This individual meets the requirements specified in Part 4 of this Regulation, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

2.7.5.2.2.3 This individual is designated as an authorized nuclear pharmacist in accordance with 2.7.5.2.4 of this section.

2.7.5.2.3 The actions authorized in 2.7.5.2.1 and 2.7.5.2.2 of this section are permitted in spite of more restrictive language in license conditions.

2.7.5.2.4 May designate a pharmacist (as defined in RHA 4.2) as an authorized nuclear pharmacist if:

2.7.5.2.4.1 The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

2.7.5.2.4.2 The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

2.7.5.2.5 Shall provide to the Department a copy of each individual's:

2.7.5.2.5.1 Certification by a specialty board whose process has been recognized by the NRC or an Agreement State as specified in RHA 4.22.1 of this regulation with the written attestation signed by a preceptor as required by RHA 4.22.3; or

2.7.5.2.5.2 The NRC or Agreement State license; or

2.7.5.2.5.3 The permit issued by a licensee of broad scope; and

2.7.5.2.5.4 State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under RHA 2.7.5.2.2.1 and 2.7.5.2.2.3, the individual to work as an authorized nuclear pharmacist.

2.7.5.3 A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-,beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

2.7.5.3.1 Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

2.7.5.3.2 Check each instrument for constancy and proper operation at the beginning of each day of use.

2.7.5.4 Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2.7.6 (Reserved)

2.7.7 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use

2.7.7.1 An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part IV of these regulations for use as a calibration, transmission, or reference source or for the uses listed in RHA 4.46, 4.56, 4.58 and 4.88 of Part IV of these regulations will be approved if:

2.7.7.1.1 The applicant satisfies the general requirements in RHA 2.6 of this Part; and

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

2.7.7.1.2.1 The radioactive material contained, its chemical and physical form, and amount;

2.7.7.1.2.2 Details of design and construction of the source or device;

2.7.7.1.2.3 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;

2.7.7.1.2.4 For devices containing radioactive material, the radiation profile of a prototype device;

2.7.7.1.2.5 Details of quality control procedures to assure that production sources and devices meet the standards of design and prototype tests;

2.7.7.1.2.6 Procedures and standards for calibrating sources and devices;

2.7.7.1.2.7 Legend and methods for labeling sources and devices as to their radioactive content;

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

2.7.7.1.3 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 (insert name of source or device) is licensed by the Department for distribution to persons licensed pursuant to RHA 4.28, RHA 4.46, 4.56 and 4.58 of Part IV of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

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

2.7.7.2.1 Primary containment (source capsule);

2.7.7.2.2 Protection of primary containment;

2.7.7.2.3 Method of sealing containment;

2.7.7.2.4 Containment construction materials;

2.7.7.2.5 Form of contained radioactive material;

2.7.7.2.6 Maximum temperature withstood during prototype tests;

2.7.7.2.7 Maximum pressure withstood during prototype tests;

2.7.7.2.8 Maximum quantity of contained radioactive material;

2.7.7.2.9 Radiotoxicity of contained radioactive material; and

2.7.7.2.10 Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

2.7.7.3 If an application is filed pursuant to RHA 2.7.7.1 on or before August 9, 1977, for a license to manufacture and distribute a source or device that was distributed commercially on or before July 9, 1977, the applicant may continue the distribution of such source or device to authorized licenses until the Department issues the license or notifies the applicant otherwise.

2.7.8 Calibration or reference sources containing Americium-241 or Radium-226: Requirements for license to manufacture or initially transfer.

2.7.8.1 An application for a specific license to manufacture or initially transfer calibration or reference sources containing Americium-241 or Radium-226, for distribution to persons generally licensed under RHA 2.4, will be approved if:

2.7.8.1.1 The applicant satisfies the general requirements of RHA 2.6;

2.7.8.1.2 The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

2.7.8.1.2.1 Chemical and physical form and maximum quantity of Americium 241 or Radium-226 in the source;

2.7.8.1.2.2 Details of construction and design;

2.7.8.1.2.3 Details of the method of incorporation and binding of the Americium-241 or Radium-226 in the source;

2.7.8.1.2.4 Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of Americium-241 or Radium-226, to demonstrate that the Americium-241 or Radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

2.7.8.1.2.5 Details of quality control procedures to be followed in manufacture of the source;

2.7.8.1.2.6 Description of labeling to be affixed to the source or the storage container for the source;

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

2.7.8.1.3 Each source will contain no more than 5 microcuries of Americium-241 or Radium-226.

2.7.8.1.4 The Department determines, with respect to any type of source containing more than 0.005 microcuries of Americium-241 or Radium-226, that:

2.7.8.1.4.1 The method of incorporation and binding of the Americium-241 or Radium-226 in the source is such that the Americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

2.7.8.1.4.2 The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 2.7.8.4 of this Section.

2.7.8.2 Each person licensed under this Section shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or initial transferor

2.7.8.3 Each person licensed under this Section shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of Americium-241 or Radium-226 before transferring the source to a general licensee under RHA 2.4. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing Americium-241 or Radium-226 and shall not be transferred to a general licensee under RHA 2.4 or equivalent regulation.

2.7.8.4 An applicant for a license under this Section shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of Americium-241 or Radium-226, as follows:

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

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

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

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

2.7.8.4.5 *Dry wipe test*. On completion of the preceding test in this section, the dry wipe test described in 2.7.8.4.2 shall be repeated.

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

RHA 2.8 SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses.[4]

2.8.1 The Different Types of Broad Licenses are Set Forth Below:

2.8.1.1 A "Type A specific license of broad scope" is a license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but are not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

[4]Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer, and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

2.8.1.2 A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in RHA 2.26, Schedule D for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in RHA 2.26, Schedule D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in RHA 2.26, Schedule D, Column I for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

2.8.1.3 A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive

material specified in RHA 2.26, Schedule D, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for the radionuclide in RHA 2.26, Schedule D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in RHA 2.26, Schedule D, Column II for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

2.8.2 An application for a Type A specific license of broad scope will be approved if:

2.8.2.1 The applicant satisfies the general requirements specified in RHA 2.6 and;

2.8.2.2 The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

2.8.2.3 The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

2.8.2.3.1 The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials;

2.8.2.3.2 The appointment of a radiological safety officer who is qualified by training and experienced in radiation protection, and who is available for advice and assistance on radiological safety matters; and

2.8.2.3.3 The establishment of appropriate administrative procedures to assure:

2.8.2.3.3.1 Control of procurement and use of radioactive material;

2.8.2.3.3.2 Completion of safety evaluation of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

2.8.2.3.3.3 Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 2.8.2.3.3.2 of this subparagraph 2.8.2.3.3 prior to use of the radioactive material.

2.8.3 An Application for a Type B Specific License of Broad Scope Will Be Approved If::

2.8.3.1 The applicant satisfies the general requirements specified in RHA 2.6; and

2.8.3.2 The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

2.8.3.2.1 The appointment of a radiological safety officer who is qualified by training and experienced in radiation protection, and who is available for advice and assistance on radiological safety matters; and

2.8.3.2.2 The establishment of appropriate administrative procedures to assure:

2.8.3.2.2.1 Control of procurement and use of radioactive material;

2.8.3.2.2.2 Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

2.8.3.2.2.3 Review, approval, and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with 2.8.3.2.2.2 of this subparagraph 2.8.3.2.2 prior to use of the radioactive material.

2.8.4 An Application For a Type C Specific License of Broad Scope Will Be Approved If:

2.8.4.1 The applicant satisfies the general requirements specified in RHA 2.6; and

2.8.4.2 The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

2.8.4.2.1 A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

2.8.4.2.2 At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

2.8.4.3 The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

2.8.5 Specific Licenses of Broad Scope are Subject to the Following Conditions:

2.8.5.1 Persons licensed pursuant to RHA 2.8 shall not:

2.8.5.1.1 Conduct tracer studies in the environmental involving direct release of radioactive material;

2.8.5.1.2 Receive, acquire, own, possess, use of transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

2.8.5.1.3 Conduct activities for which a specific license issued by the Department under 2.7 is required; or

2.8.5.1.4 Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

2.8.5.2 Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

2.8.5.3 Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiological safety officer.

2.8.5.4 Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy requirements of 2.8.4 of RHA 2.8.

RHA 2.9 ISSUANCE OF SPECIFIC LICENSES

2.9.1 Upon determination that an application meets the requirements of the Act and the regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

2.9.2 The Department may incorporate in any license at the time of issuance or thereafter, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Part it deems appropriate or necessary in order to:

2.9.2.1 Protect health or to minimize danger to life and property;

2.9.2.2 Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

2.9.2.3 Prevent loss or theft of licensed material.

RHA 2.10 SPECIFIC TERMS AND CONDITIONS OF LICENSES

2.10.1 Each license issued pursuant to these regulations shall be subject to all the provisions of the Act, and to all rules, regulations, and Orders of the Department, now or hereafter in effect.

2.10.2 Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act.

2.10.3 Each person licensed by the Department pursuant to these regulations shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

2.10.4 Each specific licensee authorized under 2.7.1 to distribute certain devices to generally licensed persons:

2.10.4.1 Shall report to the Department all transfers of such devices to persons generally licensed under 2.4.2.1. Such report shall identify the type of radioactive material contained in the device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to generally licensed persons; and

2.10.4.2 Shall furnish to each general licensee to whom he transfers such a device a copy of the general license contained in 2.4.2.

2.10.5 Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

2.10.6 Each general licensee that is required to register by RHA 2.4.2.3.11 of this Part and each specific licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

2.10.6.1 The licensee:

2.10.6.2 An entity (as that term is defined in 11 U.S.C. 101 (14)) controlling the licensee or listing the license or licensee as property of the estate; or

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

2.10.7 Security requirements for portable gauges.

2.10.7.1 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.

2.10.8 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. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

2.10.9.1Authorization under Part 2 of this Regulation to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2.10.9.2Each licensee authorized under Part 2 of this Regulation to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

2.10.9.2.1 Satisfy the labeling requirements in Part 2 of this Regulation 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.

2.10.9.2.2 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 Part 2 of this Regulation.

2.10.9.3A licensee that is a pharmacy authorized under Part 2 of this Regulation 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:

2.10.9.3.1 an authorized nuclear pharmacist that meets the requirements in Part 2 of this Regulation; or

2.10.9.3.2 an individual under the supervision of an authorized nuclear pharmacist as specified in Part 2 of this Regulation.

2.10.9.4A pharmacy, authorized under Part 2 of this Regulation 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 Part 2 of this Regulation.

RHA 2.11 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDINGS OR OUTDOOR AREAS

2.11.1 Each specific license expires at midnight on the expiration date stated in the license unless the licensee has filed an application for renewal under RHA 2.12 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Department makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

2.11.2 Each specific license revoked by the Department expires at midnight on the date of the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by the Department Order.

2.11.3 Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of byproduct material, source material, or special nuclear material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

2.11.3.1 Limit actions involving byproduct material, source material, or special nuclear material to those related to decommissioning; and

2.11.3.2 Continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements.

2.11.4 Within 60 days of the occurrence of any of the following, consistent with administrative directions in RHA 2.32, each licensee shall provide notification to the Department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Department requirements, or submit within 12 months of notification a decommissioning plan, if required by RHA 2.11.7.1, and begin decommissioning upon approval of that plan if:

2.11.4.1 The license has expired pursuant to RHA 2.11.1 or 2.11.2; or

2.11.4.2 The licensee has decided to permanently cease principal activities, as defined, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or

2.11.4.3 No principal activities under the license have been conducted for a period of 24 months; or

2.11.4.4 No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements.

2.11.5 Coincident with the notification required by RHA 2.11.4, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to RHA 1.15 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to RHA 2.11.7.4.5.

2.11.5.1 Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1998.

2.11.5.2 Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department.

2.11.6 The Department may grant a request to extend the time periods established in RHA 2.11.4 if the Department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to RHA 2.11.4. The schedule for decommissioning set forth in RHA 2.11.4 may not commence until the Department has made a determination on the request.

2.11.7 The Decommissioning Plan.

2.11.7.1 A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or the public, such as in any of the following cases:

2.11.7.1.1 Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

2.11.7.1.2 Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

2.11.7.1.3 Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

2.11.7.1.4 Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

2.11.7.2 The Department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to RHA 2.11.4 if the Department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

2.11.7.3 Procedures such as those listed in RHA 2.11.7.1 with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

2.11.7.4 The proposed decommissioning plan for the site or separate building or outdoor area must include:

2.11.7.4.1 A description of the condition of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

2.11.7.4.2 A description of planned decommissioning activities;

2.11.7.4.3 A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

2.11.7.4.4 A description of the planned final radiation survey; and

2.11.7.4.5 An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

2.11.7.4.6 For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in RHA 2.11.9.

2.11.7.4.7 A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

2.11.7.5 The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

2.11.8 Decommissioning and Termination

2.11.8.1 Except as provided in RHA 2.11.9, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

2.11.8.2 Except as provided in RHA 2.11.9, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

2.11.9 The Department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Department determines that the alternative is warranted by consideration of the following:

2.11.9.1 Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

2.11.9.2 Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

2.11.9.3 Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

2.11.9.4 Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

2.11.9.5 Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

2.11.10 As the final step in decommissioning, the licensee shall:

2.11.10.1 Certify the disposition of all licensed material, including accumulated wastes, in writing to the Department; and

2.11.10.2 Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

2.11.10.2.1 Report levels of gamma radiation in units of millisieverts and microroentgen per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels and disintegrations per minute or microcuries per 100 square centimeters—removable and fixed—for surfaces, megabecquerels and microcuries per milliliter for water, and becquerels and picocuries per gram for solids such as soils or concrete; and

2.11.10.2.2 Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

2.11.11 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines that:

2.11.11.1 Byproduct material, source material, and special nuclear material have been properly disposed;

2.11.11.2 Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

2.11.11.3 A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Department requirements, or other information has been submitted by the licensee that will be sufficient to demonstrate that the premises are suitable for release in accordance with Department requirements. Residual contamination levels must be ALARA and must be approved by the Department.

2.11.11.4 Records required by RHA 3.34.5 and 3.34.6 have been received.

RHA 2.12 RENEWAL OF SPECIFIC LICENSES

2.12.1 An application of renewal of specific licenses shall be filed in accordance with RHA 2.5.

2.12.2 In any case in which a licensee, not less than thirty (30) days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license including the same activities, such existing license shall not expire until the application has been finally acted upon by the Department, or the time for seeking judicial review has elapsed.

RHA 2.13 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE

Applications for amendment of a license shall be filed in accordance with RHA 2.5 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

RHA 2.14 DEPARTMENT ACTION ON APPLICATIONS TO RENEW OR AMEND

In considering an application by a licensee to renew or amend his license the Department will apply the criteria set forth in RHA 2.6, RHA 2.7, and RHA 2.8 of this Part and Parts IV, V, VII and VIII of these regulations, as applicable.

RHA 2.15 INALIENABILITY OF LICENSES

No license issued or granted under these regulations and no right to possess or utilize radioactive material granted by any license issued pursuant to these regulations shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, indirectly or directly through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

RHA 2.16 PERSONS POSSESSING A LICENSE FOR SOURCE, BY-PRODUCT, OR SPECIAL NUCLEAR MATERIAL IN QUANTITIES NOT SUFFICIENT TO FORM A CRITICAL MASS ON EFFECTIVE DATE OF THESE REGULATIONS

Any person, who, on the effective date of these regulations possesses a general or specific license for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass, issued by the United States Nuclear Regulatory Commission, shall be deemed to possess a like license under these regulations and the Act, such license to expire either ninety (90) days after receipt from the Department of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

RHA 2.17 PERSONS POSSESSING RADIOACTIVE MATERIAL OTHER THAN AGREEMENT MATERIAL ON EFFECTIVE DATE OF THESE REGULATIONS

Any person, who, on the effective date of these regulations, possesses naturally occurring or accelerator-produced radioactive material for which a specific license is required by the Act or this Part shall be deemed to possess such a license issued under the Act and this Part. Such license shall expire ninety (90) days after the effective date of these regulations; provided, however, that if within the ninety days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Department.

RHA 2.18 TRANSFER OF MATERIAL

2.18.1 No licensee shall transfer radioactive material except as authorized pursuant to this regulation (RHA 2.18).

2.18.2 Any licensee may transfer radioactive material, subject to the acceptance of the transferee:

2.18.2.1 To the Department;

2.18.2.2 To the United States Nuclear Regulatory Commission;

2.18.2.3 To any person exempt from these regulations to the extent permitted under such exemption;

2.18.2.4 To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license, or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State, or any Licensing State or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, any Agreement State, or a Licensing State; or

2.18.2.5 As otherwise authorized by the Department in writing.

2.18.3 Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

2.18.4 The following methods for the verification required by RHA 2.18.3 are acceptable:

2.18.4.1 The transferor may have in this possession, and read, a current copy of the transferee's specific license or registration certificate;

2.18.4.2 The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

2.18.4.3 For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten (10) days;

2.18.4.4 The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, the Licensing agency of an Agreement State, or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

2.18.4.5 When none of the methods of verification described in RHA 2.18.4.1 to 2.18.4.4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, the Licensing Agency of an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

2.18.5 Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of RHA 2.22.

RHA 2.19 MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES

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

2.19.2 Any license may be revoked, suspended, or modified, in whole or in part for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which could warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or the license, or of any rule, regulation or order of the Department.

2.19.3 Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no license will be modified, suspended, or revoked unless, prior to the institution of proceedings thereof, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

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

RHA 2.20 EXEMPTIONS

2.20.1 Source Material

2.20.1.1 Any person is exempt from these regulations to the extent that such person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05%) of the mixture, compound, solution, or alloy.

2.20.1.2 Any person is exempt from these regulations to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

2.20.1.3 Any person is exempt from these regulations to the extent that such person receives, possesses, uses, or transfers:

2.20.1.3.1 Any quantities of thorium contained in (1) incandescent gas mantles, (2) vacuum tubes, (3) welding rods, (4) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium, (5) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium, or (6) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or (7) personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium.

2.20.1.3.2 Source material contained in the following products; (1) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material; (2) piezoelectric ceramic containing not more than 2 percent by weight source material; (3) glassware containing not more than 10 percent by weight source materials, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in constructions; and (4) glass enamel or glass

enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States before July 25, 1983.

2.20.1.3.3 Photographic film, negatives, and prints containing uranium or thorium;

2.20.1.3.4 Any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys; provided that the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subparagraph (2.20.1.3.4) shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

2.20.1.3.5 Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights provided that**:**

2.20.1.3.5.1 The counterweights are manufactured in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State authorizing distribution by the licensee pursuant to this subparagraph (2.20.1.3.5) or equivalent regulations of the NRC or any Agreement State;

2.20.1.3.5.2 Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM"

2.20.1.3.5.3 Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer, and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";[5] and

2.20.1.3.5.4 The exemption contained in this subparagraph (2.20.1.3.5) shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

2.20.1.3.6 Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

2.20.1.3.6.1 The shipping container is conspicuously and legibly impressed with the legend

"CAUTION – RADIOACTIVE SHIELDING – URANIUM." and

2.20.1.3.6.2 The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm);

2.20.1.3.6.3 The shipping container meets the specifications for containers for radioactive materials prescribed by Section 178.250, Specification 55, Part 178, of the regulations published by the Department of Transportation (49 CFR 178.250)

[5]The requirements specified in subdivisions 2.20.1.3.5.2 and 2.20.1.3.5.3 of this subparagraph need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, **"CAUTION – RADIOACTIVE MATERIAL – URANIUM"**, as previously required by the regulations.

2.20.1.3.7 Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium. The exemption contained in this subparagraph (2.20.1.3.7) shall not be deemed to authorize either:

2.20.1.3.7.1 The shaping, grinding, or polishing of such lenses or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or

2.20.1.3.7.2 The receipt, possession, use or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or optical instruments.

2.20.1.3.8 Uranium contained in detector heads for use in fire protection units, provided that each detector head contains not more than 0.005 microcurie of uranium.

2.20.1.3.9 Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

2.20.1.3.9.1 The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

2.20.1.3.9.2 The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

2.20.1.4 The exemptions in this subsection (2.20.1) do not authorize the manufacture, processing, or production of any of the products described herein.

2.20.2 Radioactive Materials Other Than Source Material

2.20.2.1 Exempt concentrations.

2.20.2.1.1 Except as provided in RHA 2.20.2.1.3 and 2.20.2.1.4, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Schedule C of this part.

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

2.20.2.1.3 A manufacturer, processor, or producer of a product or material is exempt from this part to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Schedule C of this part and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

2.20.2.1.4 No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent NRC or Agreement State regulations, except in accordance with a license issued under RHA 2.7.2.

2.20.2.2 Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person

is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[6]

2.20.2.2.1 Timepieces or hands or dials containing radium or not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

2.20.2.2.1.1 25 millicuries of tritium per timepiece;

2.20.2.2.1.2 5 millicuries of tritium per hand;

2.20.2.2.1.3 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

2.20.2.2.1.4 100 microcuries of Promethium-147 per watch or 200 microcuries of Promethium-147 per any other timepiece.

2.20.2.2.1.5 20 microcuries of Promethium-147 per watch hand or 40 microcuries of Promethium-147 per other timepiece hand and;

2.20.2.2.1.6 60 microcuries of Promethium-147 per watch dial or 120 microcuries of Promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

2.20.2.2.1.7 The levels of radiation from hands and dials containing Promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber: (a) for wrist watches, 0.1 millirad per hour at 10 centimeters from any surface. (b) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surfaces; (c) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

2.20.2.2.1.8 1 microcurie (37 kBq) of Radium-226 per timepiece in timepieces manufactured prior to November 30, 2007.

2.20.2.2.2 Reserved.

2.20.2.2.3 Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

2.20.2.2.4 Reserved.

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

2.20.2.2.6 Reserved.

2.20.2.2.7 Electron tubes: provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

[6]Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer, and disposal by all other persons who are exempt from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

2.20.2.2.7.1 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

2.20.2.2.7.2 1 microcurie of Cobalt-60;

2.20.2.2.7.3 5 microcuries of Nickel-63;

2.20.2.2.7.4 30 microcuries of Krypton-85;

2.20.2.2.7.5 5 microcuries of Cesium-137;

2.20.2.2.7.6 30 microcuries of Promethium-147; and provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[7]

2.20.2.2.8 Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material; provided that:

2.20.2.2.8.1 Each source contains no more than one exempt quantity set forth in RHA 2.24. Schedule B.

2.20.2.2.8.2 Each instrument contains no more than 10 exempt quantities. For purposes of paragraph 2.20.2.2.8, instrument source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in RHA 2.24, Schedule B, provided that the sum of such fractions shall not exceed unity; and

2.20.2.2.8.3 For purposes of paragraph 2.20.2.2.8, 0.05 microcuries of Americium-241 is considered an exempt quantity under RHA 2.24, Schedule B.

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

2.20.2.3 Gas and aerosol detectors containing byproduct material. Except for persons who manufacture, possess, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32 which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured before November 30, 2007 in accordance with a specific license issued by a Licensing State with comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2.20.2.3.1 Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under 2.20.2.3,

[7]For purposes of this paragraph, 2.20.2.2.7 "electron tubes" include spark gap tubes, power tubes, gas tubes, including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 2.28.4.

2.20.2.4 Self-luminous products containing Tritium, Krypton-85, Promethium-147 or Radium except for persons who manufacture, process, or produce self-luminous products containing Tritium, Krypton-85, or Promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires Tritium, Krypton-85, or Promethium-147 in self-luminous products manufactured, possessed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this paragraph 2.20.2.4 does not apply to Tritium, Krypton-85, or Promethium-147 used in products for frivolous purposes or in toys or adornments.

2.20.2.4.1 Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less that 0.1 microcurie of Radium-226 which are acquired prior to the effective date of this regulation.

2.20.2.5 Exempt quantities

2.20.2.5.1 Except as provided in subparagraphs 2.20.2.5.3 through 2.20.2.5.5, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in RHA 2.24, Schedule B.

2.20.2.5.2 Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license formerly provided in Paragraph 2.4.1 is exempt from the requirements for a license set forth in this Part to the extent that this person possesses, uses, transfers, or owns byproduct material.

2.20.2.5.3 This paragraph 2.20.2.5 does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

2.20.2.5.4 No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in RHA 2.24 Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this paragraph or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph 2.20.2.5 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.

2.20.2.5.5 No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in RHA 2.24, Schedule B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

2.20.2.6 Reserved.

2.20.2.7 Radioactive drug: Capsules containing Carbon-14 urea for "in vivo" diagnostic use for humans.

2.20.2.7.1 Except as provided in 2.20.2.7.2 and 2.20.2.7.3, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires capsules containing 1 uCi (37kBq) Carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use of humans.

2.20.2.7.2 Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part IV of these regulations.

2.20.2.7.3 Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to RHA 2.7.5.

2.20.2.7.4 Nothing in this section relieves persons from complying with applicable FDA, Federal, and other State requirements governing receipt, administration, and use of drugs.

RHA 2.21 RECIPROCAL RECOGNITION OF LICENSES

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

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

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

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

2.21.1.4 The out-of-state licensee supplies such other information as the Department may reasonably request.

2.21.1.5 The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material.

2.21.1.6 The general license granted in RHA 2.21.1 concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time.

2.21.2 Notwithstanding the provisions of 2.21 any person who holds a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State authorizing the holder to manufacture, transfer, install or service a device described in 2.4.2.1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, and service such a device in this State provided that:

2.21.2.1 Such person shall satisfy the requirement of 2.10.4.1 and 2.10.4.2.

2.21.2.2 The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; and

2.21.2.3 Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this Label is Prohibited."

2.21.2.4 The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such a copy of the general license contained in Section 2.4.2.

2.21.2.5 The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency or Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to protect health or minimize danger to life or property.

RHA 2.22 TRANSPORTATION OF RADIOACTIVE MATERIAL

2.22.1 The transportation of radioactive material shall be in accordance with the requirements in 10 CFR Part 71 as revised January 1, 2006. which is incorporated by reference, with the exception of the following sections: 71.2, 71.6, 71.14(b), 71.19, 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100. The provisions of this section apply to the transportation of radioactive material, or delivery of radioactive material to a carrier for transportation, regardless of whether or not the carrier is also subject to the rules and regulations of the Nuclear Regulatory Commission contained in Title 10 CFR Part 71 and other agencies of the United States having jurisdiction. (10/06)

RHA 2.23 SCHEDULE A. GENERALLY LICENSED EQUIPMENT WHEN MANUFACTURED IN ACCORDANCE WITH THE SPECIFICATION CONTAINED IN A SPECIFIC LICENSE.

A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to him by the NRC or equivalent Agreement State Regulations.

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

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

PART II
SCHEDULE B

Exempt Quantities

RHA 2.24

Radioactive Material	MicroCuries
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-14 (C-14)	100
Carbon-11 (C-11)	10
Cerium-141 (Ce-14)	100
Cerium-143 (Ce-143)	100
Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152/9.2h)	100
Europium-152 (Eu-152/13yr)	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Flourine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-69 (Ge-69)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au-195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10

PART II
SCHEDULE B

Exempt Quantities

Radioactive Material	MicroCuries
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100
Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Nitrogen-13 (N-13)	10
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Oxygen-15 (O-15)	10
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platinum-197 (Pt-197)	100
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Radium-226 (Ra-226)	0.1
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100
Rhodium-103m (Rh-103m)	100
Rhodium-105 (RH-105)	100
Rubidium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
Ruthenium-97 (Ru-97)	100
Ruthenium-103 (Ru-103)	10
Ruthenium-105 (Ru-105)	10
Ruthenium-106 (Ru-106)	1
Samarium-151 (Sm-151)	10
Samarium-153 (Sm-153)	100
Scandium-46 (Sc-46)	10
Scandium-47 (Sc-47)	100
Scandium-48 (Sc-48)	10
Selenium-75 (Se-75)	10
Silicon-31 (Si-31)	100
Silver-105 (Ag-105)	10
Silver-110m (Ag-110m)	1
Silver-111 (Ag-111)	100
Sodium-22 (Na-22)	10
Sodium-24 (Na-24)	10
Strontium-85 (Sr-85)	10
Strontium-89 (Sr-89)	1
Strontium-90 (Sr-90)	0.1
Strontium-91 (Sr-91)	10
Strontium-92 (Sr-92)	10
Sulfur-35 (S-35)	100
Tantalum-182 (Ta-182)	10
Technetium-96 (Tc-96)	10
Technetium-97m (Tc-97m)	100
Technetium-97 (Tc-97)	100
Technetium-99m (Tc-99m)	100
Technetium-99 (Tc-99)	10
Tellurium-125m (Te-125m)	10
Tellurium-127m (Te-127m)	10
Tellurium-129m (Te-129m)	10
Tellurium-129 (Te-129)	100
Tellurium-131m (Te-131m)	10
Tellurium-132 (Te-132)	10
Terbium-160 (Tb-160)	10

PART II
SCHEDULE B

Exempt Quantities

Radioactive Material	**MicroCuries**
Thallium-200 (Tl-200)	100
Thallium-201 (Tl-201)	100
Thallium-202 (Tl-202)	100
Thallium-204 (Tl-204)	10
Thulium-170 (Tm-170)	10
Thulium-171 (Tm-171)	10
Tin-113 (Sn-113)	10
Tin-125 (Sn-125)	10
Tungsten-181 (W-181)	10
Tungsten-185 (W-185)	10
Tungsten-187 (W-187)	100
Vanadium-48 (V-48)	10
Xenon-131m (Xe-131m)	1,000
Xenon-133 (Xe-133)	100
Xenon-135 (Xe-135)	100
Ytterbium-175 (Yb-175)	100
Yttrium-87 (Y-87)	10
Yttrium-88 (Y-88)……	10
Yttrium-90 (Y-90)	10
Yttrium-91 (Y-91)	10
Yttrium-92 (Y-92)	100
Yttrium-93 (Y-93)	100
Zinc-65 (Zn-65)	10
Zinc-69m (Zn-69m)	100
Zinc-69 (Zn-69)	1,000
Zirconium-93 (Zr-93)	10
Zirconium-95 (Zr-95)	10
Zirconium-97 (Zr-97)	10

Any radioactive material not listed above other than alpha emitting radioactive material..... .0.1

PART II
SCHEDULE C

Exempt Concentrations

RHA 2.25

Element & (Atomic Number)	Isotope	Column I Gas Concentration[1] μCi/ml	Column II Liquid & Solid[2] Concentration μCi/ml
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	A-37	1×10^{-3}	
	A-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}

PART II
SCHEDULE C

Exempt Concentrations

RHA 2.25

Element & (Atomic Number)	Isotope	Column I Gas Concentration[1] μCi/ml	Column II Liquid & Solid[2] Concentration μCi/ml
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 (T/2 = 9.2 hrs)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}

PART II
SCHEDULE C

Exempt Concentrations

RHA 2.25

Element & (Atomic Number)	Isotope	Column I Gas Concentration[1] μCi/ml	Column II Liquid & Solid[2] Concentration μCi/ml
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-149		3×10^{-3}
	Nd-147		6×10^{-4}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (41) (Columbium)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}

PART II
SCHEDULE C

Exempt Concentrations

RHA 2.25

Element & (Atomic Number)	Isotope	Column I Gas Concentration[1] μCi/ml	Column II Liquid & Solid[2] Concentration μCi/ml
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Polonium (84)	Po-210	2×10^{-10}	7×10^{-6}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Radium (88)	Ra-226	1×10^{-11}	1×10^{-7}
	Ra-228	2×10^{-11}	3×10^{-7}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{3}

PART II
SCHEDULE C

Exempt Concentrations

RHA 2.25

Element & (Atomic Number)	Isotope	Column I Gas Concentration[1] µCi/ml	Column II Liquid & Solid[2] Concentration µCi/ml
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (74) (Wolfram)	W-181		4×10^{-3}
	W-187		7×10^{-4}

PART II
SCHEDULE C

Exempt Concentrations

RHA 2.25

Element & (Atomic Number)	Isotope	Column I Gas Concentration[1] μCi/ml	Column II Liquid & Solid[2] Concentration μCi/ml
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}

Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.....1×10^{-10}.....1×10^{-6}

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 2.9.2.1 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ration between the concentration present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example: $\frac{\text{Concentration of Isotope a in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = 1$

[1]Values are given only for those materials normally used as gases.
[2] μCi/g for solids.

SCHEDULE D
Broad Licensed Quantities

RHA 2.26

Radioactive Material	Column I Curies	Column II Curies
Antimony-122	1	.01
Antimony-124	1	.01
Antimony-125	1	.01
Arsenic-73	10	0.1
Arsenic-74	1	.01
Arsenic-76	1	.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	.01
Beryllium-7	10	0.1
Bismuth-210	0.1	.001
Bromine-82	10	0.1
Cadmium-109	1	.01
Cadmium-115m	1	.01
Cadmium-115	10	0.1
Calcium-45	1	.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	.001
Cesium-135	1	.01
Cesium-136	10	0.1
Cesium-137	0.1	.001
Chlorine-36	1	.01
Chlorine-38	100	1
Chromium-51	100	1

SCHEDULE D
Broad Licensed Quantities

RHA 2.26

Radioactive Material	Column I Curies	Column II Curies
Colbalt-57	10	0.1
Colbalt-58m	100	1
Colbalt-58	1	.01
Colbalt-60	0.1	.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 9.2h	10	0.1
Europium-152 13 Y	.1	.001
Europium-154	.1	.001
Europium-155	1	.01
Fluorine-18	100	1
Gadolinium-153	1	.01
Gadolinium-159	10	.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	.01
Indium-115m	100	1
Indium-115	1	.01

SCHEDULE D
Broad Licensed Quantities

RHA 2.26

Radioactive Material	Column I Curies	Column II Curies
Iodine-125	0.1	.001
Iodine-126	0.1	.001
Iodine-129	0.1	.001
Iodine-131	0.1	.001
Iodine-132	10	0.1
Iodine-133	1	.01
Iodine-134	10	0.1
Iodine-135	1	.01
Iridium-192	1	.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	.01
Lutetium-177	10	0.1
Manganese-52	1	.01
Manganese-54	1	.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury 197	10	0.1
Mercury-203	1	.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	.01
Nickel-65	10	0.1
Niobium-93m	1	.01
Niobium-95	1	.01
Niobium-97	100	1

SCHEDULE D
Broad Licensed Quantities

RHA 2.26

Radioactive Material	Column I Curies	Column II Curies
Osmium-185	1	.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	10	0.1
Polonium-210	.01	.0001
Potassium-42	1	.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1000	10
Rhodium-105	10	0.1
Rubidium-86	1	.01
Rubidium-87	1	.01
Ruthenium-97	100	1
Ruthenium-103	1	.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	.001

SCHEDULE D
Broad Licensed Quantities

RHA 2.26

Radioactive Material	Column I Curies	Column II Curies
Samarium-151	1	.01
Samarium-153	10	0.1
Scandium-46	1	.01
Scandium-47	10	0.1
Scandium-48	1	.01
Selenium-75	1	.01
Silicon-31	10	0.1
Silver-105	1	.01
Silver-110m	0.1	.001
Silver-111	10	0.1
Sodium-22	0.1	.001
Sodium-24	1	.01
Strontium-85m	1000	10
Strontium-85	1	.01
Strontium-89	1	.01
Strontium-90	.01	.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	.01
Tellurium-125m	1	.01
Tellurium-127m	1	.01
Tellurium-127	10	0.1
Tellurium-129m	1	.01
Tellurium-129	100	1
Tellurium-131m	10	0.1
Tellurium-132	1	.01

SCHEDULE D
Broad Licensed Quantities

RHA 2.26

Radioactive Material	Column I Curies	Column II Curies
Terbium-160	1	.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	.01
Thulium-170	1	.01
Thulium-171	1	.01
Tin-113	1	.01
Tin-125	1	.01
Tungsten-181	1	.01
Tungsten-185	1	.01
Tungsten-187	10	0.1
Vanadium-48	1	.01
Xenon-131m	1000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-17	10	0.1
Yttrium-90	1	.01
Yttrium-91	1	.01
Yttrium-92	10	0.1
Yttrium-93	1	.01
Zinc-65	1	.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	.01
Zirconium-95	1	.01
Zirconium-97	1	.01
Any radioactive material other than alpha emitting radioactive material not listed above	0.1	.001

RHA 2.27 REQUIREMENTS FOR LICENSE TO MANUFACTURE AND DISTRIBUTE INDUSTRIAL PRODUCTS CONTAINING DEPLETED URANIUM FOR MASS-VOLUME APPLICATIONS

2.27.1 An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to RHA 2.3.4 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

2.27.1.1 The applicant satisfies the requirements specified in RHA 2.6.

2.27.1.2 The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, and transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in RHA 3.5.1.

2.27.1.3 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.

2.27.2 In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under RHA 2.27 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.

2.27.3 The Department may deny any application for a specific license under RHA 2.27 if the end use of the industrial product or device cannot be reasonably foreseen.

2.27.4 Each person licensed pursuant to RHA 2.27.1 shall:

2.27.4.1 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;

2.27.4.2 Label or mark each unit to: (a) 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 (b) state the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

2.27.4.3 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";

2.27.4.4 (a) Furnish a copy of the general license contained in RHA 2.3.4 and a copy of Department Form RHA-100-2 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in RHA 2.3.4; or (b) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to RHA 2.3.4 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 RHA 2.3.4 and a copy of Department Form RHA-100-2 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 the use of the product or device is regulated by the U.S. Regulatory Commission or an Agreement State under requirements substantially the same as those in RHA 2.3.4.

2.27.4.5 Report to the Department all transfers of industrial products or devices to persons for use under the general license in RHA 2.3.4. Such reports shall identify each general licensee by name and address, an individual byname and/or position who may constitute a point of contact between the Department 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 RHA 2.3.4 during the reporting period, the report shall so indicate;

2.27.4.6 Report to the U.S. Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40. Report to the responsible Agreement State agency all transfers of devices manufactured and distributed pursuant to RHA 2.27 for use under a general license in that State's regulations equivalent to RHA 2.3.4.

Such reports 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 Department and the general licensee, 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 quarter in which such product or device is transferred to the generally licensed person.

If no transfers have been made to the U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

If no transfers have been made to the general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency.

2.27.4.7 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 licenses provided in RHA 2.3.4 or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records 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 this section.

RHA 2.28 REQUIREMENTS FOR SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR, OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM).

2.28.1 Licensing the Distribution of NARM in Exempt Quantities.[11]

[11]Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

An application for a specific license to distribute NARM in exempt quantities to persons exempted from these regulations pursuant to 2.20.2.5 will be approved if:

2.28.1.1 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;

2.28.1.2 The radioactive material is in the form of processed chemical elements, compounds, or 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

2.28.1.3 The applicant submits copies of prototype labels and brochures and the Department approves such labels and brochures.

2.28.2 The license issued under 2.28.1 is subject to the following conditions:

2.28.2.1 No more than 10 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.

2.28.2.2 Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 2.20.2.5. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

2.28.2.3 The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

2.28.2.3.1 Identifies the radionuclide and the quantity of radioactivity, and

2.28.2.3.2 Bears the words "Radioactive Material."

2.28.2.4 In addition to the labeling information required by 2.28.2.3, the label affixed to the immediate container, or an accompanying brochure, shall:

2.28.2.4.1 State that the contents are exempt from Licensing State requirements,

2.28.2.4.2 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,

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

2.28.3 Each person licensed under 2.28.1 shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 2.20.2.5 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 Department. 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 2.28.1 during the reporting period, the report shall so indicate.

2.28.4 Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors.

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 2.20.2.3 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of Radium-226 in each device shall not exceed 0.1 microcurie.

2.28.5 Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under 2.4.5.

An application for a specific license to manufacture calibration and reference sources containing Americium-241, Plutonium or radium-226 to persons generally licensed under 2.4.5 will be approved if:

2.28.5.1 The applicant satisfies the general requirements of 2.6, and

2.28.5.2 The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and 70.39 of 10 CFR Part 70 or their equivalent.

RHA 2.29 REGISTRATION OF SEALED SOURCES AND DEVICES CONTAINING SEALED SOURCES

2.29.1 Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the Department for evaluation of radiation safety information about its product and for its registration.

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

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

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

2.29.5 The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

2.29.5.1 The statements and representations, including quality control program, contained in the request; and

2.29.5.2 The provisions of the registration certificate.

RHA 2.30 EMERGENCY PLAN FOR LARGE QUANTITY USERS

2.30.1 Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in RHA 2.31 "Schedule E – Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

2.30.1.1 An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2.30.1.2 An emergency plan for responding to a release of radioactive material.

2.30.2 One or more of the following factors may be used to support an evaluation submitted under RHA 2.30.1.1 of this section:

2.30.2.1 The radioactive material is physically separated so that only a portion could be involved in an accident;

2.30.2.2 All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

2.30.2.3 The release fraction in the respirable size range would be lower than the release fraction shown in RHA 2.31 due to the chemical or physical form of the material;

2.30.2.4 The solubility of the radioactive material would reduce the dose received;

2.30.2.5 Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in RHA 2.31, Schedule E.

2.30.2.6 Operating restrictions or procedures would prevent a release fraction as large as that shown in RHA 2.31, Schedule E; or

2.30.2.7 Other factors appropriate for the specific facility.

2.30.3 An emergency plan for responding to a release of radioactive material submitted under RHA 2.30.1.2 of this section must include the following information:

2.30.3.1 Facility description. A brief description of the licensee's facility and area near the site.

2.30.3.2 Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

2.30.3.3 Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

2.30.3.4 Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

2.30.3.5 Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment.

2.30.3.6 Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

2.30.3.7 Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.

2.30.3.8 Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[12]

2.30.3.9 Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.

2.30.3.10 Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instruction and orientation tours the licensee would offer to fire, police, medical and other emergency

personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

2.30.3.11 Safe shutdown. A brief description of the means of restoring the facility to safe condition after an accident.

2.30.3.12 Exercises. Provision for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required.

Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must

[12]The requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L-99-499 or other state or federal reporting requirements.

evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

2.30.3.13 Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

2.30.4 The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Department. The licensee shall provide any comments received within the 60 days to the Department with the emergency plan.

RHA 2.31 SCHEDULE E – QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.001	9 (20 mg)
Carbon-14	0.01	50,000
	Non CO	
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Colbalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Garmanium-68	0.01	2,000
Gadolinium-153	0.01	5,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Iodine-125	0.5	10
Iodine-131	0.5	10
Indium-114m	0.01	1,000
Iridium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6,000,000

RHA 2.31 SCHEDULE E – QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorous-32	0.5	100
Phosphorous-33	0.5	1,000
Polonium-210	0.01	10
Potassium-42	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Radium-226	0.001	100
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75	0.01	10,000
Silver-110m	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulfur-35	0.5	900
Technetium-99	0.01	10,000
Technetium-99m	0.01	400,00
Tellurium-127m	0.01	5,000
Tellurium-129m	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170	0.01	4,000
Tin-13	0.01	10,000
Tin-123	0.01	3,000
Tin-126	0.01	1,000
Titanium-44	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65	0.01	5,000
Zirconium-93	0.01	400
Zirconium-95	0.01	5,000
Any other beta gamma emitter	0.01	10,000
Mixed fission products	0.01	1,000
Contaminated equipment beta gamma	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Mixed radioactive waste, beta gamma	0.01	1,000

RHA 2.31 SCHEDULE E – QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
Packaged mixed waste, beta gamma[1]	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment, alpha	0.0001	20
Packaged waste, alpha	0.0001	20
Combinations of radioactive materials listed above[2]		

[1]Waste packaged in Type B containers does not require an emergency plan.

[2]For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule E exceeds one.

RHA 2.32 REPORTING REQUIREMENTS

2.32.1 Immediate report. Each licensee shall notify the Department as soon as possible but not later than 4 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.).

2.32.2 Twenty-four hour report. Each licensee shall notify the Department within 24 hours after the discovery of any of the following events involving licensed material:

2.32.2.1 An unplanned contamination event that:

2.32.2.1.1 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;

2.32.2.1.2 Involves a quantity of material greater than five times the lowest annual limit on intake specified in RHA 3.53, Appendix B for the material; and

2.32.2.1.3 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.

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

2.32.2.2.1 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;

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

2.32.2.2.3 No redundant equipment is available and operable to perform the required safety function.

2.32.2.3 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.

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

2.32.2.4.1 The quantity of material involved is greater than five times the lowest annual limit on intake specified in RHA 3.53 Appendix B for the material; and

2.32.2.4.2 The damage affects the integrity of the licensed material or its container.

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

2.32.3.1 Licensees shall make reports required by RHA 2.32.1 & RHA 2.32.2 of this section by telephone to the Bureau of Radiological Health. To the extent that the information is available at the time of notification, the information provided in these reports must include:

2.32.3.1.1 The caller's name and call back telephone number;

2.32.3.1.2 A description of the event, including date and time;

2.32.3.1.3 The exact location of the event;

2.32.3.1.4 The isotopes, quantities, and chemical and physical form of the licensed material involved; and

2.32.3.1.5 Any personnel radiation exposure data available.

2.32.3.2 Written report. Each licensee who makes a report required by RHA 2.32.1 or RHA 2.32.2 of this section 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 appropriate distribution is made. These written reports must be sent to the S.C. Department of Health and Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, S.C. 29201. The reports must include the following:

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

2.32.3.2.2 The exact location of the event;

2.32.3.2.3 The isotopes, quantities, chemical and physical form of the licensed material involved;

2.32.3.2.4 Date and time of the event;

2.32.3.2.5 Corrective actions taken or planned and the results of any evaluations or assessments; and

2.32.3.2.6 The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.